UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
Under the Securities Exchange Act of 1934

For the month of August, 2018

Commission File Number 001-38522

Realm Therapeutics plc
(Translation of registrant's name into English)

267 Great Valley Parkway
Malvern, PA 19355
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

Realm Therapeutics Reports Preliminary Top-line Data from Phase 2 Trial of PR022 in Atopic Dermatitis and First Half 2018 Financial Results

On August 14, 2018, Realm Therapeutics plc (the "Company") reported preliminary top-line data from its Phase 2 trial of PR022 in Atopic Dermatitis, as well as financial results for the six months ended June 30, 2018. A copy of the Company's press release is attached to this Report on Form 6-K as Exhibit 99.1 and is incorporated by reference herein.

Exhibits 99.1, 99.2, 99.3 and 99.4 to this Report on Form 6-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of trebhat section, nor shall they be deemed incorporated by reference in any filing of the company under the Securities Act of 1933 or the Exchange Act.

Exhibit

99.1	Press Release, dated August 14, 2018
99.2	Unaudited Consolidated Interim Balance Sheet as of June 30, 2018 and December 31, 2017, Unaudited Consolidated Interim Statement of Operations and Comprehensive Loss, Statements of Changes in Shareholders' Equity, Statements of Cash Flows for the six months ended June 30, 2018 and 2017 and related Notes to unaudited Interim Financial Statements
99.3	Managements' Discussion and Analysis of Financial Condition and Results of Operations
99.4	Risks Factors

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.

Realm Therapeutics plc

August 14, 2018

By: /s/ Marella Thorell
Marella Thorell
Chief Financial Officer and Chief Operating Officer

Exhibit 99.1

Realm Therapeutics Reports Top-line Data from Phase 2 Trial of PR022 in Atopic Dermatitis and First Half 2018 Financial Results

Company Hosting Conference Call Today at 9:00 AM ET / 2:00 PM BST

MALVERN, PA, August 14, 2018 - Realm Therapeutics plc (NASDAQ:RLM / AIM:RLM), a clinical stage biopharmaceutical company focused on developing novel therapeutics in immune-mediated diseases, today reports preliminary top-line data from its Phase 2 trial of PR022 in Atopic Dermatitis, as well as financial results for the six months ended June 30, 2018.

In a randomized, double-blind, vehicle controlled, Phase 2 clinical trial of 122 patients, PR022 showed no difference from vehicle in the primary endpoint of percent change in Eczema Area Severity Index (EASI) versus baseline.

"PR022 did not show the desired effect in this trial," said Alex Martin, CEO of Realm Therapeutics. "Having just received the data, we are working to better understand this outcome and to analyze all of the data collected in the study. We are conducting a full review to determine whether there is a path forward for our proprietary technology in Atopic Dermatitis, and to evaluate the implications for our Acne and Psoriasis programs. We will provide an update on our plans in September. I would like to thank the patients and investigators who participated in this trial."

CORPORATE AND FINANCIAL HIGHLIGHTS

- Cash, cash equivalents and short-term investments were $23.7 million at June 30, 2018 (at December 31, 2017: $33.9m).
- Investments in Research & Development increased to $7.4 million (H1 2017: $3.0m) driven by increased investment in clinical development activities.
- General and Administrative expenses increased to $3.5 million (H1 2017: $1.6m) primarily due to Nasdaq listing costs.
- In July 2018, Realm listed American Depositary Shares (ADSs) representing the Company's ordinary shares on the Nasdaq Capital Market to facilitate the creation of a trading market in the US for the Company's securities and in satisfaction of obligations under a registration rights agreement entered into with investors who participated in the Company's October 2017 private placement.
- The US Patent and Trademark Office issued two new patents to Realm that expand the intellectual property portfolio around the Company's proprietary immunomodulatory technology in the treatment of inflammatory and autoimmune disorders.

Conference Call

The Company will host a conference call and audio webcast today at 9:00 a.m. ET / 2:00 p.m. BST to discuss the Atopic Dermatitis Phase 2 trial results and the financial results. To access the conference call, please use the dial in details below:

US Toll-Free: +1 855-857-0686
US Toll: +1 631-913-1422

UK Toll-Free: 08003589473
UK Toll: +44 3333000804

Conference call pin code: 51680194#

Please dial in at least 10 minutes prior to the start time. A live and archived audio webcast of the call will be available on the Events and Presentations page of the Company's website, www.realmtx.com.

Availability of Other Information

The Company has submitted a Form 6-K to the Securities and Exchange Commission (SEC) which includes as exhibits: Unaudited Financial Statements and Notes prepared on a US GAAP basis, Management's Discussion & Analysis, Risk Factors related to the business and a copy of this press release. These documents can be accessed from the Investor section of the Company's website at www.realmtx.com.

About Realm Therapeutics

Realm Therapeutics is a clinical-stage biopharmaceutical company developing novel therapeutics that target the interplay between innate and adaptive immunity. The Company's programs seek to influence immune signalling and change the course of immune-mediated diseases in adults and children. Realm's lead drug development program utilizes the Company's proprietary immunomodulatory technology for the treatment of Atopic Dermatitis, and the Company is exploring its efficacy in other dermatology indications which include Acne Vulgaris and Psoriasis, as well as other therapeutic areas. For more information on Realm Therapeutics please visit www.realmtx.com.

Pipeline

PR022 is a proprietary, non-alcohol based, topical gel formulation of high concentration hypochlorous acid (HOCl). Realm is evaluating PR022 for potential application in Atopic Dermatitis and Psoriasis. RLM023 is a topical formulation of HOCl that is being optimized and evaluated for Acne Vulgaris.

Forward Looking Statements

Certain statements made in this announcement are forward-looking statements, including with respect to the Company's clinical trials, results of clinical trials, pipeline of candidates and product candidate development plans including trial results, next steps in clinical development, regulatory strategy, costs and timelines. Words such as 'anticipates,' 'expects,' 'intends,' 'plans,' 'believes,' 'seeks,' 'estimates,' and similar expressions are intended to identify forward-looking statements. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from our expectations expressed or implied by the forward-looking statements, including, but not limited to, the following: our history of operating losses; the recently announced results of the Phase 2 trial of PR022 in Atopic Dermatitis and the uncertainty around future plans for PR022 or any other product candidates; the impact of the PR022 Phase 2 results on our development plans for other potential product candidates or indications; uncertainty around our need for additional funding to advance development and commercialization of any current or future product candidates, which may not be available and which may force us to delay, reduce or eliminate our development or commercialization efforts; the reliance of our business on PR022 in Atopic Dermatitis; economic, regulatory and other risks; the lengthy and expensive process of drug development, which has an uncertain outcome; undesirable or unacceptable side effects associated with any of our pipeline candidate; the uncertainty of our ability to develop or acquire products not based on our active pharmaceutical ingredient (API) hypochlorous acid (HOCl) or outside of dermatology leading to a high concentration of risk in limited areas; certain risks associated with HOCl including its inherent instability and the fact that there are other companies which make HOCl-based products; the loss of any key personnel from our relatively small team; potential material differences between our reported top-line data and final data; our reliance on third parties, including clinical research organizations, investigators, manufacturers and other suppliers; and lawsuits related to patents covering HOCl, PR022 and our pipeline candidates and the potential for our patents to be found invalid or unenforceable. In addition, following the listing of ADSs representing our ordinary shares on Nasdaq, the Company is listed on two stock exchanges which results in higher operating costs and varied regulatory obligations both of which are impacted by the Company's status as a Foreign Private Issuer and Emerging Growth Company which could change over time; and the uncertainty with respect to an active market being established for the ADSs. These risks and uncertainties and other important factors are referred to in an exhibit to our Form 6-K filed with the Securities and Exchange Commission (SEC) on August 14, 2018, and our other reports filed with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change, except as required by law or by any appropriate regulatory authority. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

Realm Therapeutics plc
Consolidated Balance Sheets
(in thousands except share and per share data)
(unaudited)

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 16,236	$ 9,508
Marketable securities	7,433	24,345
Royalty receivable	757	444
Prepaid expenses and other assets	203	245
Total current assets	24,629	34,542
Property and equipment, net	252	246
Royalty receivable, net of current portion	1,570	—
Other assets	280	320
Total assets	$ 26,731	$ 35,108
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 1,233	$ 1,009
Accrued expenses	1,216	1,902
Total liabilities	2,449	2,911
Shareholders' equity:		
Ordinary shares, £0.10 nominal value: 154,897,265 ordinary shares authorized at June 30, 2018: 116,561,917 ordinary shares were issued and outstanding at June 30, 2018 and December 31, 2017	24,259	24,259
Additional paid-in capital	198,009	197,722
Accumulated other comprehensive loss	(27)	(11)
Accumulated deficit	(197,959)	(189,773)
Total shareholders' equity	24,282	32,197
Total liabilities and shareholders' equity	$ 26,731	$ 35,108

Realm Therapeutics plc
Consolidated Statements of Operations and Comprehensive Loss
(in thousands except share and per share data)
(unaudited)

	Six Months Ended June 30,	
	2018	**2017**
Revenues	$ -	$ 619
Operating expenses:		
Research and development	7,376	2,968
General and administrative	3,518	1,602
	10,894	4,570
Loss from operations	(10,894)	(3,951)
Interest income	248	18
Net loss	(10,646)	(3,933)
Other comprehensive loss:		
Unrealized loss on investments	(13)	-
Foreign exchange translation adjustment	(3)	9
Total comprehensive loss	$ (10,662)	$ (3,924)
Net loss per ordinary share - basic and diluted	$ (0.09)	$ (0.08)
Weighted average ordinary shares - basic and diluted	116,561,917	50,165,432

Realm Therapeutics plc
Consolidated Statement of Cash Flows
(in thousands)
(unaudited)

	Six Months Ended June 30,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (10,646)	$ (3,933)
Adjustments to reconcile net loss to net cash used in operating activities		
Loss on disposal of property and equipment	-	3
Depreciation and amortization	39	39
Noncash interest income	(70)	-
Share-based compensation	287	141
Changes in operating assets and liabilities:		
Royalty receivable	647	(210)
Prepaid expenses and other assets	81	3
Accounts payable and accrued expenses	(462)	(718)
Net cash used in operating activities	(10,124)	(4,675)
Cash flows from investing activities:		
Purchase of marketable securities	(10,932)	-
Proceeds from sale of marketable securities	27,831	-
Purchases of property and equipment	(45)	(108)
Net cash provided by (used in) continuing investing activities	16,854	(108)
Net cash used in discontinued investing activities	-	(1,093)
Net cash provided by (used in) investing activities	16,854	(1,201)
Effect of exchange rate changes on cash	(2)	9
Net increase (decrease) in cash and cash equivalents	6,728	(5,867)
Cash and cash equivalents, beginning of period	9,508	21,430
Cash and cash equivalents, end of period	$ 16,236	$ 15,563
Supplemental cashflow information:		
Adjustment to royalty receivables upon adoption of ASC 606	$ (2,460)	$ -

Contacts:

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Marella Thorell, Chief Financial Officer and Chief Operating Officer
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US: +1 212 600 1902

Argot Partners
Laura Perry / Maghan Meyers
+1 212 600 1902

Exhibit 99.2

Realm Therapeutics plc
Consolidated Balance Sheets
(in thousands except share and per share data)
(unaudited)

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 16,236	$ 9,508
Marketable securities	7,433	24,345
Royalty receivable	757	444
Prepaid expenses and other assets	203	245
Total current assets	24,629	34,542
Property and equipment, net	252	246
Royalty receivable, net of current portion	1,570	—
Other assets	280	320
Total assets	$ 26,731	$ 35,108
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 1,233	$ 1,009
Accrued expenses	1,216	1,902
Total liabilities	2,449	2,911
Shareholders' equity:		
Ordinary shares, £0.10 nominal value: 154,897,265 ordinary shares authorized at June 30, 2018: 116,561,917 ordinary shares were issued and outstanding at June 30, 2018 and December 31, 2017	24,259	24,259
Additional paid-in capital	198,009	197,722
Accumulated other comprehensive loss	(27)	(11)
Accumulated deficit	(197,959)	(189,773)
Total shareholders' equity	24,282	32,197
Total liabilities and shareholders' equity	$ 26,731	$ 35,108

See notes to unaudited interim consolidated financial statements

Realm Therapeutics plc
Consolidated Statements of Operations and Comprehensive Loss
(in thousands except share and per share data)
(unaudited)

