UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2020

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38667

Urovant Sciences Ltd.

(Exact Name of Registrant as Specified in its Charter)

Bermuda	**98-1463899**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
Suite 1, 3rd Floor **11-12 St. James's Square** **London SW1Y 4LB, United Kingdom**	
(Address of principal executive offices)	**Not Applicable** (Zip Code)

Registrant's telephone number, including area code: +44 (0)207 400-3347

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

(Title of each class)	*(Trading Symbol)*	*(Name of each exchange on which registered)*
Common Shares, $0.000037453 par value	UROV	Nasdaq Global Select Market

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

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

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

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

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

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

As of August 12, 2020, the registrant had 31,181,794 common shares, $0.000037453 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

UROVANT SCIENCES LTD.
Condensed Consolidated Balance Sheets
(*in thousands, except share and per share data*)

	June 30, 2020	March 31, 2020 (Note 2)
Assets		
Current assets:		
Cash	$ 63,039	$ 51,414
Restricted cash	250	243
Prepaid expenses and other current assets	8,980	6,489
Due from Sumitovant Biopharma Ltd.	—	172
Total current assets	72,269	58,318
Property and equipment, net	1,237	1,210
Operating lease right-of-use assets	3,939	3,135
Restricted cash, net of current portion	623	623
Other assets	69	9
Total assets	$ 78,137	$ 63,295
Liabilities and Shareholders' Deficit		
Current liabilities:		
Accounts payable	$ 130	$ 1,589
Accrued expenses	23,098	21,756
Due to Roivant Sciences Ltd.	2	31
Current portion of share-based compensation liabilities	6,919	7,204
Current portion of operating lease liabilities	422	351
Total current liabilities	30,571	30,931
Share-based compensation liabilities, net of current portion	370	32
Related-party long-term debt	128,270	87,252
Operating lease liabilities, net of current portion	3,862	3,086
Total liabilities	163,073	121,301
Commitments and contingencies (Note 10)		
Shareholders' deficit		
Common shares, par value $0.000037453 per share, 267,001,308 shares authorized, 30,906,598 and 30,635,258 issued and outstanding at June 30, 2020 and March 31, 2020, respectively	1	1
Common shares subscribed	(1)	(1)
Accumulated other comprehensive income	495	452
Additional paid-in capital	267,339	263,818
Accumulated deficit	(352,770)	(322,276)
Total shareholders' deficit	(84,936)	(58,006)
Total liabilities and shareholders' deficit	$ 78,137	$ 63,295

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

UROVANT SCIENCES LTD.
Condensed Consolidated Statements of Operations
(*in thousands, except share and per share data*)

	Three Months Ended June 30,	
	2020	**2019**
Operating expenses:		
Research and development	$ 16,354	$ 22,014
General and administrative[1]	12,489	5,465
Total operating expenses	28,843	27,479
Other expense:		
Interest expense, net[2]	(1,443)	(513)
Loss on disposal of property and equipment	—	(236)
Other expense, net	(118)	(190)
Loss before provision for income taxes	(30,404)	(28,418)
Provision for income taxes	90	67
Net loss	$ (30,494)	$ (28,485)
Net loss per common share—basic and diluted	$ (0.99)	$ (0.94)
Weighted average common shares outstanding—basic and diluted	30,705,334	30,325,169

(1) Includes $0 and $60 of costs allocated from Roivant Sciences Ltd. during the three months ended June 30, 2020 and 2019, respectively.
(2) Includes $1,456 of interest expense from related-party long-term debt with Sumitomo Dainippon Pharma Co., Ltd. during the three months ended June 30, 2020 (see Note 4).

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

UROVANT SCIENCES LTD.
Condensed Consolidated Statements of Comprehensive Loss
(in thousands)

	Three Months Ended June 30,	
	2020	**2019**
Net loss	$ (30,494)	$ (28,485)
Other comprehensive income:		
Foreign currency translation adjustment	43	188
Total other comprehensive income	43	188
Comprehensive loss	$ (30,451)	$ (28,297)

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

UROVANT SCIENCES LTD.
Condensed Consolidated Statements of Shareholders' (Deficit) Equity
(in thousands, except share data)

	Common Shares		Common Shares Subscribed	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Shareholders' Deficit
	Shares	Amount					
Balance at March 31, 2020	30,635,258	$ 1	$ (1)	$ 263,818	$ (322,276)	$ 452	$ (58,006)
Share-based compensation expense	—	—	—	1,032	—	—	1,032
Exercise of stock options	231,799	—	—	1,205	—	—	1,205
Share-based compensation liabilities reclassified to equity upon exercise of stock options	—	—	—	988	—	—	988
Share-based compensation expense reclassified to liabilities	—	—	—	(35)	—	—	(35)
Issuance of common shares pursuant to 2019 ESPP	39,541	—	—	331	—	—	331
Foreign currency translation adjustment	—	—	—	—	—	43	43
Net loss	—	—	—	—	(30,494)	—	(30,494)
Balance at June 30, 2020	30,906,598	$ 1	$ (1)	$ 267,339	$ (352,770)	$ 495	$ (84,936)

	Common Shares		Common Shares Subscribed	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Shareholders' Equity
	Shares	Amount					
Balance at March 31, 2019	30,322,911	$ 1	$ (1)	$ 250,032	$ (175,531)	$ 269	$ 74,770
Capital contributions from RSI and RSG	—	—	—	130	—	—	130
Share-based compensation expense	—	—	—	1,047	—	—	1,047
Exercise of stock options	17,521	—	—	70	—	—	70
Foreign currency translation adjustment	—	—	—	—	—	188	188
Net loss	—	—	—	—	(28,485)	—	(28,485)
Balance at June 30, 2019	30,340,432	$ 1	$ (1)	$ 251,279	$ (204,016)	$ 457	$ 47,720

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

UROVANT SCIENCES LTD.
Condensed Consolidated Statements of Cash Flows
(in thousands)

	Three Months Ended June 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (30,494)	$ (28,485)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	77	54
Share-based compensation expense	2,038	1,047
Amortization of debt discount and issuance costs	18	194
Non-cash operating lease cost	229	63
Loss on disposal of property and equipment	—	236
Unrealized foreign currency translation adjustment	43	188
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,491)	4,498
Other assets	(60)	67
Due from Sumitovant Biopharma Ltd.	172	—
Due to Roivant Sciences Ltd.	(29)	19
Accounts payable	(1,459)	834
Accrued expenses	1,342	(1,220)
Operating lease liabilities	(186)	—
Net cash used in operating activities	(30,800)	(22,505)
Cash flows from investing activities:		
Purchases of property and equipment	(104)	(278)
Net cash used in investing activities	(104)	(278)
Cash flows from financing activities:		
Proceeds from capital contributions from Roivant Sciences Ltd.	—	130
Proceeds from exercise of stock options	1,205	70
Debt financing costs paid	—	(387)
Cash proceeds from related-party debt financing	41,000	—
Proceeds from issuance of common shares pursuant to 2019 ESPP	331	—
Net cash provided by (used in) financing activities	42,536	(187)
Net change in cash and restricted cash	11,632	(22,970)
Cash and restricted cash—beginning of period	52,280	86,196
Cash and restricted cash—end of period	$ 63,912	$ 63,226
Non-cash investing and financing activities:		
Property and equipment included in accounts payable and accrued expenses	$ —	$ 229
Property and equipment included in due to Roivant Sciences Ltd.	$ —	$ 63
Reclassification of share-based compensation liabilities to additional paid-in capital upon exercise of stock options	$ 988	$ —
Reclassification of share-based compensation expense from additional paid-in capital to liabilities	$ 35	$ —
Supplemental disclosure of cash paid:		
Income taxes	$ —	$ —
Interest	$ 1,438	$ 385

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

Note 1—Description of business and liquidity

[A] Description of business:

Urovant Sciences Ltd. and its subsidiaries (collectively, the "Company" and, on an unconsolidated basis and excluding its subsidiaries, "USL") is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions. The Company's lead product candidate, vibegron, is an oral, once-daily, small molecule beta-3 agonist. The Company is currently developing vibegron for the treatment of overactive bladder ("OAB"). The Company is also developing vibegron for the treatment of two additional potential indications: OAB in men with benign prostatic hyperplasia and abdominal pain due to irritable bowel syndrome. The Company's second product candidate, URO-902, is a gene therapy that the Company is developing for patients with OAB who have failed oral pharmacological therapy. There are no currently available U.S. Food and Drug Administration ("FDA") approved gene therapy treatments for OAB. The Company was founded on January 27, 2016 as a Bermuda Exempted Limited Company and a wholly owned subsidiary of Roivant Sciences Ltd. ("RSL"). As of June 30, 2020, the Company has the following wholly owned subsidiaries (1) Urovant Holdings Ltd. ("UHL"), a private limited company incorporated under the laws of England and Wales, (2) Urovant Sciences GmbH ("USG"), a company with limited liability formed under the laws of Switzerland, (3) Urovant Sciences, Inc. ("USI"), a Delaware corporation based in the United States of America, (4) Urovant Treasury Holdings, Inc. ("UTH"), a Delaware corporation based in the United States of America, and (5) Urovant Sciences Treasury, Inc. ("UST"), a Delaware corporation based in the United States of America.

On December 27, 2019, Sumitomo Dainippon Pharma Co., Ltd. ("Sumitomo Dainippon Pharma") and RSL announced the closing of the transactions between Sumitomo Dainippon Pharma and RSL and certain of its affiliates contemplated by the definitive transaction agreement entered into on October 31, 2019 (the "Sumitomo Transaction"), pursuant to which all of the Company's common shares held by RSL were contributed to Sumitovant Biopharma Ltd., a wholly-owned subsidiary of RSL at the time of such contribution ("Sumitovant"), and subsequent to such contribution, Sumitomo Dainippon Pharma acquired all issued and outstanding equity securities of Sumitovant.

Since its inception, the Company has devoted substantially all of its efforts to organizing and staffing the Company, acquiring its product candidates, vibegron and URO-902, and preparing for and advancing vibegron into clinical development. Vibegron was licensed from Merck Sharp & Dohme Corp. ("Merck"), a subsidiary of Merck & Co., in February 2017. URO-902 was licensed from Ion Channel Innovations, LLC ("ICI") in August 2018. The Company has determined that it has one operating and reporting segment as it allocates resources and assesses financial performance on a consolidated basis.

[B] Liquidity:

The Company has historically been capitalized with funding from its initial public offering, which was completed in October 2018, and debt financings.

The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. Since inception, the Company has incurred and expects to continue to incur significant and increasing operating losses and negative cash flows for at least the next several years. To date, the Company has not generated any revenues and does not anticipate generating any revenues unless and until it successfully completes development of, obtains regulatory approval for, and commercializes one of its product candidates. At June 30, 2020, the Company reported cash of $63.0 million and a shareholders' deficit of $84.9 million. The Company currently believes its existing cash, together with the draw down under the Sumitomo Loan Agreement (as defined below) of $43.0 million in July 2020 and the remaining financing commitment from Sumitomo Dainippon Pharma of $128.5 million, which is available to the Company based on funding requests made in accordance with the operating budget approved by the Company's Board of Directors (the "Board") (see Notes 4 and 12), will be sufficient to fund its committed operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance of these condensed consolidated financial statements. This estimate is based on the Company's current assumptions, including assumptions relating to the timing of regulatory approval and subsequent launch of vibegron for OAB and its ability to manage the amount and timing of its spend. The Company's available capital may also be consumed faster than anticipated due to other events, including the length and severity of the global novel coronavirus ("COVID-19") pandemic and measures taken to control the spread of COVID-19, as well as changes in and progress of our development activities and the impact of commercialization efforts due to the COVID-19 pandemic. The Company will seek to obtain additional capital as needed through equity financings, debt or other financing arrangements, but given the impact of COVID-19 on the U.S. and global financial markets and any limitations on future financing arrangements pursuant to the terms of the Sumitomo Loan Agreement, as well as Sumitomo Dainippon Pharma's ability to exert substantial influence and control over the Company due to Sumitomo Dainippon Pharma's majority ownership of the Company's outstanding common shares, the Company may be unable to access further equity or debt financing when needed. As such, there can be no assurance that the Company will be able to raise additional capital when needed or under acceptable terms, if at all. The sale of additional equity may dilute existing shareholders and newly issued shares may contain senior rights and preferences compared to currently outstanding common shares. The Company's agreement with Sumitomo Dainippon Pharma involves, and any agreements for future debt or preferred equity financings, if available, may involve, covenants limiting or

restricting the Company's ability to take specific actions, such as incurring additional debt, incurring capital expenditures or declaring dividends. If the Company is unable to obtain such additional financing, as needed, in sufficient amounts or on terms acceptable to the Company, or if the remaining financing commitment of $128.5 million available to the Company under the Sumitomo Loan Agreement is no longer available to the Company despite future funding requests made in accordance with its Board approved operating budget, the Company may have to significantly delay or scale back its operations to reduce working capital requirements beginning in the first calendar quarter of 2021 and substantial uncertainty would exist with respect to the Company's ability to continue as a going concern. The Company will prioritize necessary and appropriate steps to enable the continued operations of the business and preservation of the value of its assets beyond the next twelve months, including but not limited to actions such as reduced personnel-related costs, curtailment of the Company's pre-commercial launch efforts, development activities and other discretionary expenditures that are within the Company's control. These reductions in expenditures, if required, may have an adverse impact on the Company's ability to achieve certain of the Company's planned objectives in fiscal years 2020 and 2021.

The Company's future operations are highly dependent on a combination of factors, including (1) the success of its research and development programs; (2) regulatory approval and market acceptance of vibegron, URO-902 or any future product candidate; (3) the development of competitive therapies by other biotechnology and pharmaceutical companies; (4) the Company's ability to manage growth of the organization; (5) the Company's ability to protect its technology and products; and, ultimately (6) the timely and successful completion of any additional financing.

Note 2—Summary of significant accounting policies

[A] Basis of presentation:

The Company's fiscal year ends on March 31. The accompanying interim condensed consolidated balance sheet as of June 30, 2020, the condensed consolidated statements of operations, comprehensive loss and cash flows for the three months ended June 30, 2020 and 2019 and the condensed consolidated statements of shareholders' (deficit) equity for the three months ended June 30, 2020 and 2019 are unaudited. The accompanying interim unaudited consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for complete financial statements, as certain footnotes or other financial information that are required by U.S. GAAP can be condensed or omitted. These interim unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes thereto for the fiscal year ended March 31, 2020 included in the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2020, filed with the Securities and Exchange Commission ("SEC") on June 19, 2020.

The condensed consolidated balance sheet as of March 31, 2020 has been derived from the audited consolidated financial statements at that date. In the opinion of management, the interim consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of the Company's consolidated financial position and its results of operations and cash flows for the interim periods presented. The results for the three months ended June 30, 2020 are not necessarily indicative of the results to be expected for the year ending March 31, 2021 or for any future period.

Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB"). The consolidated financial statements include the accounts of USL and UHL, USG, USI, UTH and UST, USL's wholly owned subsidiaries. USL has no unconsolidated subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

There have been no significant changes in the Company's accounting policies from those disclosed in its Annual Report on Form 10-K for the fiscal year ended March 31, 2020 filed with the SEC on June 19, 2020.

[B] Use of estimates:

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. The Company regularly evaluates estimates and assumptions related to assets, liabilities, costs, and expenses including the evaluation of the Company's ability to continue as a going concern, as well as share-based compensation expenses, research and development expenses and accruals, and income taxes. The Company bases its estimates and assumptions on historical experience and on various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and such differences may be material.

***[C] Risks and uncertainties*:**

The Company is subject to risks common to early stage companies in the biopharmaceutical industry including, but not limited to, uncertainties related to commercialization of products, including the need to successfully commercialize and gain market acceptance of its product candidates, the need to obtain marketing approval for its product candidates, risks of failure or unsatisfactory results of nonclinical studies and clinical trials, the need to obtain additional financing to fund the future development and commercialization of its product candidates,

dependence on key products, third-party service providers such as contract research organizations and contract manufacturing organizations, protection of intellectual property rights, compliance with government regulations, and the ability to make milestone, royalty or other payments due under any license, collaboration or supply agreements.

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. Due to the COVID-19 pandemic, there has been uncertainty and disruption in the global economy and financial markets. Through August 13, 2020, the date of issuance of this Quarterly Report on Form 10-Q, the Company's results of operations and cash flows have not been significantly impacted by the COVID-19 outbreak. The Company is not aware of any specific event or circumstance that would require an update to its estimates, judgments and assumptions or a revision of the carrying value of the Company's assets or liabilities as of August 13, 2020.

***[D] Cash, cash equivalents, and restricted cash*:**

Cash includes cash deposits in banks. The Company considers all highly liquid investments purchased with original maturities of three months or less to be cash equivalents. The Company maintains cash deposits in federally-insured financial institutions in excess of federally insured limits. The Company has established guidelines relative to diversification and maturities to maintain liquidity and preservation of capital. The Company has not experienced any credit losses related to these financial instruments and does not believe that it is exposed to any significant credit risk related to these instruments.

Restricted cash consists of legally restricted non-interest-bearing deposit accounts held as compensating balances against the Company's corporate credit card program and irrevocable standby letters of credit connected to its office leases (see Note 11). Restricted cash classified as a current asset consists of the restricted deposit account relating to the Company's corporate credit card agreement. Restricted cash classified as a long-term asset consists of the restricted deposit account related to the irrevocable standby letters of credit.

Cash as reported in the condensed consolidated statements of cash flows includes the aggregate amounts of cash and restricted cash as presented on the condensed consolidated balance sheets. Cash as reported in the condensed consolidated statements of cash flows consists of (in thousands):

	June 30, 2020	March 31, 2020
Cash	$ 63,039	$ 51,414
Restricted cash	873	866
Cash and restricted cash	$ 63,912	$ 52,280

[E] Financial instruments:

The Company applies a fair value framework in order to measure and disclose its financial assets and liabilities. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The fair value hierarchy requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. There are three levels of inputs that may be used to measure fair value:

- **Level 1 -** Quoted prices in active markets for identical assets or liabilities.
- **Level 2 -** Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Fair values are determined by utilizing quoted prices for similar assets and liabilities in active markets or other market observable inputs such as interest rates and yield curves.
- **Level 3 -** Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

To the extent the valuation is based on models or inputs that are less observable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The Company's financial instruments consist of cash, restricted cash, accounts payable, accrued expenses, amounts due to and from RSL and Sumitovant, share-based compensation liabilities, and debt obligations. The carrying value of the Company's debt obligations approximates fair value based on current interest rates for similar types of borrowings and is included in Level 2 of the fair value hierarchy. The share-based compensation liabilities are remeasured at fair value on a recurring basis and are included in Level 3 of the fair value hierarchy. The remaining financial instruments are stated at their respective historical carrying amounts, which approximates fair value due to their short-term nature.

The Company measured the share-based compensation liabilities at fair value based on significant inputs not observable in the market, which caused them to be classified as a Level 3 measurement within the fair value hierarchy (see Note 9). The valuation of the share-based compensation liabilities used assumptions and estimates the Company believed would be made by a market participant in making the same valuation.

The stock options liability is marked-to-market each reporting period with the change in fair value recorded as share-based compensation expense on the Company's condensed consolidated statements of operations until the stock options are exercised and are sold to Sumitovant or to the market or the former Principal Executive Officer has held the exercised and unsold shares for a period of at least six months. The fair value of the stock options liability is determined at each reporting period by utilizing the Black-Scholes option-pricing model.

The stock appreciation rights ("SARs") liability is marked-to-market each reporting period with the change in fair value recorded as share-based compensation expense on the Company's condensed consolidated statements of operations over the vesting term and until the SARs are exercised. The fair value of the SARs liability is determined at each reporting period by utilizing a binominal lattice model.

***[F] Net loss per common share*:**

Basic net loss per common share is computed by dividing net loss applicable to common shareholders by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is computed by dividing the net loss applicable to common shareholders by the diluted weighted-average number of common shares outstanding during the period calculated in accordance with the treasury stock method. In periods in which the Company reports a net loss, all common share equivalents are deemed anti-dilutive such that basic net loss per common share and diluted net loss per common share are equivalent. Potentially dilutive common shares have been excluded from the diluted net loss per common share computations in all periods presented because such securities have an anti-dilutive effect on net loss per common share due to the Company's net loss. There are no reconciling items used to calculate the weighted-average number of total common shares outstanding for basic and diluted net loss per common share data.

At June 30, 2020 and 2019, potentially dilutive securities were as follows:

	June 30,	
	2020	2019
Options	4,268,295	4,031,231
Restricted stock units (unvested)	1,510,162	5,000
Stock appreciation rights	845,732	—
Warrants	99,777	33,259
Total	6,723,966	4,069,490

***[G] Recently adopted accounting pronouncements*:**

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820) Disclosure Framework Changes to the Disclosure Requirements for Fair Value Measurement*, ("ASU No. 2018-13"), which provides guidance that removes, modifies and adds to the disclosure requirements related to fair value measurements. The guidance removes the requirements to disclose the amount and reasons for transfers between Level 1 and Level 2 assets, the policy for timing and transfers between levels and the valuation process for Level 3 fair value measurements. The guidance modifies disclosure requirements for investments in certain entities that calculate net asset value and clarifies the purpose of the measurement uncertainty disclosure. The guidance adds requirements to disclose changes in unrealized gains or losses included in other comprehensive income for recurring Level 3 fair value measurements and to disclose the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. The guidance is effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. The adoption of ASU No. 2018-13 on April 1, 2020 did not have a material impact on the Company's consolidated financial position, results of operations and related disclosures.