	Six Months Ended June 30,	
	2018	**2017**
Revenues	$ -	$ 619
Operating expenses:		
Research and development	7,376	2,968
General and administrative	3,518	1,602
	10,894	4,570
Loss from operations	(10,894)	(3,951)
Interest income	248	18
Net loss	(10,646)	(3,933)
Other comprehensive loss:		
Unrealized loss on investments	(13)	-
Foreign exchange translation adjustment	(3)	9
Total comprehensive loss	$ (10,662)	$ (3,924)
Net loss per ordinary share - basic and diluted	$ (0.09)	$ (0.08)
Weighted average ordinary shares - basic and diluted	116,561,917	50,165,432

See notes to unaudited interim consolidated financial statements

Realm Therapeutics plc
Consolidated Statement of Changes in Shareholders' Equity
(in thousands except share data)
(unaudited)

	Ordinary Shares		Additional Paid-in Additional	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
Balance at December 31, 2017	116,561,917	$ 24,259	$ 197,722	$ (11)	$ (189,773)	$ 32,197
Adoption of ASC 606	—	—	—	—	2,460	2,460
Share-based compensation expense	—	—	287	—	—	287
Unrealized loss on investments	—	—	—	(13)	—	(13)
Currency translation adjustments	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	(10,646)	(10,646)
Balance at June 30, 2018	116,561,917	$ 24,259	$ 198,009	$ (27)	$ (197,959)	$ 24,282

See notes to unaudited interim consolidated financial statements

Realm Therapeutics plc
Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Six Months Ended June 30,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (10,646)	$ (3,933)
Adjustments to reconcile net loss to net cash used in operating activities		
Loss on disposal of property and equipment	-	3
Depreciation and amortization	39	39
Noncash interest income	(70)	-
Share-based compensation	287	141
Changes in operating assets and liabilities:		
Royalty receivable	647	(210)
Prepaid expenses and other assets	81	3
Accounts payable and accrued expenses	(462)	(718)
Net cash used in operating activities	(10,124)	(4,675)
Cash flows from investing activities:		
Purchase of marketable securities	(10,932)	-
Proceeds from sale of marketable securities	27,831	-
Purchases of property and equipment	(45)	(108)
Net cash provided by (used in) continuing investing activities	16,854	(108)
Net cash used in discontinued investing activities	-	(1,093)
Net cash provided by (used in) investing activities	16,854	(1,201)
Effect of exchange rate changes on cash	(2)	9
Net increase (decrease) in cash and cash equivalents	6,728	(5,867)
Cash and cash equivalents, beginning of period	9,508	21,430
Cash and cash equivalents, end of period	$ 16,236	$ 15,563
Supplemental cashflow information:		
Adjustment to royalty receivables upon adoption of ASC 606	$ (2,460)	$ -

See notes to unaudited interim consolidated financial statements

1. Organization and description of business

Realm Therapeutics plc (the Company), a company incorporated under the laws of England and Wales, which is domiciled in the United Kingdom (U.K.), is a clinical-stage biopharmaceutical company developing novel therapeutics that target the interplay between innate and adaptive immunity. The Company's programs seek to influence immune signaling and change the course of immune-mediated diseases in adults and children. Realm's lead drug development program utilizes the Company's proprietary immunomodulatory technology for the treatment of Atopic Dermatitis, and the Company is exploring its efficacy in other dermatology indications which include Acne Vulgaris and Psoriasis, as well as other therapeutic areas.

On August 14, 2018, the Company reported top-line data from its Phase 2 clinical trial of PR022 in Atopic Dermatitis. In a randomized, double-blind, vehicle controlled, Phase 2 clinical trial of 122 patients, PR022 showed no difference from vehicle in the primary endpoint of percent change in Eczema Area Severity Index (EASI) versus baseline. As the data was just received, the Company, is working to better understand this outcome and to analyze all of the data collected in the study. The Company is conducting a full review to determine whether there is a path forward for its proprietary technology in Atopic Dermatitis, and to evaluate the implications for its Acne and Psoriasis programs. The Company expects to provide an update on its plans in September 2018.

While the initial clinical development focus has been on Dermatology, the Company is also exploring other potential applications, in immune-mediated diseases generally. While the other indications are in the early stage of evaluation, Realm believes that the anti-inflammatory and immunomodulatory properties of its formulations demonstrated in pre-clinical studies to date provide scientific rationale for continuing to explore other indications and, subject to the full analysis of the PR022 results, intends to further evaluate the potential applications through pre-clinical models and other research. In addition, the Company is actively exploring opportunities to in-license new assets with potential in immune-mediated diseases to complement its portfolio.

In March 2018, the Company announced that in a Phase 2 clinical trial for Allergic Conjunctivitis, or AC, an ophthalmic disease, its product candidate, PR013, a topical solution containing HOCl as its active ingredient, did not demonstrate efficacy. As a result, the Company is no longer pursing the clinical development of PR013 and other than the costs of completing the trial in 2018 and closing out the program, the Company does not intend to make any additional investments in this program.

In October 2016, the Company completed the sale of its Supermarket Retail business to facilitate its continued focus on and provide resources in support of its development of novel immunomodulatory therapies as drugs. The cash flows related to the payment of transaction costs associated with this sale have been presented as discontinued operations within investing activities during the six months ended June 30, 2017.

2. Liquidity

At June 30, 2018, the Company had cash, cash equivalents and marketable securities of $23.7 million, working capital of $22.2 million, and an accumulated deficit of $198.0 million. The Company has incurred net losses and negative cash flows from operations and expects to continue to incur significant losses for the foreseeable future. The Company has no pharmaceutical products approved for commercialization from which to generate revenue and there is no assurance that it will obtain future approvals, or if the Company does, it will be able to generate revenues.

Management believes that the Company’s existing cash, cash equivalents and marketable securities are sufficient to fund the Company’s operations for at least twelve months from the date of issuance of these financial statements.

The Company expects to continue to incur significant expenses and operating losses over the next several years. Company net losses may fluctuate significantly from quarter to quarter and year to year, and the Company anticipates that its expenses will increase substantially:

- if and to the extent that it continues ongoing clinical trials evaluating PR022 for the treatment of Atopic Dermatitis, or initiate and complete additional clinical trials of PR022 in such indication, as needed;
- if and to the extent that it continues development of and pursues regulatory approvals for its product candidates for the treatment of Acne and Psoriasis;
- if it seeks to develop additional product candidates based upon the Company's proprietary technology;
- if it ultimately establishes a commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize any product candidates for which it may obtain regulatory approval;
- if it seeks to in-license or acquire additional product candidates for development to expand and/or diversify its product pipeline;
- if it is required to adapt its regulatory compliance efforts to incorporate requirements applicable to any marketed products for which it may obtain regulatory approval;
- as it maintains and protects, and to the extent that it expands, its intellectual property portfolio;
- if it hires additional clinical, manufacturing, scientific, operational, financial, information technology or other personnel; and
- assuming that it incurs incremental legal, accounting and other expenses operating as a public company in both the United States (U.S.) and the United Kingdom (UK).

3. Basis of presentation and summary of significant accounting policies

The accompanying unaudited interim consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States (U.S. GAAP). Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASU) of the Financial Accounting Standards Board (FASB).

In the opinion of management, the accompanying unaudited interim consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's financial position as of June 30, 2018 and its results of operations and cash flows for the six months ended June 30, 2018 and 2017. Operating results for the six months ended June 30, 2018 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2018.

The unaudited interim consolidated financial statements, presented herein, do not contain the required disclosures under GAAP for annual consolidated financial statements. The accompanying unaudited interim consolidated financial statements should be read in conjunction with the annual audited consolidated financial statements and related notes as of and for the year ended December 31, 2017 included in the Company's Registration Statement filed with the Securities and Exchange Commission (SEC) on July 3, 2018 on Form F-1. Since the date of such financial statements, there have been no changes to the Company's significant accounting policies.

Use of estimates

The preparation of the unaudited interim consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Due to the uncertainty of factors surrounding the estimates or judgments used in the preparation of the consolidated financial statements, actual results may materially vary from these estimates. Estimates and assumptions are periodically reviewed and the effects of revisions are reflected in the consolidated financial statements in the period they are determined to be necessary.

Revenue recognition

The Company adopted ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* effective January 1, 2018 using the modified retrospective method with the impact of the adoption reflected in opening accumulated deficit. The impact of Topic 606 relates to the Company's license and distribution agreement for Vashe, primarily regarding the recognition of the future minimum guaranteed royalty payments. Under Topic 606, minimum royalty payments are included in the transaction price as variable consideration, subject to a constraint. Therefore, the future minimum payments are recognized at a point in time rather than over the future periods. The revenue recognized is net of the effect of significant financing components calculated using customer-specific, risk-adjusted lending rates and will be recognized as interest income over time on an effective interest rate basis.

The Company recognized the cumulative impact of the adoption of Topic 606 with a decrease of $2.5 million in the opening balance of its accumulated deficit on January 1, 2018 and a corresponding increase in royalty receivable. The comparative information for the prior period has not been restated and continues to be reported under the revenue recognition rules then in effect (Topic 605). Royalties in excess of the estimated future minimum royalty amount will be recognized if and when they are earned. The Company concluded that the minimum guaranteed royalty amounts are fixed in substance and are recognized upon transferring the license to the distributor under Topic 606 rather than upon billing under Topic 605. As a consequence of the acceleration of revenue recognition, we will not recognize royalty income until the minimum guaranteed amount has been achieved. Any royalties in excess of the minimum guarantee will be recognized as revenue in the period they are earned.

Adoption of Topic 606 had no impact to cash provided by (used in) operating, investing, or financing activities within the Company's unaudited interim consolidated statement of cash flows. In accordance with Topic 606, the disclosure of the impact of adoption to the Company's unaudited interim consolidated statement of operations and consolidated balance sheet was as follows (in thousands):

	Six Months Ended June 30, 2018		
	As Reported	Effect of Change	Amounts Under ASC 605
Revenues	$ —	$ 434	$ 434
Operating expenses:			
Research and development	7,376	—	7,376
General and administrative	3,518	—	3,518
	10,894	—	10,894
Loss from operations	(10,894)	434	(10,460)
Interest income	248	(70)	178
Net loss	$ (10,646)	$ 364	$ (10,282)

	June 30, 2018		
	As Reported	Effect of Change	Amounts Under ASC 605
Assets			
Royalty receivable	$ 757	$ (526)	$ 231
Royalty receivable, net of current portion	$ 1,570	$ (1,570)	$ -
Shareholders' Equity			
Accumulated deficit	$ (197,959)	$ (2,096)	$ (200,055)

Net loss per ordinary share

Basic loss per share is computed by dividing net loss by the weighted average number of ordinary shares outstanding during each period. Diluted loss per share includes the effect, if any, from the potential exercise or conversion of securities, such as warrants and options which would result in the issuance of incremental ordinary shares. In computing basic and diluted net loss per share, the weighted average number of shares is the same for both calculations due to the Company's net loss for the six months ended June 30, 2018 and 2017.

The following potentially dilutive securities outstanding as of June 30, 2018 and 2017 have been excluded from the computation of diluted weighted average shares outstanding, as they would be anti-dilutive:

	Six Months Ended June 30,	
	2018	**2017**
Share options	11,263,655	3,924,468
Warrants	26,917,173	154,229
	38,180,828	4,078,697

Recent accounting pronouncements

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842),* with guidance regarding the accounting for and disclosure of leases. The update requires lessees to recognize all leases, including operating leases, with a term greater than twelve months on the balance sheet. This update also requires lessees and lessors to disclose key information about their leasing transactions. The guidance will be effective for annual and interim periods beginning after December 15, 2018. The Company is currently evaluating the effect that this guidance will have on its consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU 2016-09, *Compensation — Stock Compensation (Topic 718) Improvements to Employee Share-Based Payment Accounting*, which simplifies several aspects of the accounting for employee share-based payment transactions including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. The new standard is effective for annual reporting periods beginning after December 15, 2017. The adoption of this guidance effective January 1, 2018, was not material to the consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. ASU No. 2016-15 addresses eight specific cash flow issues with the objective of reducing diversity in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The new standard is effective for fiscal years beginning after December 15, 2018 and interim periods within fiscal years beginning after December 15, 2018. Early adoption is permitted. The Company is currently evaluating the accounting, transition, and disclosure requirements of the standard and its impact on the Company's consolidated statement of cash flows.

In May 2017, the FASB issued ASU 2017-09, *Compensation — Stock Compensation* (Topic 718): *Scope of Modification Accounting*, which provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The guidance will be effective for annual and interim periods beginning after December 15, 2017, with early adoption permitted. The amendments in this ASU should be applied prospectively to an award modified on or after the adoption date. The adoption of this guidance effective as of January 1, 2018 was not material to the consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, *Compensation — Stock Compensation (Topic 718) Improvements to Nonemployee Share-Based Payment Accounting.* The amendments in this update expand the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. Under this ASU, an entity should apply the requirements of Topic 718 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of costs (that is, the period of time over which share-based payment awards vest and the pattern of cost recognition over that period). The guidance is applicable to public business entities for fiscal years beginning after December 15, 2019 and interim periods within those years with early adoption permitted. The Company is currently evaluating the effect that this guidance will have on its consolidated financial statements and related disclosures.

4. Fair value and marketable securities

As of June 30, 2018 and December 31, 2017, marketable securities were comprised of the following (in thousands):

	June 30, 2018			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. government agency	$ 7,432	$ 1	$ —	$ 7,433

	December 31, 2017			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. government agency	$ 20,857	$ 14	$ —	$ 20,871
Certificates of deposit	3,475	—	(1)	3,474
	$ 24,332	$ 14	$ (1)	$ 24,345

The Company follows FASB's accounting guidance on fair value measurements for financial assets and liabilities measured on a recurring basis. The guidance requires fair value measurements to be classified and disclosed in one of the following three categories:

- Level 1 — Quoted prices (unadjusted in active markets for identical assets or liabilities)
- Level 2 — Inputs other than quoted prices in active markets that are observable either directly or indirectly
- Level 3 — Unobservable inputs in which there is little or no market data, which require the Company to develop its own assumptions

This hierarchy requires the use of observable market data when available and to minimize the use of unobservable inputs when determining fair value.

The Company has classified assets and liabilities measured at fair value on a recurring basis as follows (in thousands):

	June 30, 2018				
			Fair Value Measurement Based on		
	Carrying Amount	Fair Value	Quoted Prices in Active Markets (Level 1)	Significant other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets					
Cash equivalents[1]	$ 14,315	$ 14,315	$ 14,315	$ —	$ —
U.S. government agency	7,432	7,433	—	7,433	—
	$ 21,747	$ 21,748	$ 14,315	$ 7,433	$ —

	December 31, 2017				
			Fair Value Measurement Based on		
	Carrying Amount	Fair Value	Quoted Prices in Active Markets (Level 1)	Significant other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets					
Cash equivalents[1]	$ 8,978	$ 8,978	$ 8,978	$ —	$ —
U.S. government agency	20,871	20,871	—	20,871	—
Certificates of deposit	3,474	3,474	3,474	—	—
	$ 33,323	$ 33,323	$ 12,452	$ 20,871	$ —

(1) Includes cash sweep accounts, U.S. Treasury money market mutual fund, and bank certificates of deposit and U.S. Treasury bills that have a maturity of three months or less from the original acquisition date.

5. Accrued expenses

Accrued expenses consisted of (in thousands):

	June 30, 2018	December 31, 2017
Compensation and related benefits	427	$ 994
Consulting and professional fees	40	105
Research and development expenses	692	745
Other	57	58
	$ 1,216	$ 1,902

6. Share-based compensation

The Company operates the Realm Therapeutics 2016 Executive Omnibus Incentive Plan (the Plan), an equity compensation plan under which a variety of equity instruments can be issued to employees. As of June 30, 2018, there were 392,537 shares available for future issuance under the Plan.

The amount and terms of grants are determined by the Company's board of directors. The term of the options may be up to 10 years, and options are exercisable in cash or as otherwise determined by the board of directors. Generally, options vest annually over a three year period or, for certain key executives, vest upon the achievement of performance conditions measured over a three year period.

All options granted have exercise prices equal to the fair value of the underlying ordinary shares on the date of the grant.

The Company recorded share-based compensation expense in the following expense categories of its consolidated statements of operations for the six months ended June 30, 2018 and 2017 (in thousands):

	Six Months Ended June 30,	
	2018	**2017**
Research and development	$ 108	$ 51
General and administrative	179	90
	$ 287	$ 141

The fair value of options is estimated using the Black-Scholes option pricing model, which takes into account inputs such as the exercise price, the value of the underlying ordinary shares at the grant date, expected term, expected volatility, risk-free interest rate and dividend yield. The fair value of each grant of options during the six months ended June 30, 2018 and 2017 was determined using the methods and assumptions discussed below.

- The expected term of employee options is determined using the "simplified" method, as prescribed in SEC's Staff Accounting Bulletin (SAB) No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option due to the Company's lack of sufficient historical data. The expected term of nonemployee options is equal to the contractual term.

- The expected volatility is based on historical volatility of the Company's ordinary shares commensurate with the expected term assumption.

- The risk-free interest rate is based on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected term.

- The expected dividend yield is 0% because the Company has not historically paid, and does not expect for the foreseeable future to pay, a dividend on its common stock.

For the six months ended June 30, 2018 and 2017, the grant date fair value of all option grants was estimated at the time of grant using the Black-Scholes option-pricing model using the following weighted average assumptions:

	Six Months Ended June 30,	
	2018	**2017**
Expected term (in years)	6.0	5.0
Expected volatility	44.4%	43.2%
Risk-free rate	2.8%	1.8%
Dividend yield	—	—

The per share weighted average fair value of the options granted during the six months ended June 30, 2018 and 2017 was estimated at $0.20 and $0.16 per share, respectively.

The following table summarizes the activity related to stock option grants to employees and nonemployees for the six months ended June 30, 2018:

	Number of Shares under Option	**Weighted-average Exercise Price per Option**	**Weighted-Average Remaining Contractual Life (in years)**
Outstanding at December 31, 2017	11,418,175	$ 0.45	
Granted	90,000	0.56	
Expired	(244,520)	1.56	
Outstanding at June 30, 2018	11,263,655	0.42	3.95
Exercisable at June 30, 2018	4,686,061	$ 0.40	2.49
Vested and expected to vest at June 30, 2018	11,263,655	$ 0.42	3.95

As of June 30, 2018, there was $0.4 million in unrecognized compensation cost that is expected to be recognized over an estimated weighted-average amortization period of 1.74 year. The aggregate intrinsic value of options outstanding and options exercisable as of June 30, 2018 was $1.0 million and $0.5 million, respectively.

7. Subsequent events

The Company has evaluated subsequent events from the balance sheet date through the date at which the consolidated financial statements were available to be issued, and determined there are no other items requiring disclosure beyond those already disclosed except as follows:

On August 14, 2018, the Company reported top-line data from its Phase 2 clinical trial of PR022 in Atopic Dermatitis. In a randomized, double-blind, vehicle controlled, Phase 2 clinical trial of 122 patients, PR022 showed no difference from vehicle in the primary endpoint of percent change in Eczema Area Severity Index (EASI) versus baseline. As the data was just received, the Company, is working to better understand this outcome and to analyze all of the data collected in the study. The Company is conducting a full review to determine whether there is a path forward for its proprietary technology in Atopic Dermatitis, and to evaluate the implications for its Acne and Psoriasis programs. The Company expects to provide an update on its plans in September 2018.

On July 3, 2018, the Company was approved for listing of 5,074,316 American Depositary Shares, or ADSs, on the Nasdaq Stock Market, under the symbol "RLM". Each ADS represents 25 ordinary shares. Holders of registered ADSs are permitted to sell ordinary shares not represented by ADSs in private transactions, including on Alternative Investment Market, or AIM, a market operated by the London Stock Exchange.

MANAGEMENTS' DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited interim consolidated financial statements and the related notes furnished as exhibit 99.2 to the Current Report on Form 6-K on which this discussion has been furnished and our consolidated financial statements for the year ended December 31, 2017 and the related notes thereto appearing in our prospectus on Form F-1, which was filed with the Securities and Exchange Commission (SEC) on July 3, 2018. Some of the information contained in this discussion and analysis, including information with respect to our plans, our product candidates, our results of clinical trials, the clinical development plans for our product candidates and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those set forth in the Risk Factors furnished as Exhibit 99.4 to this Current Report on Form 6-K on which this discussion has been furnished, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biopharmaceutical company developing novel therapeutics that target the interplay between innate and adaptive immunity. Our programs seek to influence immune signaling and change the course of immune-mediated diseases in adults and children. Our lead drug development program utilizes our proprietary immunomodulatory technology for the treatment of Atopic Dermatitis, and we are exploring its efficacy in other dermatology indications which include Acne Vulgaris and Psoriasis, as well as other therapeutic areas.

On August 14, 2018, we reported top-line data from our Phase 2 clinical trial of PR022 in Atopic Dermatitis. In a randomized, double-blind, vehicle controlled, Phase 2 clinical trial of 122 patients, PR022 showed no difference from vehicle in the primary endpoint of percent change in Eczema Area Severity Index (EASI) versus baseline. As we just received the data, we are working to better understand this outcome and to analyze all of the data collected in the study. We are conducting a full review to determine whether there is a path forward for our proprietary technology in Atopic Dermatitis, and to evaluate the implications for our Acne and Psoriasis programs. We will provide an update on our plans in September 2018.

While the initial clinical development focus has been on Dermatology, we are also exploring other potential applications, in immune-mediated diseases generally. While the other indications are in the early stage of evaluation, we believe that the anti-inflammatory and immunomodulatory properties of our formulations demonstrated in pre-clinical studies to date provide scientific rationale for continuing to explore other indications and, subject to the full analysis of the PR022 results, we intend to further evaluate the potential applications through pre-clinical models and other research. In addition, we are actively exploring opportunities to in-license new assets with potential in immune-mediated diseases to complement our portfolio.

We announced in July 2018 that the SEC declared effective our registration statements with respect to the listing of American Depositary Shares (ADSs), representing the Company's ordinary shares, Nasdaq approved the ADSs for listing, and ADSs were listed for trading under the symbol "RLM". The registration statements were filed to facilitate the creation of a trading market in the US for ADSs representing the Company's ordinary shares and in satisfaction of our obligations under a registration rights agreement entered into with investors who participated in the October 2017 private placement. Each ADS represents 25 ordinary shares. We did not register any new issuance of securities in connection with the listing. Our ordinary shares continue to be listed for trading on the Alternative Investment Market, or AIM, a market operated by the London Stock Exchange.

We entered into, and subsequently amended, a licensing arrangement with an independent distributor to manufacture, market and distribute Vashe, as a 510(k)-cleared medical device, for use in cleansing and debriding acute and chronic wounds. Pursuant to the terms of the agreement, we assigned all right and title of the Vashe trademark and the distributor retains sole responsibility and liability in connection with the manufacturing, marketing and distribution of Vashe. We receive royalties that are tiered and based upon net sales. We are entitled to receive minimum royalties of approximately $900,000 per each contract year, based upon annual net sales thresholds through March 2021.

On January 1, 2018, we adopted Accounting Standards Update, or ASU, No. 2014-09, *Revenue from Contracts with Customers* ("Topic 606", or "the New Revenue Standard") and all the related amendments using the modified retrospective method. We recognized the cumulative effect of initially applying the New Revenue Standard as a $2.5 million decrease to the opening balance of accumulated deficit as of January 1, 2018. The prior period comparative information has not been restated and continues to be reported under the revenue recognition rules then in effect (Topic 605).

The most significant impact of the New Revenue Standard relate to the royalties we receive from Vashe under the licensing arrangement. We have concluded that the minimum guaranteed royalty amounts are fixed in substance and are recognized upon transferring the license to the distributor under Topic 606 rather than upon billing under Topic 605. The revenue recognized is net of the effect of the financing components calculated using customer-specific, risk-adjusted lending rates and will be recognized as interest income over time on an effective interest rate basis. As a consequence of the acceleration of revenue recognition, we will not recognize royalty income until the minimum guaranteed amount has been achieved. Any royalties in excess of the minimum guarantee will be recognized in the period they are earned.

We expect to continue to incur significant expenses and operating losses over the next several years. Net losses may fluctuate significantly from quarter to quarter and year to year, and we anticipate that our expenses will increase substantially:

- if and to the extent that we continue ongoing clinical trials evaluating PR022 for the treatment of AD, or initiate and complete additional clinical trials of PR022 in such indication, as needed;
- if and to the extent that we continue development of and pursue regulatory approvals for our product candidates for the treatment of Acne and Psoriasis;
- if we seek to develop additional product candidates based upon the our proprietary technology;
- if we ultimately establish a commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- if we seek to in-license or acquire additional product candidates for development to expand and/or diversify our product pipeline;
- if we are required to adapt our regulatory compliance efforts to incorporate requirements applicable to any marketed products for which we may obtain regulatory approval;
- as we maintain and protect, and to the extent that we expand, our intellectual property portfolio;
- if we hire additional clinical, manufacturing, scientific, operational, financial, information technology or other personnel; and
- assuming, as expected, that we incur incremental legal, accounting and other expenses operating as a public company in both the United States (U.S.) and the United Kingdom (UK).