***[H] Recently issued accounting pronouncements*:**

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, ("ASU No. 2016-13"), which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU No. 2016-13 replaces the existing incurred loss impairment model with an expected loss model that requires the use of forward-looking information to calculate credit loss estimates. It also eliminates the concept of other-than-temporary impairment and requires credit losses on available-for-sale debt securities to be recorded through an allowance for credit losses instead of as a reduction in the amortized cost basis of the securities. ASU No. 2016-13 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2019. In November 2019, the FASB issued ASU No. 2019-10, *Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842) Effective Dates*, which deferred the effective date of ASU No. 2016-13 for public business entities that meet the definition of a smaller reporting company, as defined by the SEC, as of November 15, 2019. As the Company met the definition of a smaller reporting company as of November 15, 2019, ASU No. 2016-13 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2022. Early adoption is permitted, including adoption in any interim period. The Company does not expect the adoption to have a material impact on the Company's condensed consolidated financial position, results of operations, and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. The amendments of this update simplify the accounting for income taxes by removing certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new standard also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The guidance is effective for fiscal years beginning after December 15, 2020 and interim periods within those fiscal years. Early adoption is permitted. The Company is currently assessing the impact the adoption of this standard will have on its consolidated financial position, results of operations, and related disclosures.

In March 2020, the FASB issued ASU No. 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*, that provides temporary optional guidance to ease the potential burden in accounting for or recognizing the effects of reference rate reform on financial reporting. The new guidance provides expedients and exceptions for applying U.S. GAAP to contract modifications and hedging relationships affected by reference rate reform if certain criteria are met. The amendments apply only to contracts and hedging relationships that reference London Inter-bank Offered Rate ("LIBOR") or another reference rate that is expected to be discontinued due to reference rate reform. This new guidance is effective prospectively beginning on March 12, 2020 through December 31, 2022. As of June 30, 2020, the Company has not modified its contract that will be impacted by reference rate reform. The Company will continue to assess the impact the adoption of this standard will have on its consolidated financial position, results of operations, and related disclosures when its contract impacted by reference rate reform is modified.

Other recent accounting pronouncements issued by the FASB (including its Emerging Issues Task Force), the American Institute of Certified Public Accountants, and the SEC did not, or are not believed by management to, have a material impact on the Company's present or future consolidated financial position, results of operations or cash flows.

Note 3—Accrued expenses

Accrued expenses at June 30, 2020 and March 31, 2020 consist of the following (in thousands):

	June 30, 2020	March 31, 2020
Research and development expenses	$ 18,373	$ 13,728
Compensation-related expenses	2,973	6,296
Professional services expenses	273	433
Other general and administrative expenses	1,479	1,299
Total accrued expenses	$ 23,098	$ 21,756

Note 4—Related-party long-term debt

On December 27, 2019, the Company entered into a $300 million unsecured revolving debt facility with Sumitomo Dainippon Pharma (the "Sumitomo Loan Agreement"). Sumitomo Dainippon Pharma funded an initial amount of $87.5 million on December 30, 2019 under the terms of the Sumitomo Loan Agreement. In April and July 2020, Sumitomo Dainippon Pharma funded an additional amount of $41.0 million and $43.0 million, respectively (see Note 12). Additional funds may be drawn down by the Company, upon request, no more than once in any calendar quarter, subject to funding requests by the Company that are made are in accordance with the Company's Board approved operating budget.

Loans under the Sumitomo Loan Agreement ("Loans") bear a variable interest rate per annum equal to LIBOR plus a margin of 3% payable on the last day of each calendar quarter. LIBOR is currently expected to be phased out by the end of 2021, and if it becomes unavailable, the Company and Sumitomo Dainippon Pharma will negotiate in good faith to select an alternative interest rate and, if applicable as a result of such alternative interest rate, margin adjustment that is consistent with industry accepted successor rates for determining a LIBOR replacement. The interest rate on the Loans was 3.31% at June 30, 2020. The Loans mature and are payable in full on the five-year anniversary of the closing date of the Sumitomo Loan Agreement or December 27, 2024.

The Company's obligations under the Sumitomo Loan Agreement are fully and unconditionally guaranteed by each of the Company's direct and indirect subsidiaries. The Sumitomo Loan Agreement contains certain representations and warranties, affirmative covenants, negative covenants and conditions that are customarily required for similar financings.

The Sumitomo Loan Agreement also contains customary events of default (subject, in certain instances, to specified grace periods). If any event of default occurs, the principal, premium, if any, interest and any other monetary obligations on all the then outstanding amounts under the Loans may become due and payable immediately. Upon the occurrence of an event of default, a default interest rate of an additional 5% may be applied to the outstanding principal balance, and Sumitomo Dainippon Pharma may declare all outstanding obligations immediately due and payable (subject, in certain instances, to specified grace periods) and take such other actions as set forth in the Sumitomo Loan Agreement. Upon the occurrence of certain bankruptcy and insolvency events, the obligations under the Sumitomo Loan Agreement would automatically become due and payable. The Company is in compliance with the covenants pursuant to the Sumitomo Loan Agreement as of June 30, 2020.

The Company incurred financing costs of $0.3 million relating to the Sumitomo Loan Agreement which are recorded as an offset to related-party long-term debt on the Company's condensed consolidated balance sheet. The deferred financing costs are being amortized over the term of the debt using the effective interest method, and are included in interest expense in the Company's condensed consolidated statement of operations.

Outstanding debt obligations to Sumitomo Dainippon Pharma are as follows (in thousands):

	June 30, 2020	March 31, 2020
Principal amount	$ 128,500	$ 87,500
Less: unamortized debt issuance costs	(230)	(248)
Loan payable less unamortized debt issuance costs	128,270	87,252
Less: current maturities	—	—
Long-term debt, net of unamortized debt issuance costs	$ 128,270	$ 87,252

Note 5—Related party transactions

[A] Sumitomo loan agreement:

See Note 4 for information regarding the Sumitomo Loan Agreement.

[B] Investor rights agreement – Sumitomo Dainippon Pharma and Sumitovant:

On December 27, 2019, the Company entered into an investor rights agreement with Sumitomo Dainippon Pharma and Sumitovant (the "Investor Rights Agreement"). Pursuant to the Investor Rights Agreement, among other things, the Company agreed to comply with any demands by Sumitovant to register for sale, under the Securities Act of 1933, as amended, any common shares of the Company beneficially owned by Sumitovant that have an anticipated aggregate net offering price of at least $5 million, subject to certain customary exceptions and the right of the Company to refuse any demand for registration if the Company already effected two registrations for Sumitovant in the year preceding such demand. In addition, the Company agreed to periodically provide Sumitovant with (i) certain financial statements, projections, capitalization summaries and other information customarily provided to significant investors in publicly-traded companies and (ii) access to the Company's books, records, facilities and employees during the Company's normal business hours as Sumitovant may reasonably request.

Moreover, the Investor Rights Agreement also contains certain protections for the Company's minority shareholders for so long as Sumitomo Dainippon Pharma or certain of its affiliates beneficially own between 50% and 90% of the total number of votes entitled to be cast at elections of the Company's directors (the "Total Voting Power"). These protections include, among other things: (i) a requirement for a minimum of three independent directors on the Company's Board (each of whom cannot be removed by Sumitomo Dainippon Pharma or certain of its affiliates without the approval of a majority of the minority shareholders); (ii) a requirement that the audit committee of the Board (the "Audit Committee") be comprised solely of independent directors; (iii) the appointment of Mr. Pierre Legault as the Company's lead independent director; (iv) a requirement that any transaction proposed by Sumitomo Dainippon Pharma or certain of its affiliates that would increase Sumitomo Dainippon Pharma's beneficial ownership to over 76% of the Total Voting Power be approved by the Audit Committee (if occurring prior to December 27, 2021) and, if such transaction would increase Sumitomo Dainippon Pharma's beneficial ownership to over 80% of the Total Voting Power, a majority of the Company's minority shareholders must vote on such matter; and (v) a requirement that any related person transactions between Sumitomo Dainippon Pharma or certain of its affiliates and the Company be approved by the Audit Committee, consistent with the Company's existing Related Person Transactions Policy.

Pursuant to the Investor Rights Agreement, the Company also agreed that so long as Sumitomo Dainippon Pharma or certain of its affiliates beneficially own between 50% and 90% of the Total Voting Power, the Company will inform Sumitovant before issuing any new common shares and allow Sumitovant to (i) participate in such issuance up to its pro rata share (unless such issuance is in connection with the acquisition of a business or its assets) or (ii) make sufficient open market purchases of the Company's securities to ensure that Sumitomo Dainippon Pharma's beneficial ownership percentage does not decline as a result of such issuance. No amounts have been paid or received under this agreement; however, the Company believes this agreement is material to its business and operations.

[C] Information sharing agreement – Sumitovant:

On May 21, 2020, the Company entered into an information sharing and cooperation agreement (the "Sumitovant Information Sharing Agreement") with Sumitovant. The Sumitovant Information Sharing Agreement, among other things, obligates the Company to deliver to Sumitovant drafts of (i) the Company's quarterly and annual financial statements and (ii) the discussion and analysis by the Company's management of its financial condition and the results of its operations for such fiscal periods, prior to the applicable deadlines for filing such information with the SEC. The Company also agreed to coordinate with Sumitovant before releasing earnings results or any interim financial guidance and to notify Sumitovant before issuing any other material press releases.

In addition, the Sumitovant Information Sharing Agreement requires the Company to give Sumitovant's auditors access to its auditors and its books and records to facilitate the completion of Sumitovant's own internal audit and their review of the Company's financial statements and internal accounting controls and operations. The Company also agreed to provide Sumitovant any documents or materials relating to its business and access to its senior management to discuss any matters, in each case as Sumitovant may reasonably request. To the extent the

Company provides Sumitovant any information in response to such a request, Sumitovant may not (i) disclose such information to certain of its affiliates or (ii) use such information in a manner it deems, in good faith, to be detrimental to the Company or its shareholders. In addition, both parties agreed to hold any information they receive from the other party in the strictest confidence, subject to customary exceptions for information that becomes public, that has been independently developed, or that is otherwise received on a non-confidential basis from a third party.

Moreover, the Sumitovant Information Sharing Agreement provides that the Company must adopt and maintain policies to address its obligations with respect to financial reporting, audits, internal controls, record keeping, taxes, and other applicable laws. In addition, the Board must have a compliance oversight committee (the "Compliance Committee") that oversees a compliance program designed to ensure the Company complies with its obligations under applicable laws (the "Compliance Program"). The Compliance Committee, in turn, is required to (i) appoint a member of the Company's senior management to administer the Compliance Program and (ii) cause the implementation of internal reporting procedures and training to support the Compliance Program. The Sumitovant Information Sharing Agreement also requires the Company to comply in all material respects with applicable laws.

No amounts have been paid or received under this agreement; however, the Company believes this agreement is material to its business and operations.

[D] Market access services agreement – Sunovion:

On June 17, 2020, USG entered into a market access services agreement (the "Market Access Services Agreement") with Sunovion Pharmaceuticals, Inc. ("Sunovion"), a wholly-owned subsidiary of Sumitomo Dainippon Pharma. Pursuant to the Market Access Services Agreement, among other things, USG appointed Sunovion as the exclusive distributor of vibegron in the United States, including all of its territories and possessions.

Sunovion, in turn, has agreed to provide certain market access services with respect to the distribution and sale of vibegron, including, among other things: (i) adding vibegron to Sunovion's agreements with its third party logistics providers; (ii) adding vibegron to certain of Sunovion's contracts with wholesalers, group purchasing organizations and integrated delivery networks; (iii) facilitating USG's entry into new contracts with certain health organizations regarding vibegron; (iv) managing the validation, processing and payment of rebates, chargebacks, and certain administrative, distribution and service fees related to vibegron; (v) providing USG with price reporting metrics and other information required for it to comply with applicable government price reporting requirements; (vi) coordinating with USG and any applicable wholesalers to address any recalls, investigations, or product holds; and (vii) providing certain other ancillary support services to facilitate the foregoing.

In order to facilitate Sunovion's provision of these services, USG agreed, among other things, to: (i) grant Sunovion a non-exclusive license under all intellectual property owned or controlled by USG, solely to enable Sunovion to perform the contemplated services; (ii) provide Sunovion periodic reports of sales projections and volume requirements, as well as such other information as Sunovion reasonably requests or may need to perform the services; (iii) comply with the provisions of any agreements between Sunovion and third parties pursuant to which vibegron will be distributed or sold; (iv) cooperate with certain investigations related to orders and audits of USG's quality systems; and (v) promptly notify Sunovion in the event vibegron is recalled.

As consideration for the services, USG will pay Sunovion an agreed-upon monthly service charge for each of the first two years of the agreement term. After the second year of the agreement term, the monthly service charges will be subject to good faith negotiations between the parties. In addition, USG also agreed to (x) reimburse Sunovion for any pass-through expenses it incurs while providing the services and (y) establish an escrow fund for use by Sunovion when managing any rebates, chargebacks and similar fees.

The Market Access Services Agreement also contains customary representations and warranties by the parties and customary provisions related to confidentiality, indemnification and insurance. The initial term of the Market Access Services Agreement is three years. Thereafter, the term will be automatically extended for one-year periods, unless either party provides notice of its intent to terminate the agreement at least nine (9) months prior to the expiration of the applicable term. Either party may also terminate the agreement prior to the end of its term in the event of an uncured material breach by the other party or if such other party becomes insolvent or undergoes a change of control. Finally, USG may also terminate the Market Access Services Agreement if Sunovion fails to satisfy certain market access milestones or upon payment of a break-up fee.

No amounts have been paid or received under this agreement; however, the Company believes this agreement is material to its business and operations.

[E] Operating lease – Roivant:

In June 2019, the Company entered into a sublease agreement with a related party, RSI, for 2,784 square feet of office space located in Durham, North Carolina that expires in July 2025. The sublease has scheduled rent increases each year and the total sublease payment obligations under the agreement are $0.6 million. See Note 11 for more details on the sublease.

Note 6—Income taxes

The Company is not subject to taxation under the laws of Bermuda since it was organized as a Bermuda Exempted Limited Company, for which there is no current tax regime. The Company's provision for income taxes is primarily based on income taxes in the U.S. for federal and state taxes.

The Company's effective tax rate for the three months ended June 30, 2020 and 2019 was (0.30)% and (0.24)%, respectively. The effective tax rate is driven by the Company's jurisdictional earnings by location and a valuation allowance that eliminates the Company's global net deferred tax assets.

The Company assesses the realizability of its deferred tax assets at each balance sheet date based on available positive and negative evidence in order to determine the amount which is more likely than not to be realized and records a valuation allowance as necessary.

Note 7—Shareholders' deficit

At-the-market equity offering program:

In November 2019, the Company entered into a sales agreement with Jefferies LLC ("Jefferies") to sell its common shares having an aggregate offering price of up to $50 million from time to time through an "at-the-market" equity offering program under which Jefferies acts as the Company's agent. As of June 30, 2020, the Company has not sold any common shares under its "at-the-market" equity offering program.

Note 8—Share-based compensation

Equity incentive plan:

On June 1, 2017, the Company adopted its 2017 Equity Incentive Plan (the "2017 Plan"), under which 2,002,509 common shares were initially reserved for grant. On June 15, 2018, the Board approved an increase in the number of common shares reserved for grant under the 2017 Plan of 1,068,006 common shares. The 2017 Plan was approved by the Company's shareholders in September 2018. In connection with the Company's initial public offering, the 2017 Plan was amended effective upon the execution of the underwriting agreement related to the offering. All references herein to the Company's 2017 Plan will be deemed to refer to the 2017 Plan, as amended and restated, unless context otherwise requires.

In September 2019, the shareholders of the Company approved an amendment to the 2017 Plan to increase the number of common shares reserved for issuance under the 2017 Plan by 3,000,000 common shares.

Pursuant to the "evergreen" provision contained in the 2017 Plan, the number of common shares reserved for issuance under the 2017 Plan automatically increases on November 1 of each year, commencing on November 1, 2018 and ending on November 1, 2028, in an amount equal to 4% of the total number of the Company's common shares outstanding on the last day of the preceding month, or by a lesser number of common shares as may be determined by the Company's Board prior to any such increase date. On November 1, 2019 and 2018, the number of common shares authorized for issuance increased automatically by 1,215,257 shares and 1,212,916 shares, respectively, in accordance with the evergreen provision of the 2017 Plan.

At June 30, 2020, a total of 1,330,353 common shares were available for future issuance under the 2017 Plan.

2019 Employee Stock Purchase Plan:

In July 2019, the Company's Board adopted the 2019 Employee Stock Purchase Plan (the "2019 ESPP"). In September 2019, the Company's shareholders approved the 2019 ESPP. A total of 450,000 common shares are authorized for issuance under the 2019 ESPP. Pursuant to the "evergreen" provision contained in the 2019 ESPP, the number of common shares reserved for issuance under the 2019 ESPP automatically increases on November 1 of each year, commencing on November 1, 2020 and ending on November 1, 2028, in an amount equal to the lesser of (i) 1% of the total number of the Company's common shares outstanding on March 31st of the preceding calendar year, and (ii) 600,000 common shares. The Company's Board may approve an increase of a lesser number of common shares prior to any such increase date.

The 2019 ESPP permits eligible employees to purchase common shares at a discount through payroll deductions during defined six month consecutive offering periods beginning on January 1st. The price at which the shares are purchased is equal to the lower of (i) 85% of the fair market value of the common shares on the first day of the offering or (ii) 85% of the fair market value of the common shares on the purchase date. A participant may purchase a maximum of 60,000 common shares during each offering period, not to exceed $25,000 worth of common shares on the offering date during each calendar year, and the maximum number of common shares that can be purchased by all participants during each offering period is 150,000 shares. The Company uses the Black-Scholes option-pricing model, in combination with the discounted employee price, in determining the value of the 2019 ESPP share-based compensation expense to be recognized during each offering period. The weighted-average grant date fair value per share for the offering period during the three months ended June 30, 2020 using the Black-Scholes option-pricing model was $5.26.

During the three months ended June 30, 2020, 39,541 common shares were issued pursuant to the 2019 ESPP for total proceeds of $0.3 million and, as of June 30, 2020, 410,459 shares remain available for future issuance under the 2019 ESPP. At June 30, 2020 and March 31, 2020, the Company had an outstanding liability of $0.05 million and $0.2 million, respectively, which is included in accrued expenses in the condensed consolidated balance sheets.

Stock options:

The Company estimated the fair value of each stock option on the date of grant using the Black-Scholes option pricing model applying the range of assumptions in the following table:

	Three Months Ended June 30,	
	2020	2019
Risk-free interest rate	0.41% - 0.56%	1.95% - 2.30%
Expected term, in years	6.00 - 6.11	6.11
Expected volatility	77.6% - 78.4%	64.4% - 65.1%
Expected dividend yield	—%	—%

The following table presents a summary of stock option activity and data under the Company's 2017 Plan through June 30, 2020 (in thousands, except share and per share data):

	Number of Options	Weighted Average Exercise Price	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Options outstanding at March 31, 2020	4,134,100	$ 6.85	$ 4.24	8.38	
Granted	365,994	$ 10.05	$ 6.72		
Exercised	(231,799)	$ 5.20	$ 3.23		
Options outstanding at June 30, 2020	4,268,295	$ 7.21	$ 4.59	8.30	$ 12,590
Options exercisable at June 30, 2020	3,643,501	$ 6.67	$ 4.22	8.06	$ 12,442

The aggregate intrinsic value is calculated as the difference between the exercise price of all outstanding and exercisable stock options and the quoted market price of our common shares at June 30, 2020. At June 30, 2020, there were 3,643,501 vested or exercisable options outstanding. During the three months ended June 30, 2020, the Company granted options to purchase 365,994 common shares to certain employees and directors of the Company with a weighted-average exercise price and grant date fair value per share of $10.05 and $6.72, respectively, under the 2017 Plan. The aggregate intrinsic value of options exercised to purchase 231,799 common shares during the three months ended June 30, 2020 was $1.2 million.

During the year ended March 31, 2020, in connection with the resignation of the Company's former Principal Executive Officer, fully-vested stock options to purchase 1,416,166 common shares with a weighted-average exercise price of $5.59 per share held by the former Principal Executive Officer were reclassified from equity to liabilities following the modification of the stock options to include a share repurchase feature (see Note 9). The share repurchase feature is in the form of a right of first refusal for Sumitovant to purchase up to 1,416,666 shares underlying the stock options upon exercise by the former Principal Executive Officer. The stock options remain exercisable through October 1, 2021. No shares issued upon exercise of stock options by the former Principal Executive Officer during the three months ended June 30, 2020 were purchased by Sumitovant.

Stock appreciation rights ("SARs"):

SARs entitle the holder to receive, upon exercise, an amount of the Company's common shares or cash (or a combination thereof) determined by reference to appreciation, from and after the date of grant, in the fair market value of the Company's common shares over the strike price on the exercise date. The SARs are subject to vesting terms similar to the Company's stock options and restricted stock units.

In March 2020, a total of 845,732 SARs were granted under the 2017 Plan to the Company's new Principal Executive Officer pursuant to his employment agreement. The SARs vest as to 25% on the one-year anniversary of the grant date with the remaining SARs vesting in 12 equal quarterly installments thereafter, subject to the Principal Executive Officer providing continuous service to the Company through each such vesting date. The SARs can be settled in shares or cash upon exercise, at the sole discretion of the Company's Board. Due to the current presumption that the SARs will be settled in cash upon exercise, the SARs have been classified as a liability instrument requiring the Company to remeasure the SARs at each reporting period until exercise (see Note 9). The estimated fair value of the SARs granted was $5.4 million and $5.2 million, respectively, at June 30, 2020 and March 31, 2020.

Restricted stock unit ("RSUs"):

A summary of restricted stock unit activity under the Company's 2017 Plan through June 30, 2020 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested balance at March 31, 2020	751,927	$ 13.84
Granted	957,915	$ 9.12
Forfeited	(199,680)	$ 14.39
Unvested balance at June 30, 2020	1,510,162	$ 10.77

The fair value of the RSUs is estimated at the grant date using the Company's common share price. The weighted average grant-date fair value of RSUs granted during the three months ended June 30, 2020 was $9.12 per unit.

Share-based compensation expense:

Share-based compensation expense was as follows (in thousands):

	Three Months Ended June 30,	
	2020	2019
Share-based compensation recognized as:		
Research and development	$ 369	$ 265
General and administrative	1,669	782
	$ 2,038	$ 1,047

Share-based compensation expense is included in research and development and general and administrative expenses in the accompanying condensed consolidated statements of operations consistent with the grantee's salary classification. Share-based compensation expense presented in the table above includes share-based compensation expense from those share-based awards classified as liability instruments mentioned above.

Total unrecognized share-based compensation expense was approximately $23.7 million at June 30, 2020 and is expected to be recognized over a weighted-average period of 3.63 years.

Note 9—Fair value measurements

As of June 30, 2020 and March 31, 2020, the liabilities measured at fair value on a recurring basis consisted of certain liability classified stock options and SARs (see Note 8), which are included in share-based compensation liabilities in the accompanying condensed consolidated balance sheets. There were no assets measured at fair value on a recurring basis as of June 30, 2020 and March 31, 2020. The following represents the fair value using the hierarchy described in Note 2[E] for the Company's financial liabilities that are required to be measured at fair value on a recurring basis as of June 30, 2020 and March 31, 2020 (in thousands):

	As of June 30, 2020			
	Level 1	Level 2	Level 3	Total Fair Value
Liabilities:				
Share-based compensation liability - stock options	$ —	$ —	$ 6,919	$ 6,919
Share-based compensation liability - SARs	—	—	370	370
Total liabilities	$ —	$ —	$ 7,289	$ 7,289

	As of March 31, 2020			
	Level 1	Level 2	Level 3	Total Fair Value
Liabilities:				
Share-based compensation liability - stock options	$ —	$ —	$ 7,204	$ 7,204
Share-based compensation liability - SARs	—	—	32	32
Total liabilities	$ —	$ —	$ 7,236	$ 7,236

The fair value of the stock options liability as of June 30, 2020 was calculated using the following significant unobservable inputs:

Input	June 30, 2020
Risk-free interest rate	0.16%
Expected dividend yield	—%
Expected term, in years	1.25
Expected volatility	79.6%
Exercise price (per share)	$3.86 - $14.00
Share price (per share)	$9.84
Number of stock options valued	1,272,914

The fair value of the SARs liability as of June 30, 2020 was calculated using the following significant unobservable inputs:

Input	June 30, 2020
Risk-free interest rate	0.64%
Expected dividend yield	—%
Expected term, in years	9.73
Expected volatility	77.1%
Post-vesting cancellation rate	5.0%
Exercise ratio	2.8
Exercise price (per share)	$9.16
Share price (per share)	$9.84
Number of SARs granted	845,732

The table presented below is a summary of changes in the fair value of the Company's Level 3 valuation for the share-based compensation liabilities for the three months ended June 30, 2020 (in thousands):

	Stock Options	SARs
Balance at March 31, 2020	$ 7,204	$ 32
Additions	—	—
Change in fair value	703	338
Settlements	(988)	—
Balance at June 30, 2020	$ 6,919	$ 370

Note 10—Commitments and contingencies

The Company entered into certain commitments under the Merck license agreement, the ICI license agreement, the enzyme supply agreement with Codexis, Inc., and the information sharing collaboration agreement with Kyorin Pharmaceutical Co., Ltd.

In addition, the Company has entered into services agreements with third parties for pharmaceutical research and development and manufacturing activities. Expenditures to contract research organizations, or CROs, and contract manufacturing organizations, or CMOs, represent significant costs in the Company's clinical development of its product candidates. Subject to required notice periods, a nominal early termination fee, in certain cases, and the Company's remaining obligations under binding purchase orders, the Company can elect to discontinue the work under these agreements at any time. The Company expects to enter into additional commitments as the business further develops.

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company accrues for loss contingencies when available information indicates that it is probable that a liability has been incurred and the amount of such liability can be reasonably estimated. In the cases where the Company believes that a reasonably possible loss exists, the Company discloses the facts and circumstances of the loss contingency, including an estimable range, if possible, unless the Company has determined that any such reasonably possible losses will not have a material impact on the Company's results of operations, financial condition or cash flows.

During the three months ended June 30, 2020, there were no material changes outside the ordinary course of business to the specified contractual obligations set forth in the commitments and contingencies footnote disclosure in the Company's audited consolidated financial statements for the year ended March 31, 2020 included in the Company's Annual Report on Form 10-K filed with the SEC on June 19, 2020.

Note 11—Leases

In November 2018, the Company entered into an operating lease for office space in Irvine, California for approximately 21,489 square feet. The lease term for the operating lease is seven years with options to terminate after five years and to extend the lease term for an additional five years which are both not reasonably certain of exercise. Subject to rent abatement for the first through fifth months of the lease, the Company will be required to pay $54,367 per month for rent for the first twelve months of the lease term which will increase at a fixed rate of approximately 3% per year. The lease further provides that the Company is obligated to pay certain variable costs, including common area maintenance expenses. The lease commenced in June 2019 and the Company recognized an operating lease right-of-use asset of $3.0 million and an operating lease liability of $3.0 million. In connection with the lease, the Company maintains a standby letter of credit for the benefit of the landlord in the amount of $0.6 million. The Company secured the letter of credit for the full amount of the letter with cash on deposit, which is reported as restricted cash as of June 30, 2020 and March 31, 2020. The remaining lease term is 5.9 years at June 30, 2020 and the estimated incremental borrowing rate applied is 12.4%.

In April 2020, the Company entered into an amendment to its Irvine facility operating lease to add approximately 6,865 square feet of office space for a total of approximately 28,354 square feet. The lease term and option to extend the lease term for the additional office space is concurrent with the existing operating lease and expires in May 2026. Subject to rent abatement for the first through fifth months of the additional leased office space, the Company will be required to pay $17,918 per month for rent for the first twelve months of the lease term which will increase at a fixed rate of approximately 3% per year. The lease further provides that the Company is obligated to pay certain variable costs, including common area maintenance expenses. In accordance with ASC 842, *Leases*, the Company determined the operating lease for the additional office space to be a separate lease and not an amendment of the original lease terms of the Irvine facility. The lease commenced in May 2020 and the Company recognized an operating lease right-of-use asset of $0.9 million and an operating lease liability of $0.9 million. The remaining lease term was 5.9 years at June 30, 2020 and the estimated incremental borrowing rate applied was 11.6%.

In June 2019, the Company entered into a sublease agreement with a related party, RSI, for office space in Durham, North Carolina for approximately 2,784 square feet. The lease term for the operating lease is six years and two months with no option to extend the lease term. The Company is required to pay $7,192 per month through July 2020 which will increase at a fixed rate of 3% per year. The lease commenced in June 2019 and the Company recognized an operating lease right-of-use asset of $0.4 million and an operating lease liability of $0.4 million. In connection with the lease, the Company maintains a standby letter of credit for the benefit of RSI in the amount of $0.02 million. The Company secured the letter of credit for the full amount of the letter with cash on deposit, which is reported as restricted cash as of June 30, 2020 and March 31, 2020. The remaining lease term is 5.1 years at June 30, 2020 and the estimated incremental borrowing rate applied is 12.4%.

Supplemental balance sheet information related to operating leases was as follows (in thousands, except lease term and discount rate):

	June 30, 2020	March 31, 2020
Operating lease right-of-use assets	$ 3,939	$ 3,135
Operating lease liabilities, current portion	$ 422	$ 351
Operating lease liabilities, long-term portion	3,862	3,086
Total lease liabilities	$ 4,284	$ 3,437
Weighted average remaining lease term (years)	5.9 years	6.1 years
Weighted average discount rate	12.2%	12.4%

Supplemental cash flow information for the three months ended June 30, 2020 and 2019 related to operating leases as follows (in thousands):

	June 30,	
	2020	2019
Cash paid within cash flows used in operations	$ 186	$ 42
Operating lease right-of-use asset obtained in exchange for operating lease liabilities	$ 910	$ 3,414
Amortization of operating lease right-of-use assets	$ 106	$ 63

The undiscounted future lease payments under the lease liabilities as of June 30, 2020 were as follows (in thousands):

Years Ending March 31,	Lease Payments
Remainder of 2021	$ 679
2022	1,001
2023	1,031
2024	1,061
2025	1,094
Thereafter	1,232
Total lease payments	6,098
Less: imputed interest	(1,814)
Total lease liabilities	$ 4,284

Operating lease costs for the three months ended June 30, 2020 and 2019 were $0.2 million and $0.1 million, respectively. Short-term and variable lease costs were not material for the three months ended June 30, 2020 and 2019.

Note 12—Subsequent events

Sumitomo loan agreement funding

In July 2020, the Company received gross proceeds of $43.0 million pursuant to the Sumitomo Loan Agreement (see Note 4). Subsequent to this draw, approximately $171.5 million was outstanding under the Sumitomo Loan Agreement and approximately $128.5 million of borrowing capacity remained available to the Company, which may be drawn down by the Company, upon request, no more than once in any calendar quarter, subject to funding requests by the Company that are made in accordance with the Company's Board approved operating budget.

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

The following discussion and analysis of our financial condition, results of operations and cash flows should be read in conjunction with (1) the unaudited condensed consolidated financial statements and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q, and (2) the audited consolidated financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the fiscal year ended March 31, 2020 included in our Annual Report on Form 10-K for the fiscal year ended March 31, 2020, filed with the United States Securities and Exchange Commission, or the SEC, on June 19, 2020. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "Urovant," the "Company," "we," "us," and "our" refer to Urovant Sciences Ltd. and its wholly owned subsidiaries.

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements are often identified by the use of words such as "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "likely," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "to be," "will," "would," or the negative or plural of these words, or similar expressions or variations, although not all forward-looking statements contain these words. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur and actual results could differ materially from those expressed or implied by these forward-looking statements.

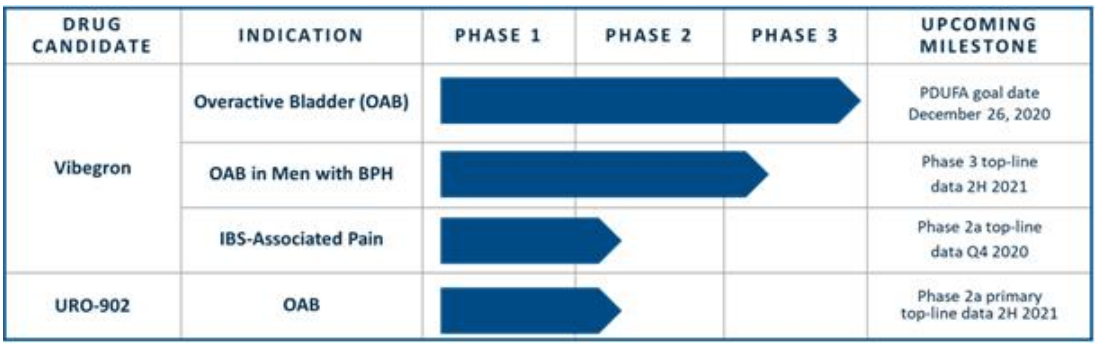
Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, and those discussed in the section titled "Risk Factors" set forth in Part II. Item 1A. of this Quarterly Report on Form 10-Q, elsewhere in this Quarterly Report on Form 10-Q and in our other filings with the SEC. These risks are not exhaustive. New risk factors emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Business Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions. Our goal is to be a leading urology company by developing, commercializing and acquiring innovative therapies. Our lead product candidate, vibegron, is an oral, once-daily, small molecule that was observed to be a highly selective agonist of the human beta-3 adrenergic receptor in *in vitro* assays. Vibegron is currently being developed for three potential indications: overactive bladder, or OAB, the treatment of OAB in men with benign prostatic hyperplasia, or BPH, and the treatment of abdominal pain due to irritable bowel syndrome, or IBS. Our second product candidate, URO-902, is a novel gene therapy that we are developing for patients with OAB who have failed oral pharmacological therapy. Vibegron was licensed to us in February 2017 by Merck Sharp & Dohme Corp., or Merck, and URO-902 was licensed to us in August 2018 by Ion Channel Innovations, LLC, or ICI.

We were incorporated in January 2016, and our operations to date have consisted of organizing and staffing our company, identifying and in-licensing our product candidates, including acquiring the rights to vibegron and URO-902, preparing for and advancing the clinical development of our product candidates and preparing for the potential commercialization of vibegron.

Our development programs and expected upcoming milestones are summarized in the following figure:



Our Product Candidates

VIBEGRON

We are currently developing vibegron in three target indications: OAB; OAB in men with BPH; and abdominal pain due to IBS. Vibegron is an oral, once-daily, small molecule that was observed to be a highly selective agonist of the human beta-3 adrenergic receptor in *in vitro* assays. We believe vibegron, if approved by the U.S. Food and Drug Administration, or FDA, may offer a differentiated profile compared to current OAB therapies, including the potential for broader efficacy claims if the FDA approves the inclusion of urgency data, rapid onset of action data, and a single convenient once-daily dose in the label. Vibegron has been well tolerated in all clinical trials to date, has not been associated with clinically relevant drug-drug interactions, such as the inhibition of CYP2D6, and has not demonstrated a QTc signal at any of the human doses tested.

Urovant Sciences GmbH, or USG, our wholly owned subsidiary, holds global commercial rights to vibegron, excluding China, Japan and certain other Asian countries. In September 2017, Kyorin Pharmaceutical Co., Ltd., or Kyorin, submitted a marketing application for vibegron to the Japan Pharmaceuticals and Medical Devices Agency, and received marketing approval from Japan's Ministry of Health, Labour and Welfare for vibegron for the treatment of adults with OAB in September 2018.

Our Phase 3 Program for the Treatment of OAB

In March 2018, we enrolled the first patients in our international pivotal Phase 3 EMPOWUR trial of vibegron in adults with OAB. The EMPOWUR trial was a randomized, double-blind, placebo- and active comparator-controlled clinical trial in men and women with OAB having or not having urge urinary incontinence, or UUI, episodes. The trial had a design in line with the Phase 2b clinical trial conducted by Merck and the Japanese Phase 3 clinical trial conducted by Kyorin. Enrollment of more than 1,500 patients into the EMPOWUR trial was completed in October 2018.

In March 2019, we reported positive top-line results from our international pivotal Phase 3 EMPOWUR trial of vibegron in adults with OAB. In this pivotal Phase 3 clinical trial with over 1,500 patients, vibegron 75 mg met both co-primary efficacy endpoints demonstrating a highly significant reduction in daily UUI episodes and micturitions. In the primary efficacy analysis, once-daily vibegron met the co-primary endpoints at week 12, achieving statistical significance over placebo on both reduction in daily UUI episodes ($p<0.0001$) and reduction in daily micturitions ($p<0.001$). The difference from placebo was statistically significant as early as week 2, which was the first timepoint measured, for both UUI episodes and micturitions ($p<0.0001$ and $p<0.001$, respectively), and statistically significant efficacy was maintained at all timepoints measured through the end of the study for both endpoints. Additionally, at all measured timepoints, vibegron achieved numerically better efficacy than tolterodine, the active control in this study, which is a currently available OAB treatment.

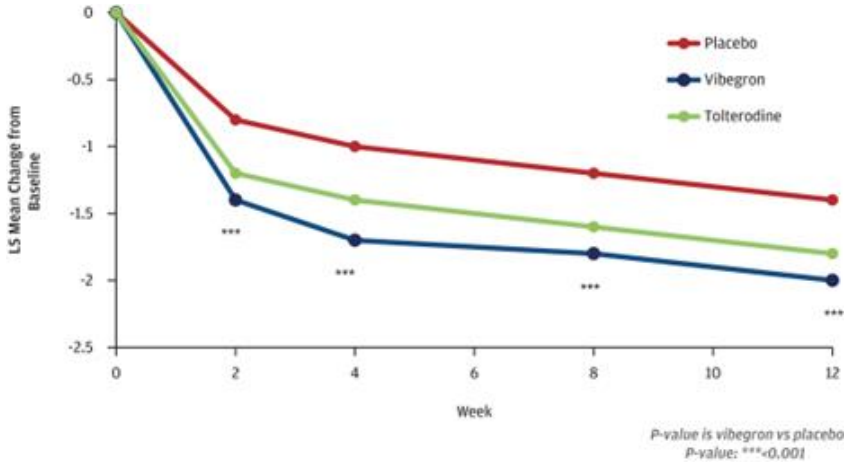
Vibegron met all seven pre-specified key secondary endpoints, including a statistically significant reduction in daily urgency episodes compared to placebo ($p=0.002$). Secondary endpoints included, among others, changes in the frequency of urgency episodes and total incontinence episodes (which includes all incontinence episodes, whether UUI or stress-related), as well as self-reported quality of life scores.

P-value is a conventional statistical method for measuring the statistical significance of clinical results. A p-value of 0.05 or less represents statistical significance, meaning there is a less than 1-in-20 likelihood that the observed results occurred by chance. The FDA utilizes statistical significance, as measured by p-value, as an evidentiary standard of efficacy and typically requires a p-value of 0.05 or less to demonstrate statistical significance. The results of the co-primary and key secondary endpoints used in our Phase 3 EMPOWUR trial at the end of the study are depicted below.

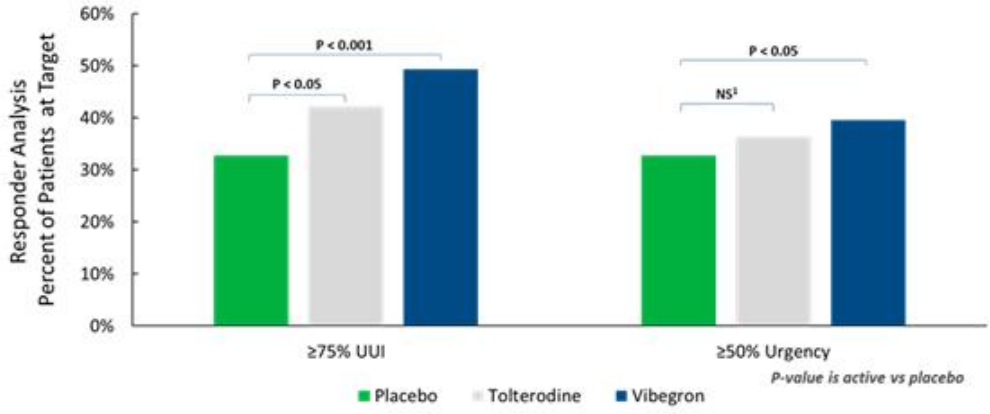
Endpoint	Vibegron	n	p-value	Tolterodine	n	p-value
UUI Episodes[1]	-0.6	383	<0.0001	-0.4	286	0.0123
Micturitions[1]	-0.5	492	<0.001	-0.3	378	0.0988
Urgency Episodes[2]	-0.7	492	0.0020	-0.4	378	0.0648
Total Incontinence Episodes[2]	-0.7	383	<0.0001	-0.5	286	0.0074
Volume Voided (ml)[2]	21.2	490	<0.0001	13.3	375	<0.001
OAB-q Coping Score[2]	3.6	512	0.0038	3.1	401	0.0212

1. Co-primary endpoint; 2. Key Secondary Endpoint; LS=Least Squares

The EMPOWUR Phase 3 clinical trial data showing reductions in daily UUI episodes over time are shown in the graphs below.



The EMPOWUR Phase 3 clinical trial data showing reductions in daily UUI episodes at the end of the study for patients in the vibegron treatment group, compared to the tolterodine treatment group and placebo treatment group, are shown in the graphs below.



1. P-values for the difference in proportions between active and placebo were calculated using the Cochran-Mantel-Haenszel risk difference estimate stratified by OAB Type (Wet vs Dry) and Sex (Female vs Male), with weights proposed by Greenland and Robins. MI has been used to impute values missing for any reason at the weeks analyzed. Adjusted proportions are presented.
Table 14.2.4.1.1 Full Analysis Set for Incontinence. 75% Reduction in UUI from Baseline at Week 12
Table 14.2.5.1.1 Full Analysis Set for Incontinence 100% Reduction in UUI from Baseline at Week 12
Table 14.2.6.1.1 Full Analysis Set 50% Reduction in Urgency from Baseline at Week 12

Vibegron was well tolerated and the most common adverse events reported versus placebo (>2% in vibegron and greater than placebo) were headache (4.0% vs 2.4%), nasopharyngitis (commonly known as a cold) (2.8% vs 1.7%), diarrhea (2.2% vs 1.1%), and nausea (2.2% vs 1.1%). The frequency of serious adverse events was similar across treatment arms (1.1% in placebo, 1.5% in vibegron, and 2.3% in tolterodine). The incidence of the reported adverse event of hypertension was equal to placebo (1.7% in vibegron, 1.7% in placebo, and 2.6% in tolterodine).

In the Phase 3 EMPOWUR trial there were two serious adverse events, or SAEs, reported in two patients in the vibegron treatment group considered to be treatment related by the investigator: (1) non-cardiac chest pain in one patient (with no evidence of an acute cardiac event) and (2) pneumonia in one patient. Our independent assessment did not consider these SAEs to be treatment related.