In March 2018, we announced that in a Phase 2 clinical trial for Allergic Conjunctivitis, or AC, an ophthalmic disease, our product candidate PR013, a topical solution, did not demonstrate efficacy. As a result, we are no longer pursing the clinical development of PR013 and other than the costs of completing the trial in 2018 and closing out the program, we do not intend to make any additional investments in this program.

At June 30, 2018, we had cash, cash equivalents and marketable securities of $23.7 million, working capital of $22.2 million, and an accumulated deficit of $198.0 million. We have not generated any product revenues in relation to our drug development business and have not achieved profitable operations. We no longer have any candidates in active clinical trials. There is no assurance that we will have products approved or commercialized in the future, that profitable operations will ever be achieved, and, if achieved, could be sustained on a continuing basis. In addition, any potential development activities, clinical and pre-clinical testing, and commercialization of our products will require significant additional capital.

Financial Operations Overview

Revenues

We earn royalty income related to our license and distribution agreement for Vashe that includes a fixed future minimum guaranteed amount. Upon adoption of the New Revenue Standard on January 1, 2018, no income from our royalty arrangement is recognized unless and until the minimum guaranteed amount has been paid.

Research and Development Expenses

We are organized and record expenses by functional department and our employees spend time on all of our development projects. Additionally, due to the platform nature of our technology, some of the efforts and expenses are attributable across multiple projects or candidates. Where practical, we capture candidate specific expenses. We categorize our research and development expenses by category and by product candidate, as shown below (in thousands):

	Six Months Ended June 30,	
	2018	**2017**
PR022	$ 3,004	$ 860
PR013	1,893	819
RLM023	811	-
Other research and development	555	475
Personnel related including share-based compensation	1,113	814
Total research and development expenses	$ 7,376	$ 2,968

Research and development expense consists primarily of costs incurred in connection with the development of our product candidates. We expense research and development costs as incurred. These expenses include:

- expenses incurred under agreements with contract research organizations, or CROs, contract manufacturing organizations, or CMOs, laboratories who perform toxicology and analytical work, as well as investigative sites and consultants that conduct our clinical and pre-clinical studies and other scientific development services;

- manufacturing scale-up expenses and the cost of acquiring, manufacturing and labeling pre-clinical study and clinical trial materials;

- employee-related expenses, including salaries and related costs, travel and share-based compensation expense for employees engaged in research and development and quality assurance functions;
- costs related to compliance with regulatory requirements; and
- facilities costs, depreciation and other expenses, which include rent and utilities.

We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, administrative, and finance functions, including share-based compensation, travel expenses and recruiting expenses. Other general and administrative expenses include facility related costs, patent filing, maintenance and prosecution costs and professional fees for legal, auditing, tax and business development services, and insurance costs. Additionally, general and administrative expenses include the cost of establishing a listing on Nasdaq and maintaining a listing on AIM, a market operated by the London Stock Exchange in the United Kingdom, which includes directors' compensation and travel, including share-based compensation, insurance and other professional fees such as legal, accounting, tax and other advisory services.

We anticipate that our general and administrative expenses will increase as a result of increased payroll, expanded infrastructure and higher consulting, legal, auditing and tax-related services associated with maintaining compliance with Nasdaq listing and U.S. Securities and Exchange Commission, or SEC, requirements, accounting and investor relations costs, and director and officer insurance premiums associated with being a public company in the United States and in the United Kingdom.Our general and administrative expenses may increase if we expand or progress our development programs. Additionally, if and when we believe a regulatory approval of any product candidate appears likely, we anticipate an increase in payroll and expense as a result of our preparation for commercial operations, particularly as it relates to the sales and marketing of our products.

Interest Income

Interest income consists of interest earned on our cash and cash equivalents held with banks and our marketable securities. Interest income also includes the non-cash financing component of the future minimum guaranteed royalties for Vashe.

Income Taxes

We have not recorded any income tax benefits for the net losses we have incurred due to the uncertainty of realizing a benefit from those losses.

Consolidated Results of Operations

Comparison of Six Months Ended June 30, 2018 and 2017

The following table sets forth our results of operations for the six months ended June 30, 2018 and 2017:

	Six Months Ended June 30,		
	2018	**2017**	**Change**
Revenues	$ -	$ 619	$ (619)
Operating expenses:			
Research and development	7,376	2,968	4,408
General and administrative	3,518	1,602	1,916
	10,894	4,570	6,324
Loss from operations	(10,894)	(3,951)	(6,943)
Interest income	248	18	230
Net loss	$ (10,646)	$ (3,933)	$ (6,713)

Revenues

Upon adoption of the New Revenue Standard on January 1, 2018, we only recognize royalty revenue from our licensing arrangement for Vashe when they exceed the minimum guaranteed royalties. Actual royalties during the six months ended June 30, 2018 did not exceed the minimum guaranteed amounts. During the six months ended June 30, 2017, we recognized royalty revenues of $0.6 million under the previous revenue recognition standards.

Research and Development Expenses

Research and development expenses increased by $4.4 million, or 149%, from $3.0 million for the six months ended June 30, 2017 to $7.4 million for the six months ended June 30, 2018. The increase was primarily due to net increases of $3.1 million in our clinical development cost, toxicology studies and regulatory support four our Phase 2 clinical trials for PR022 and PR013 which began in late 2017. As announced in March 2018, we are no longer pursuing the clinical development of PR013. We began our development of RLM023 during the six months ended June 30, 2018 which resulted in an increase to research and development expense of $0.8 million. We also had increases in consulting and compensation costs of $0.3 million as a result of our increase in consultants and headcount to support our clinical development efforts. We also had increases in facility and related costs of $0.2 million, primarily due to the increase of usage of facilities for the purpose of research and development activities.

General and Administrative Expenses

General and administrative expenses increased $1.9 million from $1.6 million for the six months ended June 30, 2017 to $3.5 million for the six months ended June 30, 2018. The increase was due primarily to the $1.5 million of professional services in connection with the registration of ADSs representing our ordinary shares in 2018.

Interest Income

Interest income increased from $18,000 during the six months ended June 30, 2017 to $0.2 million for the six months ended June 30, 2018 as a result of earnings from our cash proceeds from the private placement in October 2017 and the non-cash interest income related to the financing component of our royalty receivables.

Liquidity and Capital Resources

We have incurred net losses and negative cash flows from operations and expect to continue to incur significant losses for the foreseeable future. Our only source of operating cash flow is the royalty received from our out-licensing agreement for Vashe. We expect to increase our investments in research and development and general and administrative expenses in support of our drug development plans. We incurred net losses of $10.6 million and $3.9 million and negative cash flows from operations of $10.1 million and $4.7 million for the six months ended June 30, 2018 and 2017, respectively. As of June 30, 2018, we have an accumulated deficit of $198.0 million. We believe that our existing cash, cash equivalents and marketable securities of $23.7 million as of June 30, 2018 will be sufficient to meet our capital requirements and fund our operations for at least twelve months from the date of issuance of these interim financial statements.

Based on the final analysis of the Atopic Dermatitis trial results, we will determine how to prioritize our available cash resources either for further Atopic Dermatitis development, a proof of concept study in Acne or Psoriasis or for some other purpose which might relate to potential new assets. To further advance our product candidates in clinical development and commercialization or in in-licensing or acquiring new assets, we need to raise substantial additional capital. Please see the section entitled "Cash Flows — Funding Requirements."

Cash Flows

The following table shows a summary of our cash flows from continuing operations for the periods indicated (in thousands):

	Six Months Ended June 30,	
	2018	**2017**
Net cash used in operating activities	$ (10,124)	$ (4,675)
Net cash provided by (used in) investing activities	16,854	(108)
Net cash used in financing activities	-	-

Net Cash Used in Operating Activities

During the six months ended June 30, 2018, net cash used in operating activities was $10.1 million and was primarily attributable to our $10.6 million net loss, that was offset by noncash charges of $0.3 million and the net change in our operating assets and liabilities of $0.3 million. Noncash charges were primarily related to our share-based compensation expense. The change in our operating assets and liabilities was primarily attributable to $0.6 million of royalty payments received during the six months ended June 30, 2018 offset by an increase in our payables and accrued expenses due to the increase in professional services in connection with the registration of our ADSs completed in July 2018.

During the six months ended June 30, 2017, net cash used in operating activities was $4.7 million and was primarily attributable to our $3.9 million net loss and changes in our operating assets and liabilities of $0.9 million that were offset by noncash charges of $0.2 million.

Net Cash Provided by and Used in Investing Activities

During the six months ended June 30, 2018, net cash provided by investing activities was $16.9 million and primarily attributable to the proceeds received upon the maturity of our marketable securities of $27.8 million offset by purchases of marketable securities and property and equipment of $10.9 million and $45,000, respectively.

During the six months ended June 30, 2017, net cash used in investing activities was $0.1 million, which related to purchases of property and equipment.

Funding Requirements

Our expenses are likely to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue or initiate clinical trials of, and seek marketing approval for, our current or potential future product candidates and/or as we seek to in-license or acquire new assets. We currently have no products in clinical trials and we are evaluating the clinical development plans for our product candidates. We have no products approved for sale and there is no assurance that we will obtain future approvals or, if we do, that we will be able to generate revenues or achieve profitable operations. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution to the extent that such sales, marketing and distribution are not the responsibility of potential collaborators. Furthermore, having completed our Nasdaq listing, we expect to incur additional costs associated with operating as a dually listed public company in the United States and the United Kingdom. Accordingly, we may need to obtain substantial additional funding in connection with our continuing drug development operations. Based on the final analysis of the Atopic Dermatitis trial results, we will determine how to prioritize our resources and future needs, either for further Atopic Dermatitis development, a proof of concept study in Acne or Psoriasis or for some other purpose which might relate to potential new assets. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We expect that our cash, cash equivalents and marketable securities as of June 30, 2018 will enable us to fund our operating expenses and capital expenditure requirements for at least twelve months from the date of the issuance of these interim financial statements. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of product discovery, pre-clinical studies and clinical trials associated with current or potential future product candidates;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain potential collaborations on favorable terms, if at all;
- the ability of our potential collaboration partners to exercise options to extend research and development programs;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under collaboration agreements, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;

- the extent to which we acquire or in-license other product candidates, technologies or products;
- the costs of securing manufacturing arrangements for pre-clinical, clinical and commercial production; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates.

Identifying potential product candidates and conducting pre-clinical studies and clinical trials is a time consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of product candidates that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives.

Adequate additional financing may not be available to us on acceptable terms, or at all and may be negatively impacted by the recently announced results of our clinical trial of PR022 in Atopic Dermatitis. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, investor ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect investor rights as a common stockholder. 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 funds through 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. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Critical Accounting Policies

The Critical Accounting Policies and Significant Judgments and Estimates included in our Form F-1 for the year ended December 31, 2017, filed with the SEC on July 3, 2018, have not materially changed.

Recent Accounting Pronouncements

See Note 3 to our unaudited interim consolidated financial statements for a description of recent accounting pronouncements applicable to our consolidated financial statements.

Risk Factors

Our operations and financial results, and an investment in American Depositary Shares, or ADSs, representing our ordinary shares or our ordinary shares, are subject to various risks and uncertainties including those described below. You should carefully consider these risks, in addition to the other information contained in the Form 6-K to which these Risk Factors are furnished, including our consolidated financial statements for the six months ended June 30, 2018 and the related notes furnished as Exhibit 99.2 thereto. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of ADSs representing our ordinary shares or our ordinary shares could decline and an investor in our ADSs representing our ordinary shares or our ordinary shares may lose all or part of such investor's investment.

RISKS RELATING TO THE OUR BUSINESS AND DRUG DEVELOPMENT STRATEGY

Following our announcement of the preliminary top-line results from our Phase 2 clinical trial of our lead product candidate, PR022, for the treatment of Atopic Dermatitis (AD), we may not pursue the clinical development of PR022 or, if we do, we may not be able to obtain marketing approval from the U.S. Food and Drug Administration (FDA) or other regulatory agencies or to generate any revenues from PR022, and securing additional financing to advance the program may be more difficult.

On August 14, 2018, we announced that in our Phase 2 clinical trial of PR022 in subjects with AD, PR022 showed no difference from vehicle in the primary endpoint of percent change in Eczema Area Severity Index (EASI) versus baseline. We do not yet have full data from the study, and we are currently working with the Clinical Research Organization (CRO) to analyse the EASI results and all of the data from the study. However following these preliminary clinical results, we are uncertain as to whether we will pursue the clinical development of PR022 for the treatment of AD and we have communicated that we will update the market as to our plans in September 2018. In addition if we pursue the clinical development of PR022 for AD, we have not determined what trials would be required in order to assess the safety and efficacy of PR022 for the treatment of AD, the costs of those trials, and whether we would be able to obtain regulatory approval to market PR022 for AD from the U.S. Food and Drug Administration (FDA) or other regulatory agencies or to generate any revenues from PR022. We are uncertain as to whether the results of the Phase 2 clinical trial imply that the underlying active pharmaceutical ingredient (API), HOCl, is ineffective for the treatment of AD, or whether the results have broader implications for the clinical efficacy of HOCl for the indications in our pipeline including Acne and Psoriasis or otherwise. Additionally, after similar negative results, other companies in our industry have found it more difficult to raise capital and, when they have been able to raise capital, it has typically been on less favorable terms than they otherwise might have been able to attain had the results been favorable. In light of the foregoing, we are also currently assessing our clinical development plan for AD and our other indications and product candidates in light of our levels of cash on hand and clinical priorities. If we delay the development of our other products or decline to pursue their development, our business and financial results may suffer, and we may not achieve revenue and/or profitability on the same timeline that we otherwise would have or at all. This could have a material adverse effect on the trading value of our ordinary shares and ADSs representing our ordinary shares.

We have no product candidates in clinical trials at this time.

Following the completion of the Phase 2 clinical trial of our lead product candidate, PR022, for the treatment of AD, we have no products currently in clinical trials. Clinical development of product candidates can be a time-consuming and extended pathway, and the fact that we have no other product candidates in clinical trials means that any potential revenue opportunity from marketed products is likely to be further out than one would have anticipated prior to our receipt of the Phase 2 results. Even if we pursue the clinical development of PR022, we may be required to complete certain clinical trials or supplemental testing activities that could extend the pathway to regulatory approval, if such approval is in fact received. This could have a material adverse effect on the trading value of our ordinary shares and ADSs representing our ordinary shares.

We have incurred significant losses and negative cash flow since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

We are a clinical stage drug development company. Since inception, we have incurred significant net losses and negative cash flows from operations. We incurred net losses of $10.6 million, $3.9 million and $10.5 million, and negative cash flows from operations of $10.1 million, $4.7 million and $9.5 million for six months ended 30 June 2018 and 2017 and year ended 31 December 2017, respectively. As at 30 June 2018, we had an accumulated deficit of $198.0 million. We have no pharmaceutical products approved for commercialization from which to generate revenue. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially:

- if and to the extent that we continue ongoing clinical trials evaluating PR022 for the treatment of AD, or initiate and complete additional clinical trials of PR022 in such indication, as needed;
- if and to the extent that we continue development of and pursue regulatory approvals for our product candidates for the treatment of Acne and Psoriasis;
- if we seek to develop additional product candidates based upon our proprietary technology;
- if we ultimately establish a commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- if we seek to in-license or acquire additional product candidates for development to expand [or diversify] our product pipeline;
- if we are required to adapt our regulatory compliance efforts to incorporate requirements applicable to any marketed products for which we may obtain regulatory approval;
- as we maintain and protect, and to the extent that we expand, our intellectual property portfolio;
- if we hire additional clinical, manufacturing, scientific, operational, financial, information technology or other personnel; and
- as we incur incremental legal, accounting and other expenses operating as a public company in both the United States (U.S.) and the United Kingdom (UK).

To become and remain profitable, we must succeed in developing and eventually commercializing product candidates that generate significant revenue. This will require us to be successful in a range of challenging activities, including successfully completing pre-clinical testing and clinical trials of our product candidates, obtaining regulatory approval, and manufacturing, marketing and selling any product candidates for which we may obtain regulatory approval, as well as discovering, developing and / or acquiring additional product candidates. However following our recent announcement regarding the results from our Phase 2 clinical trial of our lead product candidate, PR022, for the treatment of AD, we may not be able to obtain marketing approval for PR022 from the FDA or other regulatory agencies or to generate any revenues from PR022. It is possible that we may never succeed in being able to market our other product candidates as well and, even if we are successful in obtaining regulatory approval, we may never be able generate revenue that is significant enough to achieve profitability.

In cases where we are successful in obtaining regulatory approval to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement, our label claims, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

Because of the numerous risks and uncertainties associated with product development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain product approvals, diversify our offerings or continue our operations. A decline in the value of our Company could also cause you to lose all or part of your investment in our ordinary shares and or your ADSs representing our ordinary shares.

We will be required to raise additional capital to support our drug development strategy, which may cause dilution to or adversely affect the rights of holders of ADSs representing our ordinary shares and our ordinary shares, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We had cash, cash equivalents and marketable securities of $23.7 million as at 30 June 2018. The costs associated with developing, testing and obtaining regulatory approval for drugs are significant, and the timelines for obtaining regulatory approvals for drugs are lengthy and uncertain. We expect to continue to incur significant expenses and operating losses over the next several years associated to support our clinical development program, the costs of which are subject to the factors set forth in the preceding risk factor. The following factors, among others, may cause our future funding requirements to be greater than anticipated or to accelerate the need for funds:

- recently announced results from our Phase 2 clinical trial of PR022 for the treatment of AD, which may require us to expend additional funds on testing the safety and efficacy of that product candidate to obtain regulatory approval, if and to the extent that we determine to pursue the clinical development of PR022 for the treatment of AD;
- unforeseen developments during pre-clinical trials, including toxicology studies;
- unfavorable or unexpected events related to or the outcomes of clinical trials, including delays in enrolment;
- delays in the timing of receipt of required regulatory approvals or clearances for next phases of clinical trials;
- broader than anticipated safety or efficacy trials imposed by regulators;
- unanticipated expenses in research and development;
- unanticipated expenses or delays in the manufacture of clinical trial material;
- the success or failure of existing or potential new therapies for the treatment of diseases being targeted by us;
- unanticipated expenses in defending or fortifying intellectual property rights;
- lack of financial resources to adequately support operations;
- the need to respond to technological changes and competition;
- unforeseen problems in attracting and retaining qualified personnel;
- claims that might be brought in excess of our insurance coverage;
- warranty claims related to the sale of our Supermarket Retail business in October 2016; or
- imposition of penalties for failure to comply with regulatory guidelines.

Until such time, if ever, as we can generate substantial product revenues, we may finance our cash needs through securities offerings, debt financings, license and collaboration agreements, or other capital raising transactions. If we raise capital through equity securities offerings, your equity interest ownership in our Company will be diluted, and the terms of the securities that we issue in such transaction may include liquidation or other preferences that adversely affect your rights as a holder of ADSs representing our ordinary shares or of our ordinary shares. Debt financing, if available, could result in fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, to acquire, sell or license intellectual property rights, to make capital expenditures, to declare dividends, or other operating restrictions. If we raise additional funds through collaboration or licensing agreements, we may have to relinquish valuable rights to our technologies, future revenue streams, or product candidates or grant licenses on terms that may not be favorable to us. In addition, we could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. Raising additional capital through any of these or other means could adversely affect our business and the holdings or rights of our security holders, and may cause the market price of ADSs representing our ordinary shares or our ordinary shares to decline. Further, the recently announced results from our Phase 2 clinical study could negatively impact the value of our Company and result in a higher cost of capital or higher level of dilution than otherwise might be incurred in the event of a dilutive financing.

All of our current product candidates contain the same API, which is the API in PR022, which showed no difference from vehicle in the primary endpoint as recently announced in the results from the Phase 2 clinical trial of PR022 for the treatment of AD, and was also the API in our former product candidate PR013 for the treatment of Allergic Conjunctivitis, or AC, which did not demonstrate efficacy in its Phase 2 clinical trial.

HOCl, based on our proprietary platform technology, is the API in all of our current product candidates. Since our current pipeline does not contain product candidates other than those with HOCl as the API, we may be limited in our future product development efforts unless we in-license or acquire additional product candidates, products or technologies, which in any such case could be costly and / or unsuccessful. On August 14, 2018, we announced that in our Phase 2 clinical trial of PR022 in subjects with AD, PR022 showed no difference from vehicle in the primary endpoint of percent change in Eczema Area Severity Index (EASI) versus baseline. In March 2018, we announced that our Phase 2 clinical trial of PR013, a product candidate designed as a topical solution for Allergic Conjunctivitis, an ophthalmic disease, did not demonstrate efficacy. As a result, we are uncertain as to whether we intend to pursue the clinical development of PR022 for the treatment of AD and we are no longer pursing the clinical development of PR013. PR022 and PR013 contain the same API as our other product candidates. There could be an actual or perceived impact on the likelihood of our other product candidates to be successful in their clinical trials. If the failure of our AD Phase 2 trial or AC Phase 2 clinical trial is indicative of an underlying inefficacy of HOCl for indications other than AD and AC, respectively, it could have a material adverse effect on the other product candidates in our pipeline and our clinical development plan related thereto and on our business, more generally.

HOCl is inherently unstable, which may affect the marketability of our product candidates.

HOCl is formed from the dissolution of chlorine in water. The form of chlorine changes from Cl2 to HOCl to OCL- depending on the pH of its environment. HOCl is the form in which chlorine predominantly exists at a pH range of 4.0 to 6.5. This presents a challenge to the stability, and therefore the marketability, of our product candidates. While we have been granted patents regarding the stabilization of HOCl, there can be no assurance that we will be able to develop and manufacture one or more formulations of HOCl that provide a sufficient shelf-life for the commercialization of product candidates based on such technology. To achieve a commercially viable shelf-life for such product candidates may require a significant investment of money and resources, as well as time to develop, test and potentially patent, new formulations and packaging designs. Cold-chain maintenance may also be required to be instituted in the drug supply chain in order to maintain the necessary shelf life in order for our product candidates, if and when approved, to be competitive in the marketplace. Additionally, we may not be able to achieve a shelf-life comparable to the products of our competitors, which could result in higher costs to manufacture and distribute our products.

Our current product candidate pipeline is focused solely on dermatological indications.

All of the candidates currently in our clinical development pipeline are targeted topical treatments for dermatological conditions. This focus on a particular subset of indications may not be sufficiently diversified to manage the risk that the failure of any specific clinical trial may implicate the prospective viability of the other product candidates in our clinical development pipeline. For example, our preliminary results from our Phase 2 clinical trial of our lead product candidate, PR022, for the treatment of AD, may actually impact or may be perceived to impact the potential for our other product candidates to be safe and effective for any or all dermatological indications. Furthermore, we may not be able to identify other therapeutic areas for which our platform technology has potential utility. If our efforts to develop our HOCl platform technology in dermatology are unsuccessful, and we are not able to pursue alternate indications, our business will be materially adversely affected.

In addition, we are aware of recent high profile failures of products in clinical trials for AD and Acne, which could negatively influence investor confidence in the ability of companies to develop new drugs for these indications and, therefore, their willingness to further invest in products being developed to treat AD or Acne.

It is not uncommon in any trial, but particularly in dermatology trials, for the placebo/vehicle to demonstrate some level of efficacy, making it more difficult to demonstrate a clinically meaningful or statistically significant difference between the drug and placebo response, which is one of the key measures for determining success in a clinical trial. In our Phase 2 clinical trial of PR022 for the treatment of AD, PR022 did not show a difference versus vehicle in the primary endpoint. If we are not able to determine clinically meaningful or statistically significant responses in clinical trials of our product candidates, it will have a material adverse effect on our ability to obtain regulatory approvals to market our product candidates, including PR022.

Clinical product development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

In clinical development, the risk of failure for product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete pre-clinical testing and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans.