In August 2019, we completed the ambulatory blood pressure study for vibegron. The purpose of the study was to rule out an effect of vibegron relative to placebo on daytime systolic blood pressure. The primary endpoint variable was the change from baseline to day 28 in mean daytime ambulatory systolic blood pressure. Secondary endpoints included: 1) change from baseline in mean daytime diastolic blood pressure and heart rate, 2) full 24 hour mean change in systolic and diastolic blood pressure and heart rates as well as 3) maximum changes 30 minutes to 6.5 hours post dosing.

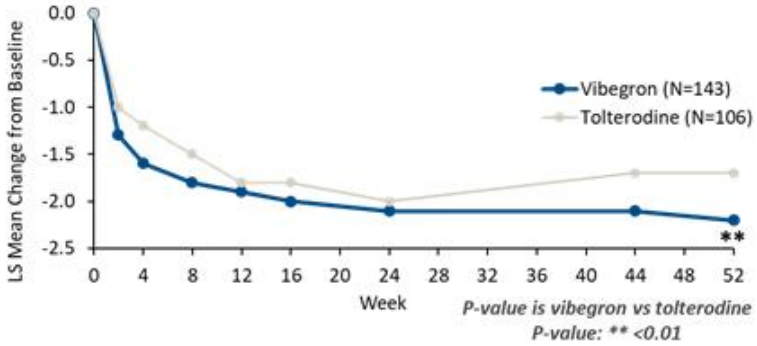
Vibegron achieved its primary endpoint demonstrating that vibegron does not have an effect on daytime systolic ambulatory blood pressure compared to placebo (where no effect was defined as a change from baseline of less than 3.5mm Hg compared to placebo within a 90% confidence interval). For mean ambulatory daytime systolic blood pressure, there was no statistically significant or clinically relevant difference for vibegron compared to placebo. The treatment differences from baseline to day 28 for vibegron in mean ambulatory systolic

blood pressure over placebo were +0.81 mm Hg, for mean diastolic blood pressure -0.04 mm Hg and for mean daytime heart rate +0.88 beats/minute. Regarding the categorical changes from baseline in systolic blood pressure for the in clinic visit vital signs, there were small, not clinically relevant, increases in the percentage of patients having a 10 mm Hg or 15mmg Hg increase in systolic blood pressure for vibegron compared to placebo. The adverse event profile was consistent with the EMPOWUR phase 3 study with the most common adverse events being headache, diarrhea, upper respiratory tract infection and urinary tract infection at rates below 5%.

We also completed the pharmacokinetic study on food effect and the crushed tablet of vibegron 75 mg. The study results support the proposed labeling for administration of vibegron with or without food and as a crushed tablet in soft food.

In September 2019, we reported positive long-term data from the double-blind extension of our pivotal Phase 3 EMPOWUR trial of vibegron in adults with OAB. In this double-blind extension of the Phase 3 EMPOWUR trial with over 500 patients, vibegron 75 mg further improved the treatment benefit on key OAB symptoms such as micturitions, UUI, urgency and total incontinence over the 40-week extension period. Among the 52-week EMPOWUR vibegron treatment group, the reduction in micturitions at week 52 was 2.4 episodes per day from a baseline of 11.32 episodes and the reduction in urgency episodes was 3.4 episodes per day from a baseline of 8.0 episodes. Vibegron demonstrated sustained efficacy for urge urinary incontinence as the reduction in urge urinary incontinence was 2.2 episodes at week 52 from a baseline of 3.18 per day. In addition, a total of 61% of patients on vibegron achieved at least a 75% reduction in their daily urge urinary incontinence episodes from baseline at week 52 and 41% of patients on vibegron became “dry” which is defined as having no urge urinary incontinence episodes at week 52. In the 40-week extension of our Phase 3 EMPOWUR trial, there was one death in the vibegron treatment group, a 63-year old patient due to arteriosclerotic disease, assessed by the investigator and the sponsor to not be treatment related. The overall adverse event profile of vibegron from the 40-week extension study was consistent with the 12-week EMPOWUR Phase 3 study. Vibegron was well tolerated and the most common adverse events reported versus tolterodine were hypertension (8.8% vs. 8.6%), urinary tract infections (6.6% vs. 7.3%), and headache (5.5% vs. 3.9%). All other common adverse events such as upper respiratory tract infection and diarrhea were below 5% for both vibegron and tolterodine. Overall, vibegron 75 mg demonstrated a continued improvement in symptoms with sustained efficacy and a favorable long-term safety and tolerability profile.

For the double-blind extension of our pivotal Phase 3 EMPOWUR trial, a post-hoc analysis was performed to compare the change from baseline to week 52 results between vibegron and tolterodine. In the post-hoc analysis, vibegron showed a statistically significant reduction in daily UUI and total incontinence episodes from baseline to 52 weeks compared to the active control, tolterodine. The trial data analysis showing reductions in daily UUI episodes between vibegron and tolterodine over time is in the graph below.



In December 2019, we submitted a new drug application, or NDA, to the FDA seeking approval of once-daily 75mg vibegron for the treatment of patients with OAB with symptoms of urge urinary incontinence, urgency, and urinary frequency. The FDA accepted our NDA in March 2020. Our NDA has been assigned a Prescription Drug User Fee Act, or PDUFA, goal date of December 26, 2020.

Our Phase 3 Program for the Treatment of OAB in Men with BPH

In March 2019, we initiated the Phase 3 COURAGE randomized, double blind, placebo-controlled trial for OAB in men with BPH who are also taking BPH medications but continue experiencing OAB symptoms in approximately 1,000 patients. The study is being conducted in two phases. In part one, we assessed the initial safety in 82 patients via an independent Data Safety Monitoring Board. Part one of the study was completed and after reviewing the safety data, the independent Data Safety Monitoring Board agreed that we could begin part two of the study, which we initiated in October 2019. Part two is assessing efficacy and safety in all patients, and testing 75 mg of vibegron versus placebo, the same dose studied in our Phase 3 EMPOWUR trial. The primary efficacy consists of the co-primary efficacy endpoints, change from baseline in the average number of micturitions per 24 hours and change from baseline in the average number of urgency episodes per 24 hours. The primary efficacy timepoint is Week 12 after treatment. Secondary endpoints include change from baseline in the average number of nocturia episodes per night, which is awakening at night to use the bathroom to urinate, UUI episodes per day, the average volume voided per micturition, prostate symptom scores and safety. The duration for the double-blind study is 24 weeks. In addition, a 28-week open-label extension study will evaluate the long-term safety and efficacy of vibegron in men with OAB symptoms and on another therapy for BPH. We expect to receive top-line data from the Phase 3 COURAGE trial in the second half of 2021.

Our Phase 2a Program for the Treatment of Abdominal Pain Due to IBS

In December 2018, we enrolled our first patient in this trial. The Phase 2a trial is a double-blind, placebo-controlled study in women with abdominal pain due to IBS with predominant diarrhea, or IBS-D, or mixed episodes of diarrhea and constipation, or IBS-M. The trial enrolled over 200 patients in the United States, randomized to receive either 75 mg of vibegron or placebo, administered orally once daily for a 12-week period. The primary endpoint is a 30% reduction in abdominal pain intensity, while secondary endpoints include Global Improvement Scale ratings, stool symptoms and safety. We have completed enrollment and expect to receive top-line data from the Phase 2a clinical trial in the fourth calendar quarter of 2020.

URO-902

In December 2019, we enrolled our first patient in the placebo-controlled, randomized, multicenter proof-of-concept Phase 2a clinical trial to evaluate the safety and efficacy of URO-902 for the treatment of OAB in 78 female patients who have not responded to oral pharmacological therapies. The Phase 2a trial is expected to enroll patients in two cohorts: the first cohort will receive either a single administration of 24 mg of URO-902 (24,000 µg) or matching placebo, and the second cohort will receive 48 mg of URO-902 (48,000 µg) or matching placebo into the bladder wall. An unblinded review of safety data via an independent Data Safety Monitoring Board will be performed after all subjects in the first cohort reach week 6. Study treatment for the second cohort will begin only after the Data Safety Monitoring Board has agreed that we can proceed with the second cohort. Patients will be followed for up to 48 weeks after initial administration. The key efficacy endpoints for this Phase 2a clinical trial include reductions per day in micturitions, urgency episodes and UUI episodes. In addition, our design of the Phase 2a clinical trial considers the safety data and preliminary efficacy data available from the two Phase 1b clinical trials in OAB conducted by ICI. We expect to receive the week 12 primary efficacy and safety top-line data from both cohorts in the Phase 2a clinical trial in the second half of 2021 and full trial data after the completion of the 48-week post-treatment period in 2022.

Recent Key Agreements

Information Sharing and Cooperation Agreement

On May 21, 2020, we entered into an information sharing and cooperation agreement, or the Sumitovant Information Sharing Agreement, with Sumitovant Biopharma Ltd., or Sumitovant. The Sumitovant Information Sharing Agreement, among other things, obligates us to deliver to Sumitovant drafts of (i) our quarterly and annual financial statements and (ii) the discussion and analysis by our management of the Company's financial condition and the results of our operations for such fiscal periods, prior to the applicable deadlines for filing such information with the SEC. We also agreed to coordinate with Sumitovant before releasing earnings results or any interim financial guidance and to notify Sumitovant before issuing any other material press releases.

In addition, the Sumitovant Information Sharing Agreement requires us to give Sumitovant's auditors access to our auditors and our books and records to facilitate the completion of Sumitovant's own internal audit and their review of our financial statements and internal accounting controls and operations. We also agreed to provide Sumitovant any documents or materials relating to our business and access to our senior management to discuss any matters, in each case as Sumitovant may reasonably request. To the extent we provide Sumitovant any information in response to such a request, Sumitovant may not (i) disclose such information to certain of its affiliates or (ii) use such information in a manner it deems, in good faith, to be detrimental to the Company or our shareholders. In addition, both parties agreed to hold any information they receive from the other party in the strictest confidence, subject to customary exceptions for information that becomes public, that has been independently developed, or that is otherwise received on a non-confidential basis from a third party.

Moreover, the Sumitovant Information Sharing Agreement provides that we must adopt and maintain policies to address our obligations with respect to financial reporting, audits, internal controls, record keeping, taxes, and other applicable laws. In addition, the Board must have a compliance oversight committee, or the Compliance Committee, that oversees a compliance program designed to ensure we comply with our obligations under applicable laws, or the Compliance Program. The Compliance Committee, in turn, is required to (i) appoint a member of our senior management to administer the Compliance Program and (ii) cause the implementation of internal reporting procedures and training to support the Compliance Program. The Sumitovant Information Sharing Agreement also requires us to comply in all material respects with applicable laws.

Market Access Services Agreement

On June 17, 2020, USG entered into a market access services agreement, or the Market Access Services Agreement, with Sunovion Pharmaceuticals, Inc., or Sunovion, a wholly-owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd., or Sumitomo Dainippon Pharma. Pursuant to the Market Access Services Agreement, among other things, USG appointed Sunovion as the exclusive distributor of vibegron in the United States, including all of its territories and possessions.

Sunovion, in turn, has agreed to provide certain market access services with respect to the distribution and sale of vibegron, including, among other things: (i) adding vibegron to Sunovion's agreements with its third party logistics providers; (ii) adding vibegron to certain of Sunovion's contracts with wholesalers, group purchasing organizations and integrated delivery networks; (iii) facilitating USG's entry into new contracts with certain health organizations regarding vibegron; (iv) managing the validation, processing and payment of rebates, chargebacks, and certain administrative, distribution and service fees related to vibegron; (v) providing USG with price reporting metrics and other information required for it to comply with applicable government price reporting requirements; (vi) coordinating with USG and any applicable wholesalers to address any recalls, investigations, or product holds; and (vii) providing certain other ancillary support services to facilitate the foregoing.

In order to facilitate Sunovion's provision of these services, USG agreed, among other things, to: (i) grant Sunovion a non-exclusive license under all intellectual property owned or controlled by USG, solely to enable Sunovion to perform the contemplated services; (ii) provide Sunovion periodic reports of sales projections and volume requirements, as well as such other information as Sunovion reasonably requests or may need to perform the services; (iii) comply with the provisions of any agreements between Sunovion and third parties pursuant to which vibegron will be distributed or sold; (iv) cooperate with certain investigations related to orders and audits of USG's quality systems; and (v) promptly notify Sunovion in the event vibegron is recalled.

As consideration for the services, USG will pay Sunovion an agreed-upon monthly service charge for each of the first two years of the agreement term. After the second year of the agreement term, the monthly service charges will be subject to good faith negotiations between the parties. In addition, USG also agreed to (x) reimburse Sunovion for any pass-through expenses it incurs while providing the services and (y) establish an escrow fund for use by Sunovion when managing any rebates, chargebacks and similar fees.

The Market Access Services Agreement also contains customary representations and warranties by the parties and customary provisions related to confidentiality, indemnification and insurance. The initial term of the Market Access Services Agreement is three years. Thereafter, the term will be automatically extended for one-year periods, unless either party provides notice of its intent to terminate the agreement at least nine (9) months prior to the expiration of the applicable term. Either party may also terminate the agreement prior to the end of its term in the event of an uncured material breach by the other party or if such other party becomes insolvent or undergoes a change of control. Finally, USG may also terminate the Market Access Services Agreement if Sunovion fails to satisfy certain market access milestones or upon payment of a break-up fee.

Impact of COVID-19

In December 2019, an outbreak of a novel strain of coronavirus, or COVID-19, was identified. Due to the rapid and global spread of the virus, in March 2020, the World Health Organization categorized the novel COVID-19 as a pandemic, and it has spread throughout the United States and other countries across the world. To limit the spread of COVID-19, governments have taken various actions including the issuance of stay-at-home orders and social distancing guidelines and causing some businesses to suspend operations. Although certain stay-at-home orders have been lifted, the impact of this pandemic has been and will likely continue to be extensive in many aspects of society, and has resulted in and will likely continue to result in significant disruptions to businesses and capital markets around the world. To date, our operations have not been significantly impacted by the COVID-19 pandemic other than, for vibegron, from March 19, 2020 to April 27, 2020, we temporarily halted the screening of new subjects into our Phase 3 COURAGE trial and Phase 2a trial for abdominal pain due to IBS. For URO-902, from March 19, 2020 to May 4, 2020, we temporarily halted the screening of new subjects in our Phase 2a trial due to the COVID-19 pandemic. Subjects that were in the run-in phase or already enrolled in our ongoing studies continued with treatment pursuant to the clinical trial protocol and treatments were not halted or delayed. Since the end of the temporary halt in screening of new subjects, we are re-opening the clinical trial sites in a stepwise manner to allow for screening of new patients. Such disruption has not and is not expected to have a material adverse impact on our clinical trial plans and timelines.

Our priorities during the COVID-19 pandemic are protecting the health and safety of our employees while continuing our mission to develop and commercialize innovative therapies for urological conditions. Beginning the week of March 16, 2020, substantially all of our workforce began working from home and we curtailed employee travel. We continue to require employees to work from home to protect their health and safety. The effects of any future stay-at-home orders or the continuation of our work from home measures for a significant period of time may negatively impact productivity, disrupt our business and delay our development programs, regulatory and commercialization timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. To date, we have not experienced these potential negative effects due to the continuation of our work from home measures. We continue to follow and monitor recommended actions of government and health authorities to protect our employees and will gradually resume normal operations once it is prudent to do so, and in compliance with all Federal, State, and local laws.

Further, the COVID-19 pandemic may negatively affect our supply chain, our ability to obtain approval of vibegron from the FDA and our pre-launch commercial readiness activities. We rely exclusively on third-party manufacturers to manufacture vibegron and URO-902 and our key third-party suppliers and manufacturers have been able to broadly maintain operations. To date, we have not experienced any significant disruption in our current supply chain for our clinical trials and as we prepare for the commercial launch of vibegron, if approved, or any negative impact or delay in our pre-launch commercial readiness activities or timelines. While we currently do not anticipate any interruptions in our manufacturing process or our pre-launch commercial readiness activities, it is possible that the COVID-19 pandemic and response efforts may have an impact in the future on our third-party suppliers and contract manufacturing partners' ability to supply and/or manufacture our products and our ability to conduct our pre-launch commercial readiness activities.

Our clinical trials may also be affected in the future by the COVID-19 pandemic. Site initiation and patient enrollment may be delayed due to prioritization of healthcare resources toward the COVID-19 pandemic. The COVID-19 pandemic may delay enrollment in our clinical trials, and some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Other than the temporary halt in screening of new subjects described above, we have not experienced these potential negative effects of the COVID-19 pandemic.

The ultimate impact of the COVID-19 pandemic is highly uncertain and we do not yet know the full extent of potential delays or impacts on our business, our financial results, our clinical trials, our supply chains, our pre-launch commercial readiness activities, end user demand for our products, if approved, healthcare systems or the global economy as a whole. The extent to which COVID-19 impacts us will depend on future developments, which are highly uncertain and cannot be predicted, including the duration of the COVID-19 pandemic, new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. As such, the full magnitude that the pandemic will have on our financial condition, liquidity, and future results of operations is uncertain and cannot be predicted.

Financial History

We have incurred, and expect to continue to incur, significant operating losses and negative cash flows as we continue to develop our product candidates and prepare for potential future regulatory approvals and commercialization of vibegron. To date, we have not generated any revenue, and we do not expect to generate revenue unless and until we successfully complete development of, obtain regulatory approval for, and commercialize at least one of our product candidates.

We have historically funded our operations primarily from the issuance and sale of our common shares, from the $300 million unsecured revolving debt facility with Sumitomo Dainippon Pharma, or the Sumitomo Loan Agreement, and from the term loans we had pursuant to the loan agreement with Hercules Capital, Inc., or Hercules. These term loans with Hercules were repaid in January 2020. Additional information about our sources of funding is included under "—Liquidity and Capital Resources—Sources of Liquidity" below.

Financial Operations Overview

Revenue

We currently do not have any products approved for sale and have not generated any revenue since inception. If we are able to successfully develop, receive regulatory approval for and commercialize vibegron, URO-902 or any future product candidate alone or in collaboration with third parties, we may generate revenue from vibegron, URO-902 or any such future product candidate.

Research and Development Expenses

Our research and development expenses to date have been primarily attributed to the license of rights to vibegron and URO-902, the initiation and ongoing activities related to our clinical programs and the increase in our personnel. Research and development expenses include program-specific costs, as well as costs that are not allocated to a specific program.

Program-specific costs include:

- direct third-party costs such as expenses incurred under agreements with clinical research organizations, or CROs, and contract manufacturing organizations, or CMOs, the cost of consultants who assist with the development of vibegron on a program-specific basis, investigator grants, sponsored research, manufacturing costs in connection with producing materials for use in conducting nonclinical studies and clinical trials, and other third-party expenses directly attributable to the development of our product candidates.

Unallocated costs primarily include:

- employee-related expenses, such as salaries, share-based compensation, benefits and travel expense for our research and development personnel; and
- other expenses, which include the costs of consultants who assist with research and development activities not specific to a program.

Research and development expenses also include in-process research and development expense related to our acquisition of the rights to our product candidates, vibegron and URO-902, from Merck and ICI, respectively.

Research and development activities will continue to be central to our business model. Product candidates in later stages of clinical development, such as vibegron, generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. It is difficult to determine with certainty the duration and completion costs of any clinical trial we may conduct. We expect our overall research and development expenses to continue to be a significant area of spend over the next several years as we advance the clinical development of vibegron and URO-902. With the completion of the Phase 3 EMPOWUR study and submission of our NDA seeking approval of vibegron for the treatment of patients with OAB, development costs for vibegron for OAB will decrease but are expected to be partially offset by increases in development costs of vibegron for other indications, particularly if the programs are successful, as well as increases in other areas, such as regulatory, pharmacovigilance, and medical affairs.

The duration, costs and timing of clinical trials of our current and future product candidates will depend on a variety of factors that include, but are not limited to: the number of trials required for approval; the per patient trial costs; the number of patients that participate in the trials; the number of sites included in the trials; the countries in which the trial is conducted; the length of time required to enroll eligible patients; the number of doses that patients receive; the drop-out or discontinuation rates of patients; the potential additional safety monitoring or other studies requested by regulatory agencies; the duration of patient follow-up; the timing and receipt of regulatory approvals; the costs of clinical trial material; the efficacy and safety profile of the product candidate; and any impact as a result of the COVID-19 pandemic. For example, beginning in mid-March 2020, we temporarily halted the screening of new subjects for six weeks in all our ongoing clinical trials due to the COVID-19 pandemic. The temporary halt in screening resulted in lower clinical trial expenses than expected during the three months ended June 30, 2020. We expect our clinical trial expenses during our second fiscal quarter to increase as screening resumed during the three months ended June 30, 2020.

In addition, the probability of success for vibegron, URO-902 and any other product candidates will depend on numerous factors, including competition, manufacturing capability and commercial viability. As a result, we are unable to determine the duration and completion costs of our programs or when and to what extent we will generate revenue from commercialization and sale of any of our product candidates. Our research and development activities may be subject to change from time to time as we evaluate our priorities and available resources.

General and Administrative Expense

General and administrative expenses consist primarily of employee-related expenses, such as salaries, share-based compensation, benefits and travel expenses for general and administrative personnel, professional fees for legal, consulting, accounting, auditing and tax services, commercial readiness costs, insurance, facilities and information technology costs, and general overhead.

We anticipate that our general and administrative expenses will increase in the future to support anticipated organizational growth, commercial readiness, commercial launch if our product candidates are approved, and increased costs of continuing to operate as a public company. These increases will likely include increased costs related to the hiring of additional personnel, professional fees and general overhead. Additionally, we anticipate increased costs associated with being a public company, including expenses related to services associated with maintaining compliance with the requirements of The Nasdaq Global Select Market, or Nasdaq, and the SEC, insurance and investor relations costs. We expect to incur increased costs associated with establishing sales, marketing, and commercialization functions in advance of potential future regulatory approvals and commercialization of our product candidates. If any of our current or future product candidates obtains U.S. regulatory approval, we expect that we would incur significantly increased expenses associated with building a sales and marketing team and funding commercial activities.