The results of pre-clinical studies and early-stage clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. The recently announced results of our Phase 2 clinical trial of PR022 for the treatment of AD indicated that PR022 did not in fact create a different effect versus vehicle. A number of companies in the biopharmaceutical industry have suffered similar significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials or pre-clinical studies. Our future clinical trial results, if any, may not be successful.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of pre-clinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

We have not completed all clinical trials required for the approval of any of our product candidates and we cannot assure you that any clinical trial that we may conduct in the future, will demonstrate adequate efficacy and safety to obtain regulatory approval to market our product candidates. We may experience numerous unforeseen events during or as a result of clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- delays in reaching, or failure to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites or prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- our Phase 2 clinical trial of PR022 for the treatment of AD produced, and future clinical trials of our product candidates may produce, negative or inconclusive results, including failure to demonstrate statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs, including with respect to PR022;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrolment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our product candidates may have undesirable side effects, cause adverse events, or AEs, or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials and in the case of AEs for us to incur losses as a result of claims, actions or settlements;
- our current or future third party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient, delayed or inadequate.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the institutional review boards of the institutions in which such trials are being conducted, by the data safety monitoring board for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly.

There are also a number of factors particular to the clinical development of our product candidate pipeline that could affect the timing and cost of development of our product candidates. The toxicology studies necessary to support the submission of a New Drug Application, or NDA, for all of our product candidates have not yet been conducted and there is no certainty as to the outcome of these studies. In addition, the toxicology studies necessary to support the submission of an IND for certain of our product candidates, have not all been completed and there is no certainty as to the outcome of these studies. Our pipeline candidates are under review in order to consider the implication of the Phase 2 AD trial results on such candidates or indications. Many of the therapeutic areas being targeted by our pipeline candidates have a significant pediatric patient population. Clinical trials and commercialization of products involving a pediatric population carry a higher degree of risk than they otherwise would, given the potential liability associated with AEs involving children.

In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate (including due to the recently announced results from our Phase 2 clinical trial of PR022 for the treatment of AD), if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not favorable or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our pre-clinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant pre-clinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize, or receive approval for, our product candidates.

Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third party payors and others in the medical community necessary for commercial success.

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the label claims and target patient populations for our product candidates;
- the efficacy, safety and potential advantages of any of our product candidates compared to alternative treatments;
- our ability to offer our products for sale at competitive prices;
- the stability, shelf life, convenience and ease of storage and administration compared to alternative treatments;
- the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments;
- our ability to hire and retain a sales force in the U.S., or to engage one or more third party distributors for our products;
- the strength of marketing and distribution support;
- the availability of third party coverage and adequate reimbursement for and any product candidates;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

If we are unable to establish sales, marketing and distribution capabilities for our product candidates that may receive regulatory approval, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have sales or marketing infrastructure. To achieve commercial success for any product candidate for which we may obtain marketing approval, we will need to establish a sales and marketing organization or to engage one or more third party distributors for our products. In the future, we expect to build a focused sales and marketing infrastructure to market or co-promote some of our product candidates in the US, if and when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. If we are unable to establish our own sales, marketing and distribution capabilities and are forced to enter into arrangements with, and rely on, third parties to perform these services, our revenue and our profitability, if any, are likely to be lower than if we had developed such capabilities ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Even if we obtain regulatory approval for any of our product candidates, such product candidate(s) will remain subject to ongoing regulatory oversight.

Even if we obtain any regulatory approval for any of our product candidates, such product candidate(s) will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-market information. Any regulatory approvals that we receive for any of our product candidates may also be subject to Risk Evaluation and Mitigation Strategies, or REMS, limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 trials, and surveillance to monitor the quality, safety and efficacy of the drug.

In addition, drug manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with Current Good Manufacturing Practices, or cGMP, requirements and adherence to commitments made in the NDA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a drug, such as Adverse Events, or AEs, of unanticipated severity or frequency, or problems with the facility where the drug is manufactured or if a regulatory authority disagrees with the promotion, marketing or labelling of that drug, a regulatory authority may impose restrictions relative to that drug, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the drug from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory authority may:

- issue an untitled letter or warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing or manufacturing of the drug;

- seize or detain the drug or otherwise require the withdrawal of the drug from the market;
- refuse to permit the import or export of product candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize PR022 or any other product candidates and harm our business, financial condition, results of operations and prospects.

We may not be successful in our efforts to increase our pipeline, including by pursuing additional indications for our current product candidates, identifying additional indications for our proprietary platform technology or in-licensing or acquiring additional product candidates for dermatological or other indications.

A key element of our strategy is to build and expand our pipeline of product candidates, including by developing our HOCl platform technology for the treatment of additional indications. The recently announced results of our Phase 2 trial of PR022 in Atopic Dermatitis may have a real or perceived impact on the ability of our HOCl technology to be effective in other dermatology indications or non-dermatology indications, thus limiting our ability to leverage the technology and expand our product portfolio. In addition, we are seeking to in-license or acquire additional product candidates potentially for dermatological and other indications. We may not be able to develop or identify product candidates that are safe, tolerable and effective. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify, in-license or acquire may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. Additionally, the failures of our recent Phase 2 trials may negatively impact our Company's reputation or negotiating position in in-licensing or acquiring assets under competitive circumstances.

The success of our product candidates will depend significantly on adequate reimbursement.

Our product candidates have neither been approved for reimbursement, nor have reimbursement rates for our product candidates been determined by commercial or government payors in the U.S. or elsewhere, since all of our product candidates remain in clinical development. Our success will depend in part on adequate reimbursement by such payors for our product candidates for their respective indications. Third party payors determine which treatments they will cover and establish reimbursement levels. Even if a third party payor covers a particular treatment, the reimbursement rate therefor may not be adequate. Reimbursement by a third party payor may depend upon a number of factors including whether a treatment is appropriate for the specific patient; is cost-effective; is supported by peer-reviewed medical journals; and is included in clinical practice guidelines. In addition, since we are pursuing clinical development of product candidates in AD, Acne and Psoriasis and given that low-cost, and often generic, steroids are one of the standards of care in each of the these three indications, payors could require step-through therapy with steroids before reimbursing a patient for our product candidates, if and when they are approved for marketing, or the low price point of these alternative steroid treatments could result in pricing pressure on our product candidates, which would have a material adverse effect on our business and financial results. Furthermore, the payor reimbursement, competition and pricing in these three indications are different. Since our product candidates are all based on the same API, we may not be able to develop products for the three different indications that are sufficiently differentiated in their formulation such that we would be able to market and price them differently or, even if we did, that clinicians won't prescribe the least-cost formulation for their patients among these different indications. This could result in price pressures across our planned portfolio of products, which would have a material adverse effect on our business and financial results.

Healthcare legislative reform measures may have a negative impact on our business and results of operations.

In the U.S., there have been, and continue to be, legislative and regulatory developments regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Additionally, there has been heightened governmental scrutiny in the U.S. of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that they will continue to seek new legislative and / or administrative measures to control drug costs. 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. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or successfully commercialize our drugs.

We are subject to significant competition in the indications that we are pursuing and also with respect to our underlying HOCl platform technology.

In view of our recently announced results in our Phase 2 trial of PR022 in Atopic Dermatitis, other companies may have more potentially efficacious formulations.

We currently rely on our HOCl technology platform as the source of the product candidates in our clinical development pipeline. Our HOCl technology platform is subject to competition from other companies whose technology may offer advantages in terms of safety, efficacy or cost. Competitors may also precede us in commercializing, developing and receiving regulatory approval for products developed based on such technology. As a result, our products may not be competitive or available in the market in a timely manner, which could have a material adverse effect on our business by limiting the potential for sales of our products or creating pricing pressure for our products, if and when they are approved for marketing.

We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from many different sources, including major pharmaceutical and specialty pharmaceutical companies, academic institutions and governmental agencies and public and private research institutions. We are aware of a significant number of commercialized products as well as products in development in each of the three therapeutic areas that we are currently targeting in our clinical development pipeline, which could result in a significantly greater field of competition by the time our products are approved and thereafter commercialized. We consider PR022's prospective competitors for the treatment of AD to be topical steroids; Crisaborole topical PDE-4 inhibitor; and Dupilumab, an injectable IL-4 and IL-13 inhibitor for moderate to severe AD. Certain calcineurin inhibitors, such as Elidel, are also prescribed for the treatment of AD. Standard treatments for Acne include antibiotics, antibacterials, retinoids and oral contraceptives. There are a number of treatments for Psoriasis on the market, including biologics, topical therapies such as corticosteroids or vitamin D, as well as systemic immunosuppressive drugs, or phototherapy.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any product that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our product, which could result in our competitors establishing a strong market position before we are able to enter the market or could result in the approval of our product being delayed until the expiration of any new chemical entity exclusivity or other regulatory exclusivity received by such competitor.

We are also aware of other companies that manufacture, market and / or sell HOCl or chlorine based products at different concentrations and formulations and for different indications than we target. Some of these products are sold over-the-counter, or OTC. If we demonstrate clinical efficacy in our trials with our HOCl based products, these other companies could use our results to promote their products as having the same or similar efficacy as our products. If successful, they may offer their products at a lower cost for the same indications, or they may seek to convince clinicians, patients or payors that their products are a good alternative to our products. If these OTC companies are successful in such efforts, our ability to market our products, if and when approved, may be limited.

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

We are dependent on third parties to support our drug development efforts.

We currently utilize one contract manufacturer for our API and a separate contract manufacturer for PR022. We do not have long-term supply agreements in place with these contract manufacturers. These contract manufacturers may not be able to scale-up sufficiently to meet our requirements for material needed for our pre-clinical studies and clinical trials and potentially for the commercialization of our product candidates, and they may not be have the capacity, ability or willingness to manufacture multiple product candidates within our required timeframe. In addition, like many development stage drug companies with small internal teams, we have partnered with third parties in relation to development efforts, clinical trial material manufacturing, pre-clinical / safety studies, analytical studies and regulatory support. As such, we are dependent on a few key partners to deliver equipment, services and products on specified timelines and costs in order to meet our development plans. In some cases, it may be necessary to dual source goods and services in order to meet timelines or other requirements, resulting in additional costs. Finally, we source a critical element of our manufacturing equipment from one supplier, so if a replacement or additional part is needed, we are reliant on that supplier to provide the component on a timely basis and in the required timeframe. The supplier's inability to meet these requirements could have a material adverse effect on the timeline, cost and viability of our clinical development program.

We rely on a small team of key management and scientists to execute our business strategy.

We rely on small management and research and development teams. In particular, we rely on the efforts of our Chief Executive Officer, Alex Martin, our Chief Financial Officer and Chief Operating Officer, Marella Thorell, and our Chief Medical Officer, Dr. Christian Peters. While we have entered into employment agreements with certain executive officers, each of these employees may terminate their employment with us at any time. We do not maintain "key person" insurance for either of these executive officers. Our scientific staff, including our Chief Medical Officer, possesses a significant amount of unregistered intellectual property or know-how regarding chlorine in general and our product candidates specifically which, if these team members were to leave our Group, it could take a significant amount of time and money to re-build. The loss of key members of either our management or research and development teams could result in a delay of our business and strategic plans and operations or require us to incur additional costs to recruit and / or train replacements, any of which could have a material adverse effect on our business.

We may become subject to claims in connection with past asset dispositions.

We sold our Supermarket Retail business in October 2016. In connection with this transaction, we provided customary representations, warranties and covenants and related indemnities to counterparties. Although we are not aware of any outstanding matters that would reasonably form a basis for a claim related to this transaction, circumstances may arise that could result in a claim against us by counterparties pursuant to our indemnification obligations thereunder and the underlying representations, warranties and covenants. If we become subject to liability based upon such contractual obligations or otherwise and we are required to indemnify the counterparties, it could have a material adverse effect on our business and financial position.

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 the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or drugs 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 drugs that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards paid to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

We currently hold $10 million in product liability insurance coverage in the aggregate, with a per incident limit of $10 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. 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.

Our business and operations would suffer in the event of computer system failures, cyberattacks or a deficiency in our cybersecurity.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyberattacks or cyber intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, damage to our reputation, and the further development of our product candidates could be delayed.

RISKS RELATING TO INTELLECTUAL PROPERTY MATTERS

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

We rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to our product candidates. The issuance, scope, validity, enforceability, strength and commercial value of patents in the pharmaceutical field involves complex legal and scientific questions and can be uncertain. Some patent applications that we own may fail to result in issued patents with claims that cover the product candidates in the U.S. or in foreign jurisdictions. If this were to occur, early generic competition could be expected against our product candidates in development. There may be relevant prior art relating to our current or future patents and patent applications which could invalidate a patent or prevent a patent from issuing based on a pending patent application.