Results of Operations

Comparison of the Three Months Ended June 30, 2020 and 2019

The following table sets forth our results of operations for the three months ended June 30, 2020 and 2019 (in thousands):

	Three Months Ended June 30,	
	2020	2019
Operating expenses:		
Research and development	$ 16,354	$ 22,014
General and administrative	12,489	5,465
Total operating expenses	28,843	27,479
Other expense:		
Interest expense, net	(1,443)	(513)
Loss on disposal of property and equipment	—	(236)
Other expense	(118)	(190)
Loss before provision for income taxes	(30,404)	(28,418)
Provision for income taxes	90	67
Net loss	$ (30,494)	$ (28,485)

Research and Development Expenses

For the three months ended June 30, 2020 and 2019, our research and development expenses consisted of the following (in thousands):

	Three Months Ended June 30,	
	2020	2019
Program-specific costs:		
Vibegron	$ 11,308	$ 19,302
URO-902	1,254	170
Unallocated costs:		
Share-based compensation	369	265
Personnel expenses	2,500	1,732
Other expense	923	545
Total research and development expenses	$ 16,354	$ 22,014

Research and development expenses decreased by $5.6 million, to $16.4 million, for the three months ended June 30, 2020 compared to $22.0 million for the three months ended June 30, 2019. The decrease in research and development expenses was primarily attributed to the following:

- a decrease of $10.2 million in CRO costs primarily due to the completion of the Phase 3 EMPOWUR study; and
- a decrease of $0.8 million in other program-specific third-party research and development costs to support the continuation of our clinical programs.

These decreased expenses were partially offset by increases primarily attributed to the following:

- an increase of $4.1 million in chemistry, manufacturing and controls costs as a result of sourcing materials and the manufacturing of validation batches of vibegron;
- an increase of $0.9 million in personnel-related costs, including share-based compensation, due to increased headcount; and
- an increase of $0.4 million in other unallocated research and development costs.

General and Administrative Expenses

General and administrative expenses increased by $7.0 million, to $12.5 million, for the three months ended June 30, 2020 compared to $5.5 million for the three months ended June 30, 2019. The increase in general and administrative expenses was primarily attributed to the following:

- an increase of $3.1 million in commercial readiness costs;
- an increase of $2.2 million in personnel-related costs due to increased headcount to support our organizational growth as we continue to prepare for our commercial launch of vibegron, if approved;
- an increase of $0.9 million in share-based compensation expense for stock options, restricted stock units and stock appreciation rights granted to employees and Board members primarily from the increased fair value of certain stock options classified as a liability instrument;
- an increase of $0.7 million in legal and other professional and consulting fees; and
- an increase of $0.1 million in general overhead and corporate expenses due to increased costs associated with operating as a public company such as director and officer insurance premiums and larger office facilities to accommodate our increased headcount.

Interest Expense, Net

Interest expense, net for the three months ended June 30, 2020 consists of interest expense related to the Sumitomo Loan Agreement as well as the associated non-cash amortization of debt issuance costs, partially offset by interest income earned on interest bearing cash deposit accounts. Interest expense, net for the three months ended June 30, 2019 includes the interest expense related to our prior loan agreement with Hercules. Interest expense, net, increased by $0.9 million, to $1.4 million, for the three months ended June 30, 2020 compared to $0.5 million for the three months ended June 30, 2019 primarily due to the Company entering into the Sumitomo Loan Agreement in December 2019.

Liquidity and Capital Resources

Sources of Liquidity

In October 2018, we completed our IPO, in which we sold 10,297,813 common shares, including 297,813 common shares pursuant to the partial exercise of the underwriters' over-allotment option to purchase additional shares, at a public offering price of $14.00 per common share. The net proceeds to us were approximately $132.9 million, after deducting $10.1 million in underwriting discounts and commissions and $1.2 million in offering expenses.

In February 2019, we entered into a loan agreement with Hercules in the amount of $100.0 million. A first tranche of $15.0 million was funded in February 2019, and a second tranche of $30.0 million was funded in September 2019. In January 2020, we terminated the loan agreement with Hercules in connection with, and as a requirement under, the Sumitomo Loan Agreement and repaid in full our remaining obligations under the loan agreement as of the date of termination totaling $48.2 million.

In November 2019, we filed a registration statement on Form S-3 under the Securities Act to register the offer and sale of up to an aggregate of $200.0 million of our securities, which includes our $50.0 million "at-the market" equity offering program. As of August 12, 2020, we have not sold any common shares under our "at-the-market" equity offering program.

In December 2019, we entered into the Sumitomo Loan Agreement in the amount of $300.0 million. Sumitomo Dainippon Pharma funded an initial amount of $87.5 million in December 2019 and additional amounts of $41.0 million and $43.0 million in April and July 2020, respectively. As of August 12, 2020, $171.5 million was outstanding under the Sumitomo Loan Agreement and approximately $128.5 million remained available, which may be drawn down by us, upon request, no more than once in any calendar quarter, subject to funding requests by us that are made in accordance with our Board approved operating budget.

As of June 30, 2020, we had an accumulated deficit of $352.8 million and a cash balance of $63.0 million, as compared to $322.3 million and $51.4 million, respectively, as of March 31, 2020. Prior to our IPO, the loan agreement with Hercules and the Sumitomo Loan Agreement, all operations had been financed through capital contributions or short-term advances from Roivant Sciences Ltd., or RSL, or its affiliates.

Capital Requirements

For the three months ended June 30, 2020 and 2019, we had a net loss of $30.5 million and $28.5 million, respectively, and we have never generated any revenue.

We expect to continue to incur significant operating losses and negative cash flows at least for the next several years. We do not expect to generate product revenue until we successfully complete development of, obtain regulatory approval for, and commercialize at least one of our current or future product candidates, which may never occur. Our net losses and negative cash flows may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our planned clinical trials, our expenditures on other research and development activities and our pre-commercialization and commercialization efforts. We anticipate that our capital requirements will increase substantially as we:

- establish a sales, marketing and distribution infrastructure;
- advance our Phase 3 COURAGE trial of vibegron for the treatment of OAB in men with BPH;
- advance the clinical development of vibegron for the treatment of abdominal pain due to IBS beyond our ongoing Phase 2a trial;
- advance the clinical development of URO-902 for the treatment of OAB in patients who have not responded to oral pharmacological therapies beyond our ongoing Phase 2a trial;
- expand our chemistry, manufacturing, and control and other manufacturing related activities, including scale up external manufacturing capabilities to commercialize any drug candidates for which we may obtain regulatory approval;
- identify, acquire, develop and commercialize additional product candidates;
- integrate acquired technologies into a comprehensive regulatory and product development strategy;
- maintain, expand and protect our intellectual property portfolio;
- hire scientific, clinical, quality control and administrative personnel;
- add operational, financial and management information systems and personnel, including personnel to support our drug development efforts;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- service debt obligations and payment of interest associated with the Sumitomo Loan Agreement; and
- continue to operate as a public company.

Our primary use of cash is to fund the development of vibegron for the treatment of OAB, advance our Phase 3 COURAGE trial for vibegron for the treatment of OAB in men with BPH, advance our Phase 2a clinical trial for vibegron in patients with abdominal pain due to IBS, advance our Phase 2a clinical trial for URO-902 for the treatment of OAB in patients who have not responded to oral pharmacological therapies, and to fund our commercial readiness and general and administrative costs. We expect our operating expenses to continue to increase in the future as we expand our operations to continue to develop our product candidates and prepare for the potential future regulatory approvals and commercialization of vibegron. Based on anticipated spend and timing of expenditure assumptions, we currently believe that our existing cash, together with the draw down under the Sumitomo Loan Agreement of $43.0 million in July 2020 and the remaining financing commitment from Sumitomo Dainippon Pharma of $128.5 million which is available to us if our future funding requests are in accordance with our Board approved operating budget, will be sufficient to fund our committed operating expenses and capital expenditure requirements for at least the next 12 months from the filing date of this Quarterly Report on Form 10-Q. This estimate is based on our current assumptions, including assumptions relating to the timing of regulatory approval and subsequent launch of vibegron for OAB and our ability to manage the amount and timing of our spend. Our current assumptions may prove to be wrong and we could use our available capital resources sooner than we currently expect. Changes may occur that would consume our available capital faster than anticipated, including the length and severity of the COVID-19 pandemic and measures taken to control the spread of COVID-19, as well as changes in and progress of our development activities and the impact on commercialization efforts due to the COVID-19 pandemic. We will need additional funding to complete the clinical development of, and seek regulatory approval for, vibegron for the treatment of OAB in men with BPH and abdominal pain due to IBS, URO-902, and commercially launch vibegron or URO-902, if approved. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic, or otherwise, as well as may be limited pursuant to the terms of the Sumitomo Loan Agreement and Sumitomo Dainippon Pharma's ability to exert substantial influence and control over us due to Sumitomo Dainippon Pharma's majority ownership of our outstanding common shares. As such, adequate additional funding may not be available to us on acceptable terms, or at all. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations, and financial condition.

Until such time, if ever, as we can generate substantial product revenue from sales of vibegron, URO-902 or any future product candidate, we expect to finance our cash needs through a combination of the remaining financing commitment available to us from the Sumitomo Loan Agreement, equity offerings, debt financings and potential collaboration, license or development agreements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common shareholder. Our agreement with Sumitomo Dainippon Pharma involves, and any agreements for future debt or preferred equity financings, if available, may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

In addition, if we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required 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 capital, when needed, in sufficient amounts or on terms acceptable to us, or if the current financing commitment of $128.5 million available to us under the Sumitomo Loan Agreement is no longer available to us despite our future funding requests being in accordance with our Board approved operating budget, we may have to significantly delay or scale back our operations to reduce working capital requirements beginning in the first calendar quarter of 2021, including but not limited to actions such as reducing personnel-related costs, curtailment of our pre-commercial launch efforts, development activities and other discretionary expenditures that are within our control. Additionally, we may have to discontinue the development or commercialization of vibegron or URO-902, grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves or potentially discontinue operations and substantial uncertainty would exist with respect to our ability to continue as a going concern. We will prioritize necessary and appropriate steps to enable the continued operations of our business and preservation of the value of our assets beyond the next twelve months. These reductions in expenditures, if required, may have an adverse impact on our ability to achieve certain of our planned objectives in fiscal years 2020 and 2021. Any of these actions could materially harm our business, results of operations and future prospects.

Cash Flows

The following table sets forth a summary of our cash flows for the three months ended June 30, 2020 and 2019 (in thousands):

	Three Months Ended June 30,	
	2020	2019
Net cash used in operating activities	$ (30,800)	$ (22,505)
Net cash used in investing activities	(104)	(278)
Net cash provided by (used in) financing activities	42,536	(187)

Operating Activities

For the three months ended June 30, 2020, $30.8 million of cash was used in operating activities. This was primarily attributable to a net loss of $30.5 million and an increase in prepaid expenses and other current assets of $2.5 million for prepayments made to our CRO in advance of services completed. This amount was partially offset by $2.0 million in share-based compensation expense from stock options, restricted stock units and stock appreciation rights granted to employees and Board members, as well as the increased fair value of certain stock options classified as liability instruments and $0.2 million in non-cash operating lease costs.

For the three months ended June 30, 2019, $22.5 million of cash was used in operating activities. This was primarily attributable to a net loss of $28.5 million and a decrease of $0.4 million in accounts payable and accrued expenses. These amounts were partially offset by a decrease of $4.5 million in prepaid expenses and other current assets, $1.0 million in share-based compensation expense from stock options and restricted stock units granted to employees and Board members, $0.2 million from the loss on disposal of property and equipment upon our move to the new Irvine, California office space, and $0.2 million for the amortization of the debt discount and issuance costs from the loan agreement with Hercules.

Investing Activities

For the three months ended June 30, 2020 and 2019, $0.1 million and $0.3 million of cash was used in investing activities, respectively, all for the purchase of property and equipment.

Financing Activities

For the three months ended June 30, 2020, cash provided by financing activities of $42.5 million was primarily attributable to proceeds of $41.0 million from the April 2020 loan under the Sumitomo Loan Agreement, proceeds of $1.2 million from the exercise of stock options, and proceeds from the issuance of common shares pursuant to the 2019 Employee Stock Purchase Plan of $0.3 million.

For the three months ended June 30, 2019, cash used in financing activities of $0.2 million was primarily attributable to the payment of debt financing costs in connection with the loan agreement with Hercules of $0.4 million, offset by proceeds of $0.1 million from the exercise of stock options and capital contributions from RSL of $0.1 million.

Contractual Obligations and Commitments

During the three months ended June 30, 2020, there were no material changes outside of the ordinary course of business to the specified contractual obligations set forth in the contractual obligations table included in our Annual Report on Form 10-K for the fiscal year ended March 31, 2020 filed with the SEC on June 19, 2020, except as described below.

During the three months ended June 30, 2020, we received a loan in the amount of $41.0 million pursuant to the Sumitomo Loan Agreement. See Note 4, “Long-term debt” to our unaudited condensed consolidated financial statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q for a further discussion of this loan agreement.

Off-Balance Sheet Arrangements

During the periods presented, we did not have nor do we currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Significant Judgments and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the dates of the consolidated balance sheets and the reported amounts of expenses during the reporting periods. In accordance with U.S. GAAP, we evaluate our estimates and judgments on an ongoing basis. Significant estimates include assumptions used to determine which costs are charged to research and development and general and administrative expense, as well as assumptions used to estimate the fair value of common share and option awards. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

During the three months ended June 30, 2020, there were no material changes to our critical accounting policies and use of estimates from those disclosed under the heading “Management’s discussion and analysis of financial condition and results of operations—Critical accounting policies and significant judgments and estimates” and in the footnotes to our audited consolidated financial statements for the year ended March 31, 2020 included in our Annual Report on Form 10-K filed with the SEC on June 19, 2020.

Recent Accounting Pronouncements

For information regarding recently issued accounting pronouncements and the expected impact on our consolidated financial statements, see Note 2, "Summary of significant accounting policies," to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Under SEC rules and regulations, because we are considered to be a "smaller reporting company," we are not required to provide the information required by this item in this report.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. These disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure.

Under the supervision of our principal executive officer and principal financial officer, we evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2020, the end of the period covered by this report. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of June 30, 2020 at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

No changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended June 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our principal executive officer and principal financial officer, does not expect that our disclosure controls and procedures or our internal controls, will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs.

Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings related to claims arising from the ordinary course of business. We are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal proceedings against us that we believe could have a material adverse effect on our business, operating results, or financial condition.

Item 1A. Risk Factors.

You should carefully consider the following risk factors, in addition to the other information contained in this Quarterly Report on Form 10-Q, including the section of this report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our unaudited condensed consolidated financial statements and related notes. 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. If any of the events described in the following risk factors and the risks described elsewhere in this report occurs, our business, operating results and financial condition could be seriously harmed and the trading price of our common shares could decline. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this report.

Risks Related to Our Business, Financial Position and Capital Requirements

We have a limited operating history and have never generated any product revenue.

We are a clinical-stage biopharmaceutical company with a limited operating history. We were incorporated in January 2016, and our operations to date have primarily been developing vibegron for the treatment of OAB, organizing and staffing our company, and acquiring rights to vibegron and URO-902. We have not yet demonstrated an ability to successfully obtain marketing approval, manufacture a commercial scale product, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, we have no meaningful operations upon which to evaluate our business and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

Our ability to generate product revenue and become profitable depends upon our ability to successfully complete the development of, and obtain the necessary regulatory approvals for, vibegron for the treatment of OAB or our other targeted indications, OAB in men with BPH and abdominal pain due to IBS, as well as URO-902 for the treatment of OAB. We have never been profitable, have no products approved for commercial sale, and have not generated any product revenue.

Even if we receive regulatory approval for one of our product candidates, we do not know when or if it will generate product revenue. Our ability to generate product revenue depends on a number of factors, including, but not limited to, our ability to:

- successfully complete clinical trials and obtain regulatory approval for the marketing of our product candidates;
- add operational, financial and management information systems personnel, including personnel to support our clinical, manufacturing and planned future commercialization efforts;
- initiate and continue relationships with third-party manufacturers and have commercial quantities of our product candidates manufactured at acceptable cost and quality levels and in compliance with FDA and other regulatory requirements;
- attract and retain experienced management and advisory teams;
- raise additional funds when needed and on terms acceptable to us;
- commercial launch of our products, whether alone or in collaboration with others, including establishing sales, marketing and distribution systems for our product candidates;
- set an acceptable price for our product candidates and obtain coverage and adequate reimbursement from third-party payors;
- achieve broad market acceptance of our products in the medical community and with third-party payors and consumers; and
- maintain, expand and protect our intellectual property portfolio.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses, or when or if, we will be able to achieve or maintain profitability. Our expenses could increase beyond expectations if we are required by the FDA or comparable non-U.S. regulatory authorities to perform studies or clinical trials in addition to those that we currently anticipate. Even if one of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with its commercial launch. If we cannot successfully execute any one of the foregoing, our business may not succeed.

We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or fail to become commercially viable. We have never generated any product revenue, and we cannot estimate with precision the extent of our future losses. We do not currently have any products that are available for commercial sale, and we may never generate product revenue or achieve profitability. Our net loss was $30.5 million and $28.5 million for the three months ended June 30, 2020 and 2019, respectively. As of June 30, 2020, we had an accumulated deficit of $352.8 million.

We expect to continue to incur substantial and increasing losses through the commercialization of our product candidates, if approved. Our product candidates have not been approved for marketing anywhere in the world, and they may never receive such approval. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to generate product revenue and achieve profitability is dependent on our ability to complete the development of, obtain necessary regulatory approvals for, and manufacture and successfully market our product candidates alone or in collaboration with others. We cannot assure you that we will be profitable even if we successfully commercialize our product candidates. If we do successfully obtain regulatory approval to market our product candidates, our revenue will be dependent upon, in part and among other things, the size of the markets in the territories for which we gain regulatory approval, the number of competitors in such markets, the accepted price for our product candidates and whether we own the commercial rights for those territories. If 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 our product candidates, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Failure to become and remain profitable may adversely affect the market price of our common shares and our ability to raise capital and continue operations.

We expect our research and development expenses in connection with our development programs for our product candidates to continue to be significant. In addition, as we prepare for and if we obtain regulatory approval for our product candidates, we expect to incur increased sales, marketing and manufacturing expenses. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses had, and will continue to have, an adverse effect on our results of operations, financial position and working capital.

We are heavily dependent on the success of our lead product candidate, vibegron, and if vibegron does not successfully complete clinical development or receive regulatory approval, or is not successfully commercialized, our business may be harmed.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to the advancement of vibegron, through clinical trials and the regulatory approval process, as well as the commercialization of vibegron following regulatory approval, if received. Accordingly, our business currently depends heavily on the successful development, regulatory approval, and commercialization of vibegron.

Even though we have submitted our NDA for vibegron, we cannot be certain that vibegron will receive regulatory approval, or be successfully commercialized even if we receive regulatory approval. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of products are, and will remain, subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market vibegron in the United States until we receive approval of our NDA, or in any foreign country until we receive the requisite approvals from the appropriate authorities in such countries for marketing authorization.

The top-line results from our Phase 3 EMPOWUR trial demonstrated a statistically significant difference for the active vibegron 75 mg dose compared to placebo for the co-primary endpoints, which are reductions in daily UUI episodes and reduction in daily micturitions, in the primary efficacy analysis. In addition, we reported a statistically significant reduction in daily urgency episodes compared to placebo ($p=0.002$), which is the first of the seven pre-specified key secondary endpoints. All seven pre-specified secondary endpoints achieved statistical significance over placebo for vibegron. As such, even if we were able to obtain approval for vibegron, these secondary endpoints may not be mentioned in the U.S. label, which could potentially adversely affect product differentiation.

We submitted our NDA for vibegron in December 2019 but have not yet submitted a Biologics License Application, or BLA, for URO-902. Obtaining approval of an NDA, BLA or similar regulatory approval is an extensive, lengthy, expensive and inherently uncertain process, and the FDA or other foreign regulatory authorities may delay, limit or deny approval of any of our current or future product candidates, including through amendments to the NDA or BLA, for many reasons, including:

- we may not be able to demonstrate that our product candidates are effective as treatments for any of our targeted indications to the satisfaction of the FDA or other relevant regulatory authorities;
- the FDA or other relevant regulatory authorities may identify unexpected efficacy or safety concerns while reviewing an NDA or similar application;
- the FDA or other relevant regulatory authorities may require additional pre-approval studies or clinical trials, which would increase our costs and prolong our development timelines;

- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or other relevant regulatory authorities for marketing approval;
- the FDA or other relevant regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA or other relevant regulatory authorities may disagree with our proposed analysis plans for any clinical trials of our product candidates;
- the CROs that we retain to conduct clinical trials may take actions outside of our control, or otherwise commit errors or breaches of protocols, that materially adversely impact our clinical trials and ability to obtain market approvals;
- the FDA or other relevant regulatory authorities may not find the data from nonclinical studies or clinical trials sufficient to demonstrate that the clinical and other benefits of these products outweigh their safety risks;
- the FDA or other relevant regulatory authorities may disagree with our interpretation of data or significance of results from the nonclinical studies and clinical trials of our product candidates, or may require that we conduct additional studies;
- the FDA or other relevant regulatory authorities may not accept data generated from our clinical trial sites;
- if our NDA or other foreign application is reviewed by an advisory committee, the FDA or other relevant regulatory authority, as the case may be, may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA or other relevant regulatory authority, as the case may be, require, as a condition of approval, additional nonclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA or other relevant regulatory authorities may require development of a risk evaluation and mitigation strategy, or REMS, or its equivalent, as a condition of approval;
- the FDA or other relevant regulatory authorities may require additional post-marketing studies, which would be costly;
- the FDA or other relevant regulatory authorities may find the chemistry, manufacturing and controls data insufficient to support the approval and quality of our product candidates;
- the FDA or other relevant regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers and third-party manufacturers may not pass the pre-approval inspections by regulatory authorities;
- the FDA or other relevant regulatory authorities may have slower response times or be under-resourced due to the global novel coronavirus disease, or COVID-19, pandemic and, as a result, review, inspection and other timelines may be materially delayed; or
- the FDA or other relevant regulatory authorities may change their approval policies or adopt new regulations.