We have in-licensed certain intellectual property, including patents, from Dr. Vitold Bakhir relating to electrochemical cell devices for production of HOCl. While our licenses are exclusive at least within our field and require cooperation from the licensor to enforce the licensed patents, there is no guarantee that these patents will be successfully enforced against competitors, or that the licensor will fully comply with the terms of the license, including obligations relating to patent enforcement and defense of the patents. Further, we have sublicensed certain intellectual property licensed from Dr. Bakhir to Chemstar Corp. for certain unrelated fields, including rights to enforce this intellectual property in these fields. Enforcement of the intellectual property in the sublicensed fields could compromise or result in invalidation of some or all of the intellectual property sublicensed to Chemstar Corp.

The patent prosecution process is expensive and time consuming. We may not be able to prepare, file, and prosecute all necessary or desirable patent applications for a commercially reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Further, there are other companies pursuing HOCl related technologies. These third parties may file patent applications or disclose concepts relevant to our technology before we are able to file our patent applications, and thus these third party patents and disclosures may constitute prior art against our patents and applications. Moreover, depending on the terms of any future in licenses to which we may become a party, we may not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain or enforce the patents, covering technology in licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how, information, or technology that is not patentable or is difficult to patent, including processes and information relating to our manufacturing and drug development programs for which patents are difficult to enforce or would not provide a competitive advantage in our market. Although we generally require 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. Also, 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, others may independently discover our trade secrets and proprietary information. For example, the FDA is 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. Furthermore, we have sold certain of our businesses over the past few years, pursuant to which licenses were granted to the acquirers of such businesses to utilize certain of our intellectual property rights, including rights to produce and market HOCl for particular purposes. We have also out-licensed our intellectual property to certain third parties. If the licensees do not respect the terms of such agreements, including limitations as to the field of use, then we could be adversely affected due to the loss of potential business opportunities outside the scope of those granted to the licensees, or we could be subject to non-contractual disclosure of such information. If we are 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, 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.

We may enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing and prosecuting patent applications and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. While we have filed patent applications in jurisdictions that we believe are important to our business, our patent position in these jurisdiction may not be the same as our position in the U.S.. 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 rights are not as strong as those in the U.S. or Europe. These products may compete with our product candidates, and our future patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications before grant. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the U.S., but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

While we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the U.S. and Europe, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property rights, which could make it difficult for us to stop the infringement of our future patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our future patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents, 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.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future patents.

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the U.S. and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific, and factual issues. Changes in either patent laws or interpretations of patent laws in the U.S. and other jurisdictions or countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have owned or licensed or that we might obtain in the future. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Similarly, changes in patent laws and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we may obtain in the future. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U.S.. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. 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, 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 U.S. and other jurisdictions or countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

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

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and / or applications, including certain in-licensed patents, will be due to be paid to the USPTO and various government patent agencies outside of the U.S. over the lifetime of our patents and / or applications and patent rights we may obtain or apply for in the future. We rely on our outside counsel to coordinate payment of these fees. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply with procedural and formal requirements relating to our patents. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patents or patent applications, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market, and this circumstance could harm our business.

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 file infringement claims, which can be expensive and time-consuming. If we initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product or product candidate is invalid and / or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity and / or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. 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. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, inter partes review, or IPR, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could be more expeditious or cost-effective for plaintiffs than a standard court proceeding, and could result in revocation of or amendment to our patents in such a way that they no longer cover our product candidates or similar products of our competitors. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. 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, could put our patent applications at risk of not issuing and could have a material adverse effect on our business.

Interference or derivation proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patent applications. 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 or derivation 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 U.S..

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 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 and ADSs representing our ordinary shares.

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

As our current and future product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. There can be no assurance that our current and future product candidates do not infringe other parties' patents or other proprietary rights, and competitors or other parties may assert that we infringe their proprietary rights in any event. For instance, we are aware of a significant patent estate around HOCl. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and future product candidates, including interference or derivation proceedings before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. There are third parties that hold significant patent estates relating to HOCl. While we do not believe these third party patent estates cover any of our technology, if we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Under certain circumstances, we could be forced, including by court orders, to cease commercializing our product candidates. In addition, in any such proceeding or litigation, we could be found liable for substantial monetary damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations.

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

We may also be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patent applications, our future 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 product candidates. 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.

RISKS RELATING TO THE OUR ORDINARY SHARES AND OUR ADSs REPRESENTING ORDINARY SHARES

The price of ADSs representing our ordinary shares or our ordinary shares may be volatile and may fluctuate due to factors beyond our control.

The trading market for publicly traded clinical stage drug development companies has been highly volatile and is likely to remain highly volatile in the future. The market price of ADSs representing our ordinary shares or our ordinary shares may fluctuate significantly due to a variety of factors, including:

- positive or negative results from, or delays in, testing or clinical trials conducted by us or our competitors;
- technological innovations or commercial product introductions by us or competitors;
- changes in U.S. and international government regulations;
- developments concerning proprietary rights, including patents and litigation matters;
- public concern relating to the commercial value or safety of our product candidates;
- financing events, or our inability to obtain financing, or other corporate transactions;
- publication of research reports or comments by securities or industry analysts;
- general market conditions in the biopharmaceutical and pharmaceutical industries or in the economy as a whole;
- other events and factors, many of which are beyond our control.

In addition, we cannot assure investors that our ordinary shares will continue to be traded on AIM. If such trading were to cease, certain investors may decide to sell their ordinary shares, which could have an adverse impact on the price of the ordinary shares and the ADSs representing our ordinary shares. For so long as our ordinary shares are traded on AIM and Nasdaq, it is possible that relatively small trades on AIM or Nasdaq could disproportionately affect the trading price of our ordinary shares on AIM and of ADSs representing our ordinary shares on Nasdaq due to the current limited trading volume of our ordinary shares on AIM and Nasdaq.

These and other market and industry factors may cause the market price and demand for ADSs representing our ordinary shares or our ordinary shares to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their ADSs representing our ordinary shares or ordinary shares and may otherwise negatively affect the liquidity of ADSs representing our ordinary shares or our ordinary shares. In addition, the U.S. and UK stock markets in general, and the equities of emerging companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past in the U.S., when the market price of a security has been volatile, holders of that security have sometimes instituted securities class action litigation against the issuer. If any of the holders of ADSs representing our ordinary shares or our ordinary shares were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our senior management would be diverted from the operation of our business. Any adverse determination in litigation could also subject us to significant liabilities.

We are incurring increased costs as a result of operating as a company with securities listed in the U.S. in addition to the UK, and our senior management is required to devote substantial time to new compliance initiatives and corporate governance practices.

As a company with securities listed in the U.S. in addition to the UK, and particularly after we no longer qualify as an emerging growth company, we will incur significant legal, accounting, insurance and other expenses that we did not incur previously. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on non-U.S. reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our senior management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will be required to furnish a report by our senior management on our internal control over financial reporting beginning with our second annual report to be filed with the U.S. Securities and Exchange Commission, or SEC. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To prepare for eventual compliance with Section 404, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. We anticipate that the process to document and evaluate our internal control over financial reporting will be both costly and challenging.

To date, there has been no public market for ADSs representing our ordinary shares, and an active market may not develop in which investors can resell such ADSs.

To date, there has been no public market for ADSs representing our ordinary shares although our ordinary shares have traded on AIM since 2014 and prior to that on the main market of the London Stock Exchange since 2006. We cannot predict the extent to which an active market for ADSs representing our ordinary shares will develop or be sustained or how the development of such a market might affect the market price for our ordinary shares on AIM..

Fluctuations in the exchange rate between the U.S. dollar and the pound sterling may increase the risk of holding the ADSs.

Our share price is quoted on AIM in pounds sterling, while the ADSs will trade on Nasdaq in U.S. dollars. Fluctuations in the exchange rate between the U.S. dollar and the pound sterling may result in temporary differences between the value of the ADSs representing our ordinary shares and the value of our ordinary shares, which may result in heavy trading by investors seeking to exploit such differences. In addition, as a result of fluctuations in the exchange rate between the U.S. dollar and the pound sterling, the U.S. dollar equivalent of the proceeds that a holder of the ADSs representing our ordinary shares would receive upon the sale in the UK of any shares withdrawn from the depositary receipts facility, and the U.S. dollar equivalent of any cash dividends paid, if any, in pounds sterling on our ordinary shares represented by the ADSs, could also decline.

Future sales, or the possibility of future sales, of a substantial number of ADSs representing our ordinary shares or our ordinary shares could adversely affect the price of such securities.

Future sales of a substantial number of ADSs representing our ordinary shares or our ordinary shares, or the perception that such sales will occur, could cause a decline in the market price of ADSs representing our ordinary shares and our ordinary shares. As at 13 August 2018, we had 116,561,917 ordinary shares issued and outstanding, and 1,653,112 ADSs representing our ordinary shares outstanding. All of our ordinary shares are freely tradeable on AIM. Holders of all of our ordinary shares are able to deposit such ordinary shares with the depositary in exchange for ADSs representing such shares at the ratio of 25 ordinary shares to 1 ADS, which ADSs are freely tradeable.

If holders sell substantial amounts of ADSs representing our ordinary shares or ordinary shares in the respective public markets therefor, or if the market perceives that such sales may occur, the market price of ADSs representing our ordinary shares and our ordinary shares and our ability to raise capital through an issue of equity securities in the future could be adversely affected.

Because we do not anticipate paying any cash dividends on our ordinary shares which underlie our ADSs in the foreseeable future, capital appreciation, if any, will be the sole source of gains on such securities and you may never receive a return on your investment.

Under the laws of England and Wales, a company's accumulated realized profits must exceed its accumulated realized losses on a non-consolidated basis before dividends can be paid. Therefore, we must have distributable profits before issuing a dividend. We have not paid dividends in the past on our ordinary shares. We intend to retain earnings, if any, for use in our business and do not anticipate paying any cash dividends in the foreseeable future. As a result, capital appreciation, if any, on ADSs representing our ordinary shares or our ordinary shares are expected to be the sole source of gains on such securities for the foreseeable future.

Securities traded on AIM may carry a higher risk than securities traded on certain other exchanges, which may impact the value of your investment.

Our ordinary shares are currently traded on AIM. Investment in equities traded on AIM is sometimes perceived to carry a higher risk than an investment in equities quoted on exchanges with more stringent listing requirements, such as the main market for listed securities of the London Stock Exchange. This is because AIM imposes less stringent corporate governance and ongoing reporting requirements than these other exchanges. In addition, AIM requires only half-yearly financial reporting, rather than the quarterly financial reporting required for U.S.-listed companies that are domestic registrants. You should be aware that the value of our ordinary shares may be influenced by many factors, some of which may be specific to us and some of which may affect AIM-quoted companies generally, including the depth and liquidity of the market, our performance, a large or small volume of trading in our ordinary shares, legislative changes, and general economic, political, or regulatory conditions, and that prices may be volatile and subject to significant fluctuations. Therefore, the market price of ADSs representing our ordinary shares and our ordinary shares may not reflect the underlying value of our company.

Holders of ADSs may not have the same voting rights as the holders of our ordinary shares and may not receive voting materials in time to be able to exercise their right to vote.

Holders of ADSs representing our ordinary shares will not be able to exercise voting rights attaching to the underlying ordinary shares on an individual basis. Holders of ADSs representing our ordinary shares must appoint the depositary or its nominee as their representative to exercise the voting rights attaching to the ordinary shares underlying such ADSs. Holders of ADSs representing our ordinary shares may not receive voting materials in time to instruct the depositary to vote, and it is possible that they, or persons who hold such ADSs representing our ordinary shares through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote. Furthermore, the depositary may not be liable for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, holders of ADSs representing our ordinary shares may not be able to exercise voting rights and may lack recourse if such ADSs representing our ordinary shares are not voted as requested. In addition, holders of ADSs representing our ordinary shares will not be able to call a shareholders' meeting.

Holders of ADSs representing our ordinary shares may not receive distributions on our ordinary shares underlying our ADSs or any value for them if it is illegal or impractical to make them available to such holders.

The depositary for ADSs representing our ordinary shares has agreed to pay to holders of such ADSs cash dividends or other distributions that it or the custodian receives on our ordinary shares after deducting its fees and expenses. Holders of ADSs representing our ordinary shares will receive these distributions in proportion to the number of our ordinary shares underlying their ADSs. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical for the depositary to make a distribution available to holders of ADSs representing our ordinary shares. We have no obligation to take any other action to permit the distribution of ADSs representing our ordinary shares, ordinary shares themselves, rights or anything else to holders of ADSs representing our ordinary shares. This means that holders of ADSs representing our ordinary shares may not receive any distributions that we make on our ordinary shares or any value from them if it is unlawful or impractical to make such distributions available to holders. These restrictions may negatively impact the trading value of ADSs representing our ordinary shares.

Holders of ADSs may be subject to limitations on transfer of their ADSs.

ADSs representing our ordinary shares are transferable on the books of the depositary. However, the depositary may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, the depositary may refuse to deliver, transfer, or register transfers of ADSs representing our ordinary shares generally when our books or the books of the depositary are closed, or at any time if we or the depositary deems it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason in accordance with the terms of the deposit agreement.

The rights accruing to holders of our ordinary shares may differ from the rights typically accruing to shareholders of a U.S. corporation.

We are incorporated under the law of England and Wales. The rights of holders of ordinary shares are governed by the laws of England and Wales, including the provisions of the U.K. Companies Act 2006, and by our Articles of Association. These rights differ in certain respects from the rights of shareholders in typical U.S. corporations.

Claims of U.S. civil liabilities may not be enforceable against us.

We are incorporated under the law of England and Wales. Certain of our directors reside outside the U.S.. As a result, it may not be possible for investors to effect service of process within the U.S. upon such persons or to enforce judgments obtained in U.S. courts against them or us, including judgments predicated upon the civil liability provisions of the U.S. federal securities laws. The U.S. and the UK do not currently have a treaty providing for recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. Consequently, a final judgment for payment given by a court in the U.S., whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in the UK. In addition, uncertainty exists as to whether English courts would entertain original actions brought in the UK against us or our directors predicated upon the securities laws of the U.S. or any state in the U.S.. Any final and conclusive monetary judgment for a definite sum obtained against us in U.S. courts would be treated by the courts of the UK as a cause of action in itself and sued upon as a debt at common law so that no retrial of the issues would be necessary, provided that certain requirements are met. Whether these requirements are met in respect of a judgment based upon the civil liability provisions of the U.S. securities laws, including whether the award of monetary damages under such laws would constitute a penalty, is an issue for the court making such decision. If an English court gives judgment for the sum payable under a U.S. judgment, the English judgment will be enforceable by methods generally available for this purpose. These methods generally permit the English court discretion to prescribe the manner of enforcement. As a result, U.S. investors may not be able to enforce against us or our certain of our directors, or certain experts named herein who are residents of the UK or countries other than the U.S., any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

We currently qualify as a foreign private issuer and, as a result, we will not be subject to U.S. proxy rules and will be subject to reporting obligations under the Exchange Act, that, to some extent, are more lenient and less frequent than those of a U.S. domestic public company.

Upon the effectiveness of our registration statement in July 2018, we now report under the Exchange Act, as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents, or authorizations in respect of a security registered under the Exchange Act; (ii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information or current reports on Form 8-K, upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their annual report on Form 20-F until 120 days after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers also are exempt from Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, holders of ADSs representing our ordinary shares or holders of our ordinary shares may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

As a foreign private issuer and as permitted by the listing requirements of Nasdaq, we may follow UK corporate governance rules instead of certain corporate governance requirements of Nasdaq.

As a foreign private issuer, we may follow our home country corporate governance rules instead of certain corporate governance requirements of Nasdaq. For example, we are exempt from Nasdaq regulations that require a listed U.S. company to:

- have a majority of the board of directors consist of independent directors as such term is defined by Nasdaq;
- promptly disclose any waivers of the code for directors or executive officers that should address certain specified items;
- have a nominating committee that is fully independent, as defined by Nasdaq;
- solicit proxies and provide proxy statements for all shareholder meetings; and
- seek shareholder approval for the implementation of certain equity compensation plans and issuances of ordinary shares.

In accordance with our Nasdaq listing, our Audit Committee is required to comply with the provisions of Section 301 of the Sarbanes-Oxley Act of 2002 and Rule 10A-3 of the Exchange Act, both of which also are applicable to Nasdaq-listed U.S. companies. Because we are a foreign private issuer, however, our Audit Committee is not subject to additional Nasdaq requirements applicable to listed U.S. companies, including an affirmative determination that all members of the Audit Committee are "independent" using more stringent criteria than those applicable to us as a foreign private issuer.

To the extent we determine to follow UK corporate governance practices instead of Nasdaq governance requirements, you may not have the same protections afforded to shareholders of companies that are subject to these Nasdaq requirements.

We may lose our foreign private issuer status, which would then require us to comply with the Exchange Act's domestic reporting regime and Nasdaq's corporate governance requirements applicable to a domestic issuer, and cause us to incur significant incremental legal, accounting and other expenses.

A significant portion of our shares are owned by U.S. residents and, following the effectiveness of our Nasdaq registration statement, an increased number of ordinary shares are expected to be beneficially owned by U.S. residents. Although we currently qualify as a foreign private issuer, in order to maintain this status, either (a) a majority of our ordinary shares, including ordinary shares represented by ADSs, must be either directly or indirectly owned of record by non-residents of the U.S. or (b)(i) a majority of our executive officers or directors must not be U.S. citizens or residents, (ii) more than 50 percent of our assets must be located outside of the U.S. and (iii) our business must be administered principally outside of the U.S.. If we lose our status as a foreign private issuer, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We would also be required to make changes in our corporate governance practices in accordance with various SEC and Nasdaq rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer will be significantly higher than the costs that we would incur as a foreign private issuer. As a result, we expect that the loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly.

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

We are an "emerging growth company" as defined in the JOBS Act. dis 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, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. As an emerging growth company, we are required to report only two years of financial results and selected financial data in this prospectus compared to three and five years, respectively, for comparable data reported by other public companies. We may take advantage of these exemptions until we are no longer an emerging growth company. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the aggregate market value of ADSs representing our ordinary shares and our ordinary shares held by non-affiliates exceeds $700 million as at any 30 June (the end of our second fiscal quarter) before that time, in which case we would no longer be an emerging growth company as of the following 31 December (our fiscal year-end). We cannot predict if investors will find ADSs representing our ordinary shares or our ordinary shares less attractive because we may rely on these exemptions. If some investors find such securities less attractive as a result, there may be a less active trading market for ADSs representing our ordinary shares or our ordinary shares and the price of such securities may be more volatile.

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

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

Management will be required to assess the effectiveness of our internal controls annually. However, for as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements requiring us to incur the expense of remediation and could also result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, the price of ADSs representing our ordinary shares or our ordinary shares and the trading volume thereof could decline.

The trading market for ADSs representing our ordinary shares and our ordinary shares will depend in part on the research and reports that securities or industry analysts publish about us or our business. Since we did not undertake an initial public offering of ADSs representing our ordinary shares in connection with the listing of ADSs representing our ordinary shares on Nasdaq, we do not anticipate that many or any industry analysts in the U.S. will publish such research and reports in the U.S. about our ordinary shares or ADSs representing our ordinary shares. Additionally, the results of our Phase 2 trial of PR022 in Atopic Dermatitis increase the likelihood that no industry analysts will commence coverage on us. If no or too few securities or industry analysts commence or continue coverage on us, the trading price for ADSs representing our ordinary shares and our ordinary shares could be affected. If one or more of the analysts who cover us downgrade such ADSs representing our ordinary shares or ordinary shares or publish inaccurate or unfavorable research about our business, the trading price of ADSs representing our ordinary shares or our ordinary shares would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for ADSs representing our ordinary shares or our ordinary shares could decrease, which might cause the price of such securities and the trading volume thereof to decline.

Changes to tax laws could materially adversely affect our company.

On 22 December 2017 new legislation was signed into law (H.R. 1 "An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018," or the Tax Cuts and Jobs Act) that significantly revised the U.S. Internal Revenue Code of 1986, as amended, or the Code. The Tax Cuts and Jobs Act, 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), implementation of a "base erosion anti-abuse tax" which requires U.S. corporations to make an alternative determination of taxable income without regard to tax deductions for certain payments to affiliates, taxation of certain non-U.S. corporations' earnings considered to be "global intangible low taxed income," or GILTI, repeal of the alternative minimum tax, or AMT, for corporations and changes to a taxpayer's ability to either utilize or refund the AMT credits previously generated, changes to the limitation on deductions for certain executive compensation particularly with respect to the removal of the previously allowed performance based compensation exception, changes in the attribution rules relating to shareholders of certain "controlled foreign corporations," 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 U.S. corporate income tax rate, the overall impact of the Tax Cuts and Jobs Act is uncertain and our business and financial condition could be adversely affected. The impact of the Tax Cuts and Jobs Act on holders of our ordinary shares or ADSs representing our ordinary shares is also uncertain and could be adverse. For example, recent changes in U.S. federal income tax law resulting in additional taxes owed by U.S. Holders (as defined below under "Material Income Tax Considerations — Material U.S. Federal Income Tax Considerations for U.S. Holders") under the new GILTI tax rules or related to "controlled foreign corporations" may discourage U.S. investors from owning or acquiring 10% or greater of our outstanding ordinary shares (directly or in the form of ADSs representing our ordinary shares), which other shareholders may have viewed as beneficial or may otherwise negatively impact the trading price of our ordinary shares or ADSs representing our ordinary shares.

The tax treatment of the company is subject to changes in tax laws, regulations and treaties, or the interpretation thereof, tax policy initiatives and reforms under consideration and the practices of tax authorities in jurisdictions in which we operate, as well as tax policy initiatives and reforms related to the Organisation for Economic Co-Operation and Development's, or OECD, Base Erosion and Profit Shifting, or BEPS, Project, the European Commission's state aid investigations and other initiatives. Such changes may include (but are not limited to) the taxation of operating income, investment income, dividends received or (in the specific context of withholding tax) dividends paid.

We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our effective tax rates in the future in countries where we have operations and have an adverse effect on our overall tax rate in the future, along with increasing the complexity, burden and cost of tax compliance. 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 or ADSs representing our ordinary shares.

If we are a passive foreign investment company, or PFIC, for U.S. federal income tax purposes, the consequences to U.S. holders of ADSs representing our ordinary shares or our ordinary shares may be adverse.

Based on our analysis of our income, assets, activities and market capitalization, we believe that we will likely be classified as a "passive foreign investment company," or PFIC, for the taxable year ended 31 December 2017, and we expect to continue to be a PFIC for our current taxable year. Under the Code, a non-U.S. company will be considered a PFIC for any taxable year in which (1) 75% or more of its gross income consists of passive income or (2) 50% or more of the average quarterly value of its assets consists of assets that produce, or are held for the production of, passive income. For purposes of these tests, passive income includes dividends, interest, gains from the sale or exchange of investment property and certain rents and royalties. In addition, for purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets and received directly its proportionate share of the income of such other corporation. If we are a PFIC for any taxable year during which a U.S. Holder (as defined below under “Material Income Tax Considerations — Material U.S. Federal Income Tax Considerations for U.S. Holders”) holds our ordinary shares or ADSs representing our ordinary shares, we will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns the ordinary shares or ADSs representing our ordinary shares, regardless of whether we continue to meet the PFIC test described above, unless the U.S. Holder makes a specified election once we cease to be a PFIC. If we are classified as a PFIC for any taxable year during which a U.S. Holder holds our ordinary shares or ADSs representing our ordinary shares, the U.S. Holder may be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC, including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements.

If a U.S. person is treated as owning at least 10% of our ordinary shares, such holder may be subject to adverse U.S. federal income tax consequences.

If a U.S. Holder is treated as owning, directly, indirectly or constructively, at least 10% of the value or voting power of our ordinary shares (directly or in the form of ADSs representing our ordinary shares), such U.S. Holder may be treated as a “U.S. shareholder” with respect to each “controlled foreign corporation” in our corporate group, if any. If such group includes one or more U.S. subsidiaries, certain of our non-U.S. subsidiaries could be treated as controlled foreign corporations, regardless of whether we are treated as a controlled foreign corporation. A U.S. shareholder of a controlled foreign corporation may be required to annually report and include in its U.S. taxable income its pro rata share of “Subpart F income,” “global intangible low-taxed income” and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a U.S. shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a U.S. shareholder that is a U.S. corporation. Failure to comply with these reporting obligations may subject a U.S. shareholder to significant monetary penalties and may prevent the statute of limitations with respect to such shareholder's U.S. federal income tax return for the year for which reporting was due from starting. We cannot provide any assurances that we will assist our investors in determining whether any of our non-U.S. subsidiaries are treated as a controlled foreign corporation or whether such investor is treated as a U.S. shareholder with respect to any of such controlled foreign corporations. Further, we cannot provide any assurances that we will furnish to any U.S. shareholder information that may be necessary to comply with the reporting and tax paying obligations described in this risk factor. U.S. Holders should consult their tax advisors regarding the potential application of these rules to their investment in our ordinary shares or ADSs representing our ordinary shares.