Our business, financial condition, results of operations and ongoing clinical trials could be harmed by the effects of the COVID-19 pandemic.

We are subject to various risks related to the global pandemic associated with COVID-19. For example, many geographic regions have imposed, or in the future may impose, “shelter-in-place” orders, quarantines or similar orders or restrictions to control the spread of COVID-19. These types of restrictions have resulted in most of our employees working from home, and could result in the employees of our key third-party vendors and manufacturers working from home. Although certain shelter-in-place orders have been lifted, we, or our suppliers or manufacturers, may continue to require employees to work from home after the orders are lifted to protect the health and safety of employees. We rely exclusively on third-party manufacturers to manufacture vibegron and URO-902. Neither we, nor our suppliers or manufacturers have significant experience operating with the majority of our respective work forces working from home, and this may disrupt standard operations for us or them, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our respective abilities to conduct business in the ordinary course. In addition, this may increase our cybersecurity risk, create data accessibility concerns and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical trial sites and other important agencies and contractors.

As our starting materials for vibegron are purchased outside of the U.S., a disruption in our ability to procure such materials may occur if exportation out of the countries where our third-party manufacturers are located is halted or delayed for a significant period of time due to COVID-19. Such a disruption could have a material adverse impact on our ability to timely manufacture sufficient product quantities for our expected future customer demand, if vibegron is approved. Additionally, timely enrollment in our clinical trials is dependent upon global clinical trial sites, which may be adversely affected by the COVID-19 pandemic. We are currently conducting clinical trials for our product candidates in many countries. Many of these regions are currently being affected or may in the future be affected by the COVID-19 pandemic. For vibegron, from March 19, 2020 to April 27, 2020, we temporarily halted the screening of new subjects into our Phase 3 COURAGE trial and Phase 2a trial for abdominal pain due to IBS and, for URO-902, from March 19, 2020 to May 4, 2020, we temporarily halted the screening

of new subjects in our Phase 2a trial due to the COVID-19 pandemic. Subjects that were in the run-in phase or already enrolled in our ongoing studies continued with treatment pursuant to the clinical trial protocol and treatments were not halted or delayed. Since the end of the temporary halt in screening of new subjects, we are re-opening the clinical trial sites in a stepwise manner to allow for screening of new patients. If the COVID-19 pandemic continues to spread in the geographies in which we are conducting clinical trials, we may experience further disruptions in those clinical trials, which could have a material adverse impact on our clinical trial plans and timelines, including:

- delays in receiving authorizations from local regulatory authorities and ethics committees to initiate planned clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruptions in global shipping that may affect the transport of clinical trial materials;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- risk that participants enrolled in our clinical trials may acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial due to missed study visits and/or data, as well as adverse events due to the COVID-19 infection;
- delays in necessary interactions with local regulators, ethics committees and other third parties and contractors due to limitations in employee resources or forced furlough of government employees;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- refusal of the FDA to accept data from clinical trials in affected geographies.

Health regulatory agencies globally may also experience disruptions in their operations as a result of the COVID-19 pandemic. The FDA and comparable foreign regulatory agencies may have slower response times or be under-resourced to continue to monitor our clinical trials and, as a result, review, inspection and other timelines may be materially delayed. For example, in March 2020, the FDA announced its intention to temporarily postpone certain inspections of both foreign and domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. It is unknown how long such delays or disruptions could last. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions, in particular any delays to our PDUFA date of December 26, 2020 for vibegron, could materially affect the development and study of our product candidates and commercialization efforts.

The COVID-19 pandemic could have an adverse impact on our commercial launch plans for vibegron, if approved, due to the continuation or re-imposition of government-imposed quarantines, stay at home orders, travel restrictions, mandated business closures and other public health safety measures which may result in limiting our ability to hire a sales force prior to launch, conduct necessary trainings of such sales force and attending and presenting at various conferences or other programs. If vibegron is approved, continuation of these government-imposed orders may also result in patients not visiting their healthcare providers or their pharmacies to get their prescriptions filled, in-person interactions by sales and medical representatives in healthcare settings such as urologists' offices and long-term care facilities may be suspended, and any remote interactions may be less effective than in-person interactions. In addition, due to the prioritization of healthcare resources toward pandemic efforts, even remote interactions may not be possible. These factors could have an adverse impact on our business and our ability to effectively launch vibegron, if approved.

The continued spread of COVID-19 has also led to extreme disruption and volatility in the global capital markets, which increases the cost of, and adversely impacts access to, capital and increases economic uncertainty. The trading prices for our common shares and other biopharmaceutical companies have been highly volatile as a result of COVID-19. Given the rapid and evolving nature of the virus and the uncertainty about its impact on society and the global economy, we cannot predict the extent to which it will affect our operations or the value of our common shares, particularly if these impacts persist or worsen over an extended period of time. To the extent the COVID-19 pandemic adversely affects our business, financial results, and value of our common shares, it may also affect our ability to raise capital when needed and to comply with certain covenants in our loan agreement or other agreements that are material to our business.

We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of vibegron.

We expect to spend substantial capital to complete the development of, seek regulatory approvals for and commercialize our product candidates. These expenditures will include costs associated with our license agreements with Merck and ICI pursuant to which we are obligated to cover the development and commercialization costs of vibegron and URO-902, respectively, make payments in connection with the achievement of certain regulatory milestones prior to generating any product sales, make further payments upon the achievement of certain sales milestones and make tiered royalty payments in connection with the sale of approved products, if any.

We will require additional capital to complete the development and potential commercialization of our product candidates. Because the length of time and activities associated with successful development of our product candidates are highly uncertain, we are unable to estimate with certainty the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the disruption to our supply chains, business operations, commercialization efforts, if approved, or clinical trials or to the resulting from the COVID-19 pandemic, including any delay in the FDA's approval of our NDA;
- the disruption to the business or operations of our contract manufacturers, CROs or other third parties with whom we conduct business resulting from the COVID-19 pandemic;
- future global financial crises and economic downturns, including those cause by widespread public health crises such as the COVID-19 pandemic;
- the timing, costs and results of our Phase 3 COURAGE clinical trial of vibegron for the treatment of OAB in men with BPH and our Phase 2a clinical trial of vibegron for the treatment of abdominal pain due to IBS;
- the timing, costs and results of our Phase 2a clinical trial for URO-902 for the treatment of OAB in patients who have not responded to oral pharmacological therapies;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- the cost and timing of completion of commercial-scale manufacturing activities;
- the cost of establishing sales, marketing and distribution capabilities for our products in regions where we choose to commercialize our products on our own;
- the initiation, progress, timing and results of our commercialization of our product candidates, if approved for commercial sale;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or any of our current or future product candidates; and
- the effect of competing technological and market developments.

We currently believe that our existing cash, together with the proceeds of $43.0 million received in July 2020 pursuant to the Sumitomo Loan Agreement and the current remaining financing commitment available to us of $128.5 million from Sumitomo Dainippon Pharma, will be sufficient to fund our committed operating expenses and capital expenditure requirements for at least the next 12 months from the filing date of this Quarterly Report on Form 10-Q. This estimate is based on assumptions that may prove to be wrong and changes may occur that would consume our available capital faster than anticipated, including the length and severity of the COVID-19 pandemic and the impact of measures taken to control the spread of COVID-19, as well as changes in and progress of our development activities and the impact of commercialization efforts due to the COVID-19 pandemic. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. We cannot be certain that additional capital when needed will be available on acceptable terms, or at all. If we are unable to raise additional capital, as needed, in sufficient amounts or on terms acceptable to us, or if the current remaining financing commitment of $128.5 million available to us under the Sumitomo Loan Agreement is no longer available to us despite our future funding requests being in accordance with our Board approved operating budget, we may have to significantly delay or scale back our operations to reduce working capital requirements beginning in the first calendar quarter of 2021, including but not limited to actions such as reducing personnel-related costs, curtailment of our pre-commercial launch efforts, development activities and other discretionary expenditures that are within our control. Additionally, we may have to discontinue the development or commercialization of our current and any future product candidates, or potentially discontinue operations altogether. Attempting to secure additional capital, as needed, may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts. Because of the numerous risks and uncertainties associated with the development and potential commercialization of our product candidates, we are unable to

estimate the amounts of increased capital outlays, operating expenditures and capital requirements associated with our current product development programs.

Our Loan Agreement with Sumitomo Dainippon Pharma contains certain covenants that could adversely affect our operations and, if an event of default were to occur, we could be forced to repay the outstanding indebtedness sooner than planned and possibly at a time when we do not have sufficient capital to meet this obligation. The occurrence of any of these events could cause a significant adverse impact on our business, prospects and share price.

Pursuant to the Sumitomo Loan Agreement, we have agreed that we may not sell or assign rights to our patents and other intellectual property without the prior consent of Sumitomo Dainippon Pharma. The Sumitomo Loan Agreement contains affirmative and negative covenants that, among other things, restrict our ability to:

- incur additional indebtedness;
- incur liens;
- make investments;
- dispose of any property;
- make distributions, including dividends;
- enter into certain transactions with affiliates of Sumitomo Dainippon Pharma;
- consolidate or merge; and
- alter the business of the Company.

These terms of the Sumitomo Loan Agreement could prevent us from taking certain actions without the consent of our lender, who is also currently our majority shareholder, which may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our minority shareholders, placing us at a competitive disadvantage compared to our competitors who have less leverage and who therefore may be able to take advantage of opportunities that our leverage prevents us from exploiting.

The Sumitomo Loan Agreement also includes events of default, including, among other things, payment defaults; breaches of certain covenants or agreements; certain bankruptcy or insolvency events; the occurrence of certain events that could reasonably be expected to have a “material adverse effect”; and defaults in respect of certain other indebtedness.

Upon the occurrence of an event of default and following any cure periods (if applicable), a default interest rate of an additional 5.0% per annum may be applied to the outstanding principal balance, and Sumitomo Dainippon Pharma may declare all outstanding obligations immediately due and payable (subject, in certain instances, to specified grace periods) and take such other actions as set forth in the Sumitomo Loan Agreement.

If an event of default under the Sumitomo Loan Agreement were to occur and Sumitomo Dainippon Pharma declared all outstanding obligations immediately due and payable, we would be required to immediately repay the outstanding indebtedness. If we are unable to repay this debt, Sumitomo Dainippon Pharma would be able to take remedies permitted under the Sumitomo Loan Agreement. Even if we are able to repay the indebtedness on an event of default, the repayment of these sums may significantly reduce our working capital and impair our ability to operate as planned. The occurrence of any of these events could cause a significant adverse impact on our business, prospects and share price.

The LIBOR calculation method may change and LIBOR is expected to be phased out after 2021.

Loans under the Sumitomo Loan Agreement bear interest at a rate per annum equal to LIBOR plus a margin of 3.0% payable on the last day of each calendar quarter. On July 27, 2017, the U.K. Financial Conduct Authority announced that it will no longer require banks to submit rates for the calculation of LIBOR after 2021.

It is unclear whether new methods of calculating LIBOR will be established such that it continues to exist after 2021. The U.S. Federal Reserve, in conjunction with the Alternative Reference Rates Committee, is considering replacing U.S. dollar LIBOR with the Secured Overnight Financing Rate, or SOFR, a newly created index, calculated with a broad set of short-term repurchase agreements backed by treasury securities. It is not possible to predict the effect of these changes, other reforms or the establishment of alternative reference rates in the United States or elsewhere. Pursuant to the Sumitomo Loan Agreement, if LIBOR becomes unavailable in the future, we and Sumitomo Dainippon Pharma will negotiate in good faith to select an alternative interest rate and, if applicable as a result of such alternative interest rate, margin adjustment that is consistent with industry accepted successor rates for determining a LIBOR replacement. To the extent our interest rates increase as a result, our interest expense will increase, in which event we may have difficulties making interest payments and funding our other fixed costs, and our available cash flow for general corporate requirements may be adversely affected.

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

Our ability to make the payment of the principal of, to pay interest on or to refinance the Sumitomo Loan Agreement, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control, including global macroeconomic effects of global pandemics such as the COVID-19 pandemic. Our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligation.

Raising additional funds by issuing securities may cause dilution to existing shareholders, raising additional funds through debt financings may involve restrictive covenants, and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

We expect that significant additional capital will be needed in the future to continue our planned operations. Until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, the Sumitomo Loan Agreement, additional debt financings, strategic alliances and license and development agreements or other collaborations. To the extent that we raise additional capital by issuing equity securities, our existing shareholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that could adversely affect the rights of a common shareholder. Additionally, any agreements for future debt or preferred equity financings, if available, may involve additional covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

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

We rely on our license agreements with Merck and ICI to provide rights to the core intellectual property relating to vibegron and URO-902, respectively. Any termination or loss of significant rights under either agreement, would adversely affect our development or commercialization of these product candidates.

We have licensed our core intellectual property relating to vibegron and URO-902 from Merck and ICI, respectively. If, for any reason, our license agreement with Merck or ICI is terminated or we otherwise lose those rights, it would adversely affect our business. Our license agreements impose on us obligations relating to exclusivity, territorial rights, development, commercialization, funding, payment, diligence, sublicensing, insurance, intellectual property protection and other matters. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages to Merck or ICI, and Merck or ICI may have the right to terminate our license, which would result in us being unable to develop, manufacture and sell our product candidates.

Pursuant to our license agreement with Merck, Merck agreed to provide a supply of the vibegron compound to support the development of vibegron. Under this agreement, we may only use such material in preclinical and clinical work. The agreement also provides for Merck to reasonably assist us during a specified period of time with a technical transfer of the manufacturing process from Merck to us or our designee for production of vibegron. Although Merck has already transferred the manufacturing process for vibegron to us, we may still need additional assistance if we experience any setbacks with the manufacturing at a larger scale. If Merck fails to fulfill its continuing obligations under this agreement, if needed, or if we require additional assistance after their obligation to assist us expires, our development of vibegron could be significantly delayed or otherwise adversely affected.

Under our license agreement with ICI, ICI has transferred the manufacturing process to us or our designee for production of URO-902. If we require additional assistance from ICI after their obligation to assist us expires, our manufacture and development of URO-902 could be significantly delayed or otherwise adversely affected.

We may be required to make significant payments to third parties under our licensing and collaboration agreements for our current product candidates.

Under our agreements with Merck, Kyorin and ICI, we are subject to significant obligations, including payment obligations upon the achievement of specified milestones and payments based on product sales, as well as other material obligations. Certain of the milestone payments payable by us under these agreements are due upon events that will occur prior to our planned commercialization of our product candidates. Accordingly, we will be required to make such payments prior to the time at which we are able to generate revenue, if any, from sales of our product candidates. There can be no assurance that we will have the funds necessary to make such payments, or be able to raise such funds when needed, on terms acceptable to us, or at all. Furthermore, if we are forced to raise additional funds, 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 develop and market ourselves.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel.

We may not be able to attract or retain qualified management and commercial, scientific and clinical personnel due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategies.

We are highly dependent on the skills and leadership of our senior management team and key employees. Our senior management and key employees may terminate their positions with us at any time. If we lose one or more members of our senior management team or key employees, our ability to successfully implement our business strategies could be adversely affected. Replacing these individuals may be difficult, cause disruption and may take an extended period of time due to the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire from this limited pool is intense, with many of our competitors seeking to hire and retain the same qualified personnel. We may, from time-to-time, hire personnel who work for our competitors or others in the industry, and our competitors may hire personnel who work for us, which could result in a material disruption to our business or even litigation. In the event we lose key personnel, we may be unable to hire, train, retain or motivate new key personnel to replace those we lose. We do not maintain “key person” insurance for any members of our senior management team or other employees.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

We expect to hire, either directly, or through any current or future subsidiaries of ours, additional employees throughout the organization. We may have difficulties identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations across our entities, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of vibegron, URO-902 and any future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate or grow revenue could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our current or future product candidates and compete effectively will partly depend on our ability to effectively manage any future growth.

Many of the other pharmaceutical companies we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer operating history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these opportunities may be more appealing to high-quality candidates and consultants than what we have to offer. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can develop product candidates and our business will be harmed.

Following the closing of the Sumitomo Transaction, Sumitomo Dainippon Pharma has committed to discuss terms on which they can support our commercialization and operations. If we are unable to obtain the contemplated commercial and operational support from Sumitomo Dainippon Pharma on terms acceptable to us, our business could be adversely impacted.

Following the closing of the Sumitomo Transaction, Sumitomo Dainippon Pharma committed to discuss with us, in good faith, terms on which Sumitomo Dainippon Pharma can provide us access to their commercial infrastructure in the United States and operational support services, which may include access to certain distributors, managed care and back office support. In June 2020, we entered into the Market Access Services Agreement with Sunovion, a wholly-owned subsidiary of Sumitomo Dainippon Pharma. Sunovion has agreed to provide certain market access services with respect to the distribution and sale of vibegron. Sunovion, because of its own business considerations, may be unable or unwilling to support our commercialization and operations pursuant to the Market Access Services Agreement and we may not be able to realize the benefits of Sunovion’s broader commercial network.

If we are unable to access Sunovion’s commercial infrastructure in the United States and obtain services that support our operations pursuant to the Market Access Services Agreement, we will have to find alternative means to support our operations and the commercialization of our product candidates. Building the commercial infrastructure that we have access to pursuant to the Market Access Services Agreement in the United States may be prohibitively expensive and time consuming. Accessing the distribution or support network of another third party could be costly or require us to agree to exclusivity or otherwise give up valuable rights. In addition, it may be difficult to find alternative service providers on terms acceptable to us. Any of these events could results in delays in the commercialization of our product candidates, which would adversely impact our business, results of operations and financial condition.

Finally, attempting to secure alternative service providers or access to commercial infrastructure if we or Sunovion is unable to perform under the Market Access Services Agreement for any reason may divert the time and attention of our management from our day-to-day operations and impair the development of our product candidates.

Our or our affiliates' employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our or our affiliates' employees and contractors, including principal investigators, CROs, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA or other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing and the FDA's Good Clinical Practice, or GCP, or current Good Manufacturing Practice, or cGMP, standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing, bribery, corruption, antitrust violations and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our nonclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee or third-party misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person, including any person who may have engaged in any fraud or misconduct, or government agency could allege such fraud or other misconduct, even if none occurred. Furthermore, we rely on our CROs and clinical trial sites to adequately report data from our ongoing clinical trials. For example, any failure by such parties to adequately report safety signals to us in a timely manner from any such trials may also affect the approvability of our product candidates or cause delays and disruptions for the approval of our product candidates, if any. If our or our affiliates' employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers or other vendors are alleged or found to be in violation of any such regulatory standards or requirements, or become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and curtailment of our operations, it could have a significant impact on our business and financial results, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, suspension or delay in our clinical trials, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, FDA debarment, contractual damages, reputational harm, diminished profits and future earnings, and additional reporting requirements and oversight, any of which could adversely affect our ability to operate our business and our results of operations. As a result of the consummation of the Sumitomo Transaction, we are affiliated with different entities, and any misconduct or improper activities by the employees of these new affiliates could have an adverse effect on our results of operations.

We may not be successful in our efforts to identify and acquire or in-license additional product candidates, or to enter into collaborations or strategic alliances for the development and commercialization of any such future product candidates.

Part of our strategy involves identifying and acquiring or in-licensing novel product candidates. The process by which we identify product candidates may fail to yield product candidates for clinical development for a number of reasons, including those discussed in these risk factors and also:

- the process by which we identify and decide to acquire product candidates may not be successful;
- potential product candidates may, upon further study, be 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;
- potential product candidates may not be effective in treating their targeted diseases; or
- the acquisition or in-licensing transactions can entail numerous operational and functional risks, including exposure to unknown liabilities, disruption of our business, or incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected acquisition or integration costs.

We may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful. We also cannot be certain that, following an acquisition or in-licensing transaction, we will achieve the revenue or specific net income that justifies such transaction. Further, time and resources spent identifying, acquiring and developing potential product candidates may distract management's attention from our primary business or other development programs. If we are unable to identify and acquire suitable product candidates for clinical development, this would adversely impact our business strategy, our financial position and share price.

In the future, we may also decide to collaborate with other pharmaceutical companies for the development and potential commercialization of our product candidates in the United States or other countries or territories of the world. We will face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

International expansion of our business exposes us to business, legal, regulatory, political, operational, financial and economic risks associated with conducting business outside of the United States.

Part of our business strategy involves international expansion, including establishing and maintaining operations outside of the United States and establishing and maintaining relationships with health care providers, payors, government officials, distributors and manufacturers globally. Conducting business internationally involves a number of risks, including:

- multiple conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, anti-bribery and anti-corruption laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our distributors to obtain appropriate licenses or regulatory approvals for the sale or use of our product candidates, if approved, in various countries;
- difficulties in managing foreign operations;
- complexities associated with managing multiple payor-reimbursement regimes or self-pay systems;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;
- reduced protection for intellectual property rights;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- failure to comply with the United States Foreign Corrupt Practices Act, or FCPA, including its books and records provisions and its anti-bribery provisions, the United Kingdom Bribery Act 2010, or UK Bribery Act, and similar antibribery and anticorruption laws in other jurisdictions, for example by failing to maintain accurate information and control over sales or distributors' activities.

Any of these risks, if encountered, could significantly harm our future international expansion and operations and, consequently, negatively impact our financial condition, results of operations and cash flows.

Legal, political, and economic uncertainty surrounding the planned exit of the United Kingdom from the European Union are a source of instability and uncertainty.

The United Kingdom held a referendum on June 23, 2016 to determine whether the United Kingdom should leave the European Union, or remain as a member state, the outcome of which was in favor of leaving the European Union, which is commonly referred to as Brexit. Under Article 50 of the 2009 Lisbon Treaty, the United Kingdom will cease to be a member state when a withdrawal agreement is entered into (such agreement will also require parliamentary approval) or, failing that, two years following the notification of an intention to leave under Article 50, unless the European Council (together with the United Kingdom) unanimously decides to extend this period. On March 29, 2017, the United Kingdom formally notified the European Council of its intention to leave the European Union. In January 2020, the European Council and the United Kingdom entered into a withdrawal agreement, which sets the terms of the withdrawal of the United Kingdom from the European Union. The United Kingdom and the European Union entered into a transition period of 11 months and, in June 2020, agreed to not extend the transition period beyond December 31, 2020. During this transition period, Brexit has involved a process of lengthy negotiations between the United Kingdom and EU member states to determine the future terms of the United Kingdom's relationship with the European Union. The transition agreement between the two parties means that the United Kingdom will abide by current regulatory and trading frameworks until December 31, 2020 pending the agreement of their future relationship.

Lack of clarity about future U.K. laws and regulations as the United Kingdom determines which EU rules and regulations to replace or replicate in the event of a withdrawal, including financial laws and regulations, tax and free trade agreements, intellectual property rights, supply chain logistics, environmental, health and safety laws and regulations, immigration laws and employment laws, could decrease foreign direct investment in the United Kingdom, increase costs, depress economic activity and restrict access to capital. In addition, if the United Kingdom and the European Union are unable to negotiate acceptable withdrawal terms or if other EU Member States pursue withdrawal, barrier-free access between the United Kingdom and other EU Member States or among the European Economic Area overall could be diminished or eliminated. The long-term effects of Brexit will depend on any agreements (or lack thereof) between the United Kingdom and

the European Union and, in particular, any arrangements for the United Kingdom to retain access to European Union markets either during a transitional period or more permanently.

Such a withdrawal from the European Union is unprecedented, and it is unclear how the United Kingdom's access to the European single market for goods, capital, services and labor within the European Union, or the European single market, and the wider commercial, legal and regulatory environment, will impact our U.K. operations. We may also face new regulatory costs and challenges that could have an adverse effect on our operations and development programs. For example, because the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety and efficacy of pharmaceutical products, clinical studies, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit could materially impact the future regulatory regime that applies to products and the approval of product candidates in the United Kingdom. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly harm our business.

Even prior to any change to the United Kingdom's relationship with the European Union, the announcement of Brexit created economic uncertainty surrounding the terms of Brexit, and its consequences could negatively impact our financial condition, results of operations and cash flows. Further, the United Kingdom's vote to exit the European Union could also result in similar referendums or votes in other European countries in which we conduct business. Given the lack of comparable precedent, it is unclear what financial, trade and legal implications the withdrawal of the United Kingdom from the European Union will have and how such withdrawal may affect us.

Cyber security risks and the failure to maintain the confidentiality, integrity, and availability of our computer hardware, software, and Internet applications and related tools and functions could result in harm to our business and/or subject us to costs, fines or lawsuits.

Our computer systems, as well as those of various third parties on which we rely, or may rely on in the future, including Sumitovant and its affiliates, our CROs and other contractors, consultants and law and accounting firms, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. We rely on sophisticated information technology systems and network infrastructure to operate and manage our business and rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. The risk of a security breach or disruption, particularly through cyber-attacks 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. Our business therefore depends on the continuous, effective, reliable, and secure operation of our computer hardware, software, networks, Internet servers, and related infrastructure. To the extent that our hardware or software malfunctions or access to our data by internal personnel or suppliers through the Internet is interrupted or compromised, it could result in a material disruption of our drug development programs and our business could suffer.

Although our computer and communications hardware is protected through physical and software safeguards, it is still vulnerable to system malfunction, computer viruses, malware and ransomware, and other cybersecurity threats such as phishing and social engineering attacks. These events could lead to the unauthorized access of our information technology systems and result in financial loss and the misappropriation or unauthorized disclosure of confidential information belonging to us, our employees, partners, or our suppliers. For example, the loss of nonclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. If our information technology systems are compromised, further development of our current or future product candidates could be delayed and we could be subject to fines, damages, litigation and enforcement actions, incur financial losses, suffer reputational damage, lose trade secrets or other confidential information, each of which could significantly harm our business.

If we fail to comply with applicable U.S. and foreign privacy and data protection laws and regulations, we may be subject to liabilities that adversely affect our business, operations and financial performance.

We are subject to federal and state laws and regulations requiring that we take measures to protect the privacy and security of certain information we gather and use in our business. For example, federal and state security breach notification laws, state health information privacy laws and federal and state consumer protection laws impose requirements regarding the collection, use, disclosure and storage of personal information. In addition, in June 2018, California enacted the California Consumer Privacy Act, or CCPA, which took effect on January 1, 2020. The CCPA gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that may increase data breach litigation. Although the CCPA includes exemptions for certain clinical trials data, and HIPAA protected health information, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. The CCPA has prompted a number of proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, increase our compliance costs and adversely affect our business.

We may also be subject to or affected by foreign laws and regulations, including regulatory guidance, governing the collection, use, disclosure, security, transfer and storage of personal data, such as information that we collect about patients and healthcare providers in connection with clinical trials and our other operations in the U.S. and abroad. The global legislative and regulatory landscape for privacy and data protection continues to evolve, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. For example, the EU has adopted the General Data Protection Regulation, or GDPR, which introduces strict requirements for processing personal data. The GDPR increases our compliance burden with respect to data protection, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and leverage information about them. The processing of sensitive personal data, such as information about health conditions, entails heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. In addition, the GDPR provides for breach reporting requirements, more robust regulatory enforcement and fines of up to the greater of 20 million euros or 4% of annual global revenue. While companies are afforded some flexibility in determining how to comply with the GDPR's various requirements, significant effort and expense are required to ensure continuing compliance with the GDPR. Moreover, the requirements under the GDPR and guidance issued by different EU member states may change periodically or may be modified, and such changes or modifications could have an adverse effect on our business operations if compliance becomes substantially costlier than under current requirements. It is also possible that each of these privacy laws may be interpreted and applied in a manner that is inconsistent with our practices. Further, Brexit has created uncertainty with regard to data protection regulation in the UK. In particular, it is unclear whether, post Brexit, the UK will enact data protection legislation equivalent to the GDPR and how data transfers to and from the United Kingdom will be regulated. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. In many jurisdictions, enforcement actions and consequences for noncompliance are rising. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, the effects of the COVID-19 pandemic on its operations and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies, including those disruptions that may be caused by the COVID-19 pandemic, may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in March 2020, the FDA announced its intention to temporarily postpone certain inspections of both foreign and domestic manufacturing facilities. In addition, between December 22, 2018 and ending on January 25, 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If temporary reductions in operations due to the COVID-19 pandemic or repeated or prolonged government shutdowns occur, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Fluctuations in insurance cost and availability could adversely affect our results of operations or our risk management profile.

We hold a number of insurance policies, including product liability insurance, directors' and officers' liability insurance, general liability insurance, property insurance and workers' compensation insurance and such policies contain customary conditions and exclusions. If the costs of maintaining adequate insurance coverage increase significantly in the future, our operating results could be materially adversely affected. Likewise, if any of our current insurance coverage should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers. Additionally, even if we maintain insurance coverage for a type of liability, a particular claim may not be covered if it is subject to a coverage exclusion or we do not otherwise meet the conditions for coverage. If we operate our business without insurance, or with inadequate insurance, we could be responsible for paying claims or judgments against us, which could adversely affect our results of operations or financial condition.

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

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, other pharmaceutical companies or others taking or otherwise coming into contact with our products. On occasion, large monetary judgments have been awarded in class action lawsuits where drugs have had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- significant costs to defend related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize our current or future product candidates, if approved;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased demand for our current or future product candidates, if approved; and
- loss of revenue.

The product liability insurance we currently carry, and any additional product liability insurance coverage we acquire in the future, may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for our product candidates, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the commercialization of our current or future product candidates, if approved.

Risks Related to Development, Regulatory Approval and Commercialization

Clinical trials are very expensive, time-consuming, difficult to design and implement, and involve uncertain outcomes.

Our product candidates are still in development and will require extensive clinical testing before we are prepared to submit an NDA, BLA or other similar application for regulatory approval. While we submitted our NDA for vibegron in December 2019, we cannot provide you any assurance that we will submit an NDA for regulatory approval for any of our other product candidates within our projected timeframes or that our NDA for vibegron or any other such applications will be approved by the relevant regulatory authorities. Clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, the FDA or other regulatory authorities may not agree with our proposed analysis plans for any clinical trials of our product candidates, and during any such review, may identify unexpected efficacy or safety concerns, which may delay the approval of an NDA or similar application. The FDA may also find that the benefits of our product candidates do not outweigh their risks in a manner sufficient to grant regulatory approval. The clinical trial process is also time-consuming and costly and relies on the collaboration with many CROs and clinical trial sites.

Failures can occur at any stage of clinical trials, and we could encounter problems that cause us to abandon or repeat clinical trials. In addition, results from clinical trials may require further evaluation, delaying the next stage of clinical development or submission of an NDA. Further, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical studies and initial clinical trials, and such product candidates may exhibit safety signals in later stage clinical trials that they did not exhibit in preclinical or earlier-stage clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in or the discontinuation of advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Likewise, the results of nonclinical testing or early clinical trials may not be predictive of the results of our planned development programs, and there can be no assurance that the results of studies conducted by collaborators or other third parties will be viewed favorably or are indicative of our own future trial results. In particular, our gene therapy product candidate, URO-902, is in early stages of development. The outcome of nonclinical testing and early clinical trials may not be predictive of the success of later stage clinical trials. The Phase 1b clinical trial conducted by ICI for URO-902 for the treatment of OAB and detrusor overactivity in women studied a small patient population, which makes it difficult to predict whether the favorable results observed in such clinical trial will be repeated in larger and more advanced clinical trials.

The commencement and completion of clinical trials may be delayed by several factors, including:

- impacts of the COVID-19 pandemic such as disruptions or delays to standard study monitoring practices, study drug shipments, biological pharmacokinetics sample shipments, data analysis and reporting of results due to changes in policies at various clinical sites, federal, state, local or foreign laws, rules and regulations, quarantines or other travel restrictions, prioritization of healthcare resources toward pandemic efforts, including diminished attention of physicians serving as our clinical trial investigators and reduced availability of site staff supporting the conduct of our clinical trials;
- failure to obtain regulatory approval to commence a trial;
- unforeseen safety issues;

- occurrence of serious adverse events in trials of the same class of agents conducted by other sponsors;
- lack of effectiveness during clinical trials;
- determination of dosing issues;
- inability to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- slower than expected rates of patient recruitment or failure to recruit suitable patients to participate in a trial;
- failure to add a sufficient number of clinical trial sites;
- unanticipated impact from changes in or modifications to protocols or clinical trial design;
- inability of trial participants to visit the study sites and continue with the studies and inability of the clinical investigators to see trial participants in a timely manner due to potential site closures;
- an institutional review board, or IRB, refusing to approve, suspending, or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- premature discontinuation of trial participants from clinical trials or missing data;
- failure to manufacture or release sufficient quantities of a product candidate or placebo, or failure to obtain sufficient quantities of active comparator medications for our clinical trials, if applicable, that in each case meet our quality standards, for use in clinical trials;
- inability to monitor patients adequately during or after treatment; or
- inappropriate unblinding of trial results.

Further, we, the FDA or other regulatory authority may suspend our clinical trials in an entire country at any time, or an IRB may suspend its clinical trial sites within any country, if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including cGMP regulations, that we are exposing participants to unacceptable health risks, or if the FDA or other regulatory authority, as the case may be, finds deficiencies in our IND or equivalent applications for other countries or the manner in which the clinical trials are conducted. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be harmed, and our ability to generate product revenue may be delayed. In addition, any delays in our clinical trials could increase our costs, cause a decline in our share price, slow down the approval process, and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may harm our business, financial condition and results of operations. 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.

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

In addition, prior to our acquisition of the rights to vibegron and URO-902, we had no involvement with or control over the nonclinical or clinical development of these product candidates. Additionally, pursuant to our collaboration agreement with Kyorin, who retains exclusive rights from Merck to develop and commercialize vibegron in Japan and certain other Asian territories, we may use supportive data generated by Kyorin in connection with seeking regulatory approval of vibegron in the territories in which we have rights to develop and commercialize vibegron. We are dependent on Merck, Kyorin and ICI having conducted such research and development in accordance with the applicable protocols and legal, regulatory and scientific standards, having accurately reported the results of all clinical trials and other research they conducted prior to our acquisition of the rights to our current product candidates, having correctly collected and interpreted the data from these trials and other research, and having supplied us with complete information, data sets and reports required to adequately demonstrate the results reported through the date of our acquisition of these assets. Problems related to predecessors could result in increased costs and delays in the development of our product candidates, which could adversely affect our ability to generate any future revenue from sales of our product candidates, if approved.

Our gene therapy product candidate, URO-902, is based on a novel technology and the regulatory landscape that governs gene therapy products is uncertain and may change, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval.

The use of gene therapy in the treatment of OAB is novel. There can be no assurance that we will not experience problems or delays with the assessment of the current drug supply and in the future with developing our product candidate and that such problems or delays will not cause unanticipated costs, or that any such development problems can be solved. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process, which may prevent us from completing our clinical studies or commercializing URO-902 on a timely or profitable basis, if at all. We expect that the supply of URO-902 that was transferred to us under the ICI license agreement will only be sufficient for us to complete our Phase 2a study. Any issues we experience in the future with respect to the manufacturing or availability of URO-902 could significantly delay our URO-902 development program and harm our business prospects.

In addition, the clinical trial requirements and the criteria used by the FDA and other foreign regulatory authorities to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of such product candidate. The regulatory approval process for novel product candidates such as URO-902 can be more expensive and take longer than for other, better known or more extensively studied product candidates. To date, only a limited number of gene therapies have received marketing authorization from the FDA or foreign regulatory authorities. Until August 2017, the FDA had never approved a gene therapy product. Since that time, the FDA has only approved a small number of gene therapy product candidates, including Kymriah by Novartis International AG, for pediatric and young adult patients with a form of acute lymphoblastic leukemia, Yescarta by Kite Pharma, Inc., for adult patients with certain forms of non-Hodgkin lymphoma, Luxturna by Spark Therapeutics, Inc. for patients with an inherited form of vision loss, and Zolgensma by AveXis, Inc. for pediatric patients with a form of spinal muscular atrophy. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for URO-902 in either the United States, or other major markets or how long it will take to commercialize URO-902, if approved. Approvals by foreign regulatory authorities may not be indicative of what the FDA may require for approval, and vice versa.

The FDA recently released a series of draft guidance documents regarding certain gene therapy product candidates, including gene therapies for rare diseases, and other clinical and manufacturing issues related to gene therapy product candidates. We cannot be certain when additional guidance will be released that could be relevant to, or have an impact on, our gene therapy product candidate or the duration or expense of any applicable regulatory review processes.

Regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future. The FDA has established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and has established the Cellular, Tissue and Gene Therapies Advisory Committee to advise the CBER in its review. In addition to the submission of an IND to the FDA before initiation of a clinical trial in the United States, certain human clinical trials for cell therapy products and gene therapy had historically been subject to review by the Recombinant DNA Advisory Committee, or the RAC, of the National Institutes of Health, or NIH, Office of Biotechnology Activities, or OBA, pursuant to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, or NIH Guidelines. On August 17, 2018, the NIH issued a notice in the Federal Register and issued a public statement proposing changes to the oversight framework for gene therapy trials, including changes to the applicable NIH Guidelines to modify the roles and responsibilities of the RAC with respect to human clinical trials of gene therapy products, and requesting public comment on its proposed modifications. During the public comment period, which closed October 16, 2018, the NIH has announced that it will no longer accept new human gene transfer protocols for review as a part of the protocol registration process or convene the RAC to review individual clinical protocols. These trials will remain subject to the FDA's oversight and other clinical trial regulations, and oversight at the local level will continue as set forth in the NIH Guidelines. Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. Even though we may not be required to submit a protocol for our gene therapy product candidates through the NIH for RAC review, we will still be subject to significant regulatory oversight by the FDA, and in addition to the government regulators, the applicable IBC and institutional review board, or IRB, of each institution at which we or our collaborators conduct clinical trials of our product candidates, or a central IRB if appropriate, would need to review and approve the proposed clinical trial. Similarly, foreign regulatory authorities may issue new guidelines concerning the development and marketing authorization for gene therapy products and require that we comply with these new guidelines.

The FDA, NIH and the European Medicines Agency, or EMA, have each expressed interest in further regulating biotechnology, including gene therapy and genetic testing. For example, the EMA advocates a risk-based approach to the development of a gene therapy product candidate. Agencies at both the federal and state level in the United States, as well as the U.S. congressional committees and other governments or governing agencies, have also expressed interest in further regulating the biotechnology industry. Such actions may delay or prevent development and, if approved, commercialization of URO-902.

These regulatory review committees and advisory groups and any new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional testing, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of URO-902 or lead to significant post-approval limitations or restrictions. As we advance our gene therapy product candidate, we will be required to consult with these regulatory and advisory groups, and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of URO-902. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations and prospects would be adversely affected.

Negative public opinion of gene therapy and increased regulatory scrutiny of gene therapy and genetic research may adversely impact public perception of our current and future product candidates.

Our gene therapy product candidate, URO-902, involves introducing genetic material into patients' cells. The clinical and commercial success of URO-902 and any future gene therapy product candidates will depend in part on public acceptance of the use of gene therapy and gene regulation for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that gene therapy and gene regulation are unsafe, unethical or immoral and, consequently, any gene therapy product candidates that we may develop may not gain the acceptance of the public or the medical community. Adverse public attitudes may adversely impact our ability to enroll patients in our clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of gene therapy product candidates that we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available.

More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of URO-902. For example, in 2003, clinical trials using early versions of murine gamma-retroviral vectors, which integrate with, and thereby alter, the host cell's DNA, have led to several well publicized adverse events, including reported cases of leukemia. Adverse events in our clinical trials, even if not ultimately attributable to our gene therapy product candidate, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of URO-902 or any future gene therapy product candidates, stricter labeling requirements for such product candidates if approved and a decrease in demand for any such product candidates. The risk of cancer remains a concern for gene therapy and we cannot assure that it will not occur in any of our planned or future clinical trials. In addition, there is the potential risk of delayed adverse events following exposure to gene therapy due to persistent biological activity of the genetic material or other components of products used to carry the genetic material. If any such adverse events occur, our clinical trials and, if approved, commercialization of URO-902 or any future product candidates could be halted or delayed, which would have a negative impact on our business and operations.

Reported data or other clinical development announcements by Kyorin or other third parties may adversely affect our clinical development plan.

Kyorin developed vibegron for the treatment of OAB in Japan and in September 2018, received marketing approval from Japan's Ministry of Health, Labour and Welfare for vibegron for the treatment of adults with OAB. In November 2018, Kyorin launched vibegron for the treatment of OAB in Japan. Previously, Kyorin reported positive results from its Phase 3 clinical trial in Japan for the treatment of OAB. If subsequent announcements by Kyorin regarding vibegron are unfavorable, or post-marketing data or Phase 4 clinical trials conducted by Kyorin are unfavorable or result in new safety signals in Japan during any such post-marketing or Phase 4 clinical trial, it could negatively impact our clinical development plans and potential approval for vibegron in the United States. Any unexpected measure by the Japanese regulatory agencies following approval of vibegron in Japan, including any measures due to unexpected post-marketing safety signals, will also affect the potential approval for vibegron in the United States. In addition, we face similar risks to the extent that third parties develop vibegron in other Asian territories.

The results of our clinical trials may not support our proposed claims for our product candidates, or regulatory approval at all.

Success in nonclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior nonclinical testing and clinical trials. Likewise, promising results in interim analyses or other preliminary analyses do not ensure that the clinical trial as a whole will be successful. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical trials, even after promising results in earlier nonclinical studies or clinical trials. These setbacks have been caused by, among other things, nonclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. The results of nonclinical studies and early 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 nonclinical and initial clinical trials. For example, we may not succeed in demonstrating that vibegron offers a differentiated profile compared to current OAB therapies, including the potential for broader efficacy claims if the FDA does not approve the inclusion of urgency data, rapid onset of action data, and a single, convenient once-daily and crushable dose in the label. A future failure of a clinical trial to meet its pre-specified endpoints would likely cause us to abandon a product candidate and may delay development of any other product candidates.

Although we submitted our NDA for vibegron in December 2019, any delay in, or termination of, our clinical trials will delay the submission of other similar applications with other relevant foreign regulatory authorities and, ultimately, our ability to commercialize vibegron and generate product revenue. Even if our clinical trials are completed as planned, we cannot be certain that their results will support these claims for differentiation or the effectiveness or safety of vibegron. The FDA has substantial discretion in the review and approval process and may disagree that our studies support the differentiated claims we propose. We cannot guarantee that we will obtain approval for the differentiated claims we propose, if at all. Any failure to support our claims for differentiation or obtain approval from the FDA for the differentiated claims we propose could adversely impact our ability to compete with other available therapies.

Interim, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or "top-line" data from our clinical trials, which is based on a preliminary analysis of then-available top-line data, and the results and related findings and conclusions are subject to change following a full analyses of all data related to the particular trial. For example, the top-line data analysis from our Phase 3 EMPOWUR study did not include full vital sign data, including blood pressure. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available. We may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our business in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, product candidate or our business. If the top-line data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, our business, operating results, prospects or financial condition may be harmed.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials on our current timelines, or at all, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. Enrollment in our clinical trials may be slower than we anticipate, leading to delays in our development timelines. For example, we may face difficulty enrolling or maintaining a sufficient number of patients in our clinical trials due to the effects of the COVID-19 pandemic or due to existing alternative treatments approved for the treatment of OAB as patients may decline to enroll or decide to withdraw from our clinical trials due to the risk of receiving placebo or the perceived risks of gene therapy as compared to more traditional treatment options. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, our ability to recruit clinical trial investigators with the appropriate competencies and experience, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites, the willingness of and ability for patients to visit clinical sites as a result of the COVID-19 pandemic, the eligibility criteria for the trial and the proportion of patients screened that meets those criteria, our ability to obtain and maintain patient consents, and the risk that patients enrolled in clinical trials will drop out of the trials before completion.

Furthermore, any negative results or new safety signals we or third parties may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in our clinical trials. Similarly, negative results reported by our competitors about their drug candidates may negatively affect patient recruitment in our clinical trials. Also, marketing authorization of competitors in this same class of drugs may impair our ability to enroll patients into our clinical trials, delaying or potentially preventing us from completing recruitment of one or more of our trials. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates, or could render further development impossible. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials, and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance, including their abilities to perform during the COVID-19 pandemic.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

Drug development is highly competitive and subject to rapid and significant technological advancements. For example, there are several large and small pharmaceutical companies focused on delivering therapeutics for OAB. Further, it is likely that additional drugs will become available in the future for the treatment of OAB and our other target indications.

We are aware of several companies that are working to develop drugs that would compete against vibegron and URO-902 for the treatment of OAB. For example, Velicept Therapeutics, Inc. is advancing solabegron, a beta-3 agonist initially developed by GlaxoSmithKline plc, as a twice-daily and once-daily formulation into Phase 2b clinical trials. In addition to solabegron, there are several other product candidates under development for the treatment of OAB. Taiho Pharmaceutical Co., Ltd., is developing TAC-302, a novel neurite outgrowth enhancer, currently in Phase 2 clinical trials in Japan. Dong-A ST Co., Ltd., is developing DA-8010, a novel anticholinergic, currently in a Phase 2 clinical trial in South Korea. Taris Biomedical LLC is developing TAR-302, an intravesicular drug-delivery system for trospium, an anticholinergic drug, currently in Phase 1b clinical trials. In addition, a number of companies are developing injectable neurotoxins (biosimilar onabotulinumtoxinA, abobotulinumtoxinA, and nivobotulinumtoxinA) for OAB, and Allergan has advanced a BOTOX-based sustained release gel (RTGel) for the treatment of OAB into Phase 2 clinical development.

We also face competition from other drugs and therapies currently approved for the treatment of OAB. Anticholinergic drugs have been the standard of pharmacologic care for OAB since the approval of flavoxate in 1970 and oxybutynin in 1975. Anticholinergics continue to account for the largest share of prescriptions written for the treatment of OAB in the United States. There are a number of widely prescribed anticholinergics approved for sale in the United States, including solifenacin, tolterodine and oxybutynin. Duchesnay USA has also signed an agreement with Apogepha to market Mictoryl® (propiverine hydrochloride) an anticholinergic and calcium antagonist in the United States once all FDA regulatory reviews have been completed. Propiverine hydrochloride was first approved in Germany in 1992 and is widely marketed outside of the United States. In addition, we will face competition from mirabegron (Myrbetriq, marketed by Astellas) and Allergan's BOTOX, each of which are FDA-approved therapies used for the treatment of OAB. Furthermore, we expect to face additional competition from generic products as the patent protection for competitor's products expire.

For example, we expect to face competition from a generic version of mirabegron following Myrbetriq's loss of marketing exclusivity, which we expect to occur in early 2024. Any such competition from generics could adversely affect the market size and opportunity for vibegron, and there can be no assurance that generic competition will not reach the market even sooner than we expect.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and in foreign countries. Many of our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a smaller number of our competitors. Competition may reduce the number and types of patients available to us to participate in clinical trials, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drugs that are more effective or less costly than any product candidate that we may develop.

Our ability to compete successfully will depend largely on our ability to:

- develop and commercialize therapies that are superior to other products in the market;
- demonstrate through our clinical trials that our product candidates are differentiated from existing and future therapies;
- attract qualified scientific, product development and commercial personnel;
- obtain patent or other proprietary protection for our technologies and product;
- obtain required regulatory approvals, including approvals to market our product candidates in ways that are differentiated from existing and future therapies;
- successfully manufacture and commercialize our product candidates, if approved;
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new therapies.

The availability of our competitors' products could limit the demand and the price we are able to charge for any product candidate we develop. The inability to compete with existing or subsequently introduced drugs would have an adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving FDA or other regulatory authority approval for or commercializing medicines before we do, which would have an adverse impact on our business and results of operations.

If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate product revenue will be materially impaired.

Activities associated with the development and commercialization of our product candidates, including the design, research, testing, manufacture, safety, efficacy, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale and distribution of our product candidates are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by similar regulatory authorities outside the United States. Failure to obtain marketing approval for, and thus commercialize our product candidates, could negatively impact our ability to generate any revenue from product sales.

We have not received approval from regulatory authorities to market any product candidate in any jurisdiction, and it is possible that none of our product candidates will ever obtain the appropriate regulatory approvals necessary for us to commence product sales. Neither we nor any current or future collaborator, is permitted to market any of our product candidates in the United States or any other jurisdiction until we receive regulatory approval of an NDA from the FDA or similar regulatory authorities outside of the United States.

The time required to obtain approval of an NDA by the FDA or similar regulatory authorities outside of the United States is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authority. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

Securing marketing approvals requires the submission of extensive nonclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the safety and efficacy of the product candidate for that indication. We expect to rely on third-party CROs and consultants to assist us in filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Delays or errors in the submission of applications for marketing approval or issues, including those related to gathering the appropriate data and the inspection process, may ultimately delay or affect our ability to obtain regulatory approval, commercialize our product candidates and generate product revenue.

Our product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events caused by our product candidates or that of adjuncts, could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials, and could result in the denial of regulatory approval. If an unacceptable frequency or severity of adverse events or new safety signals are reported in our clinical trials for our current or future product candidates, our ability to obtain regulatory approval for such product candidates may be negatively impacted. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. Any of these occurrences may harm our business, financial condition and prospects.

In particular, there have been several significant adverse side effects in gene therapy treatments in the past, including reported cases of leukemia in trials using earlier generation viral vectors. While URO-902 uses a plasmid vector, gene therapy is still a relatively new approach to disease treatment and additional adverse side effects could develop. There is the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biologic activity of the genetic material or other components of products used to carry the genetic material. Possible adverse side effects that may occur with treatment with gene therapy products include an immunologic reaction early after administration that could substantially limit the effectiveness of the treatment or represent safety risks for patients. Many times, side effects are only detectable after investigational products are tested in larger scale, pivotal clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. If any of our current or future product candidates are approved and then cause serious or unexpected side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or require a REMS (or equivalent outside the United States) to impose restrictions on its distribution or other risk management measures;
- we may be required to recall a product;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications, or require other labeling changes;

- we may be required to change the way the product is administered or to conduct additional clinical trials;
- we may be required to repeat a preclinical study or clinical trial or terminate a program, even if other studies or trials related to the program are ongoing or have been successfully completed;
- we could be sued and held liable for harm caused to patients;
- we could elect to discontinue the sale of our product;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our current or future product candidates, if approved.

The FDA may impose restrictions that limit the scope of any approved label and affect our market acceptance.

The FDA has substantial discretion in the product label review and approval process and may disagree that our studies support the differentiated claims we propose. Even if we are successful in demonstrating that our product offers a differentiated profile compared to current therapies, the FDA may restrict us from mentioning such claims in the U.S. label, which could potentially adversely affect product differentiation.

Further, the FDA could institute a “class” label for all products in the same market, which could require us to include warnings or other information on the label of our product that may not be specifically applicable to our product. For example, while the results of the ambulatory blood pressure study of vibegron demonstrated that vibegron does not have an effect on daytime systolic ambulatory blood pressure compared to placebo, the FDA may nevertheless require a safety warning for blood pressure for all drugs in this class. If the FDA were to institute such a “class” label requiring a blood pressure warning, it would adversely impact our ability to differentiate vibegron from mirabegron, which did not achieve the same positive blood pressure results as vibegron. If we are unable to differentiate our products and compete effectively, our ability to successfully commercialize vibegron and our other product candidates, our business, operating results, prospects or financial condition may be harmed.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and even if we obtain approval for a product candidate in one country or jurisdiction, we may never obtain approval for or commercialize it in any other jurisdiction, which would limit our ability to realize our full market potential.

Prior to obtaining approval to commercialize a product candidate in any jurisdiction, we or our collaborators must demonstrate with substantial evidence from well controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for a product candidate are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA does not ensure approval by regulatory authorities in any other country or jurisdiction outside the United States. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation, as well as additional administrative review periods. Prior to obtaining approval to commercialize a product candidate, we must demonstrate acceptable stability under various conducts and for commercially viable lengths of time. Given the timing for completion of validation, it is possible that we could experience delays in FDA approval and/or delays in the commercial launch of vibegron solely as a result of the time it takes to demonstrate acceptable stability. Seeking regulatory approval could result in difficulties and costs for us and require additional nonclinical studies or clinical trials, which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Even if we obtain regulatory approval for any of our current or future product candidates, we will still face extensive regulatory requirements and our product may face future development and regulatory difficulties.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment of registration and drug listing requirements, continued compliance with cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of drug product samples to physicians, recordkeeping and GCP requirements for any clinical trials that we conduct post-approval. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or the FDA or other regulatory authorities may require that contraindications, warnings or precautions-including in some cases, a boxed warning be included in the product labeling, which could limit sales of the product.

Regulatory authorities closely regulate the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Regulatory authorities impose stringent restrictions on manufacturers' communications regarding off-label use, and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act in the United States and other comparable regulations in foreign jurisdictions relating to the promotion of prescription drugs may lead to enforcement actions and investigations by the FDA, Department of Justice, State Attorneys General and other foreign regulatory agencies alleging violations of United States federal and state health care fraud and abuse laws, as well as state consumer protection laws and comparable laws in foreign jurisdictions.

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

- restrictions on the manufacture of such products;
- restrictions on the labeling or marketing of such products;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials, or any regulatory holds on our clinical trials;
- requirement of a REMS (or equivalent outside the United States);
- Warning or Untitled Letters;
- withdrawal of the products from the market;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of such products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

The FDA and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or to the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

For example, certain policies of the current U.S. administration may impact our business and industry. Namely, the current U.S. administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions, including the Executive Orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Even if any of our current or future product candidates receives marketing approval, it may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

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

- the efficacy and potential advantages compared to alternative treatments;
- the prevalence and severity of any side effects;
- the content of the approved product label;
- product label differentiation from other OAB therapies;
- the effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- utilization controls imposed by third-party payors, such as prior authorizations and step edits; and
- any restrictions on the use of our product, if approved, together with other medications.

Because we expect sales of vibegron, if approved, to generate substantially all of our product revenue for the foreseeable future, the failure of vibegron to find market acceptance would harm our business and could require us to seek additional financing.

If we are unable to establish sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we may not be successful in commercializing any of our current or future product candidate, if approved.

We are in the process of developing the infrastructure for the sales, marketing, and distribution of vibegron, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any product that may be approved, we must build our sales, distribution, marketing, managerial and other nontechnical capabilities or make arrangements with third parties to perform these services. To achieve commercial success for any product for which we obtain marketing approval, we will need a sales and marketing organization.

We expect to build a focused sales, distribution and marketing infrastructure to market our product candidate in the United States, if approved, which may also include utilizing an established infrastructure of a third party. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage geographically dispersed sales and marketing teams. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any product launch, which would adversely impact its commercialization. For example, if we recruit a sales force and establish marketing capabilities in anticipation of the commercial launch of our lead product candidate, vibegron, and such launch is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or attain adequate numbers of physicians to prescribe any drugs;
- the inability to negotiate with third party payors regarding reimbursement for our products; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our product candidates in certain markets overseas. Therefore, our future success will depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator’s strategic interest in our products, and that collaborator’s ability to successfully market and sell the product.

We intend to pursue collaborative arrangements regarding the sales and marketing of our product candidates, if approved, for certain markets overseas; however, we cannot assure you that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we depend on third parties for marketing and distribution, any revenue we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

If we are unable to build our own sales force or negotiate a collaborative relationship for the commercialization of our product candidates, we may be forced to delay potential commercialization or reduce the scope of our sales or marketing activities. If we elect to increase our expenditures to fund commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring any current or future product candidates to market or generate product revenue. We could enter into arrangements with collaborative partners at an earlier stage than otherwise would be ideal and we may be required to relinquish certain rights to any current or future product candidate or otherwise agree to terms unfavorable to us, any of which may have an adverse effect on our business, operating results and prospects.

If we are unable to establish adequate sales, marketing, and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing any current or future product candidate and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

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

If our product candidates are approved for commercialization outside of the United States, we intend to enter into agreements with third parties to market in certain jurisdictions in which we have exclusive commercialization rights. We expect that we will be subject to additional risks related to international operations or entering into international business relationships, including:

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- reduced or no protection of intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign reimbursement, pricing and insurance regimes;
- foreign taxes;
- any foreign partners or collaborators not fulfilling their respective regulatory reporting requirements and any foreign regulatory authorities taking actions with respect to such failures, which would be reportable to the FDA;
- any foreign partners or collaborators not informing us of any new post-marketing safety signals in a timely manner;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential noncompliance with the FCPA, the UK Bribery Act or similar antibribery and anticorruption laws in other jurisdictions;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

We have no prior experience in commercializing any product, and many biopharmaceutical companies have found the process of marketing their products in foreign countries to be very challenging.

Our current and future relationships with investigators, health care professionals, consultants, third-party payors, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient support, charitable organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws regulate the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our products for which we obtain marketing approval. Such laws include, among others:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;
- the federal false claims laws, including the False Claims Act, which imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or knowingly making or causing to be made, a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false or fraudulent statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which also impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information on health plans, health care clearing houses, and most providers and their business associates, defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners (covered manufacturers are required to submit reports to the government by the 90th day of each calendar year); and
- analogous state and foreign laws and regulations, such as state antikickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs or similar programs in other countries or jurisdictions, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Even the mere issuance of a subpoena or the fact of an investigation alone, regardless of the merit, may result in negative publicity,

a drop in our share price and other harm to our business, financial condition and results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

The Patient Protection and Affordable Care Act and future legislative changes may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any products for which we obtain marketing approval.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively the Affordable Care Act, was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the healthcare industry, and impose additional healthcare policy reforms. The law has continued the downward pressure on pharmaceutical pricing, especially under the Medicare program, and increased the industry's regulatory burdens and operating costs. Among the provisions of the Affordable Care Act of importance to our potential product candidates are the following:

- an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries under their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs in certain states;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

We cannot predict the full impact of the Affordable Care Act on pharmaceutical companies, as many of the reforms require the promulgation of detailed regulations implementing the statutory provisions, some of which have not yet fully occurred. For example, in January 2016, the Centers for Medicare and Medicaid Services issued a final rule regarding the Medicaid Drug Rebate Program, effective April 1, 2016, that, among other things, revises the manner in which the "average manufacturer price" is to be calculated by manufacturers participating in the program and implements certain amendments to the Medicaid rebate statute created under the Affordable Care Act. Further, there have been judicial and Congressional challenges to the Affordable Care Act, and President Trump has issued executive orders designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. We expect there will be additional challenges and amendments to the Affordable Care Act in the future. We continue to evaluate the effect that the Affordable Care Act and its possible repeal and replacement has on our business.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, then President Obama signed into law the Budget Control Act of 2011, which, among other things, included further reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2027 unless additional Congressional action is taken. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period in which the government may recover overpayments to providers from three to five years.

Further, there have been several recent United States Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the out-of-pocket cost of prescription drugs, reform government program reimbursement methodologies for drugs, increase manufacturer rebates for certain drugs in Medicare Part D and provide Medicare Part D plans more control over formularies. At the federal level, the Trump administration's recent budget proposals and executive orders propose additional drug price control measures that could be implemented through future rulemakings, pilot programs, or in future legislation, including, for example, measures to permit negotiations of prices under Medicare, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients.

Additionally , the President's proposed executive orders could enable states to import certain drugs from Canada if deemed safe and effective and consistent with current law, could allow a pilot to test international reference pricing in Medicare Part B, and could prohibit the payment of rebates to Part D Plans, Medicaid Managed Care Plans, and pharmacy benefit managers and instead permit such rebates to be provided at the point of sale to patients. The Trump administration also released a "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical 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, to encourage importation from other countries and bulk purchasing.

Moreover, the Drug Supply Chain Security Act, which was enacted in 2012 as part of the Food and Drug Administration Safety and Innovation Act, imposes new obligations on manufacturers of pharmaceutical products related to product tracking and tracing. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed, or what the impact of such changes on our business, if any, may be. In addition, increased scrutiny by the United States Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation, administrative or executive action. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidate or additional pricing pressures and make it more difficult for us to attain profitability.

Coverage and adequate reimbursement may not be available for our product candidate, which could make it difficult for us to sell it profitably, if approved.

Market acceptance and sales of any approved product that we develop will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, including government health administration authorities and private health insurers. For example, in November 2019, we commissioned a third-party market research study to assess how vibegron would be covered, if approved. The research firm interviewed representatives of payors, who are involved with, but not solely responsible for, coverage and reimbursement decisions. Such interviewees represented payors covering over 147 million U.S. commercial and Medicare Part D lives. The payor representatives interviewed expect that vibegron will likely be managed at a preferred or non-preferred branded tier, without restrictions by a majority of payors, allowing patients to make the choice of whether to pay a higher co-pay for a branded product or a lower co-pay for a generic. This market research study has no bearing on the payors, and any assumptions or interpretations based on the results of this study, may ultimately be inaccurate. The payor research does not warrant this management will take place at launch or prior to product review. There is no assurance that vibegron, if approved, would achieve adequate coverage and reimbursement levels, or that restrictions, including prior authorizations, will not be required by payors. There also is no assurance as to the timeline for obtaining any level of coverage for vibegron; coverage and reimbursement levels may not be achieved at or near launch.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Third-party payors decide which drugs they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop through approval will be made on a plan-by-plan basis. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and adequate reimbursement for the product. Additionally, a third-party payor's decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Each plan determines whether or not it will provide coverage for a drug, what amount it will pay the manufacturer for the drug, on what tier of its formulary the drug will be placed and whether to require step therapy. The position of a drug on a formulary generally determines the co-payment that a patient will need to make to obtain the drug and can strongly influence the adoption of a drug by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Further, from time to time, typically on an annual basis, payment rates are updated and revised by third-party payors. Such updates could impact the demand for our products, to the extent that patients

who are prescribed our products, if approved, are not separately reimbursed for the cost of the product. An example of payment updates is the Medicare program updates to physician payments, which is done on an annual basis. In the past, when the application of the formula resulted in lower payment, Congress has passed interim legislation to prevent the reductions. The Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, ended the use of the statutory formula and provided for a 0.5% annual increase in payment rates under the Medicare Physician Fee Schedule through 2019, but no annual update from 2020 through 2025. MACRA also introduced a merit based incentive bonus program for Medicare physicians beginning in 2019. At this time, it is unclear how the introduction of the merit based incentive program will impact overall physician reimbursement under the Medicare program. Any resulting decrease in payment under the merit based reimbursement system may adversely affect our business, financial condition and prospects. In addition, the Medicare physician fee schedule has been adapted by some private payors into their plan-specific physician payment schedule. We cannot predict how pending and future healthcare legislation will impact our business, and any changes in coverage and reimbursement that further restricts coverage of our product candidates or lowers reimbursement for procedures using our products could harm our business.

The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Even if we do obtain adequate levels of reimbursement, third-party payors, such as government or private healthcare insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for, products. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Increasingly, third-party payors are requiring that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices charged for products. We may also be required to conduct expensive pharmacoeconomic studies to justify the coverage and the amount of reimbursement for particular medications.

We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage or reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize any product candidates that we develop.

Additionally, there have been a number of legislative and regulatory proposals to change the healthcare system in the United States and in some foreign jurisdictions that could affect our ability to sell any future drugs profitably. There can be no assurance that any of our current or future product candidates, if approved, will be considered medically reasonable and necessary, that they will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available, or that reimbursement policies and practices in the United States and in foreign countries where our products are sold will not adversely affect our ability to sell our product candidates profitably, if they are approved for sale.

Risks Related to Our Dependence on Third Parties

We do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of our current and future product candidates.

We do not have the capabilities to conduct drug formulation or manufacturing and do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution or testing. Both Merck and ICI are obligated to reasonably assist us during a specified time-period with a technical transfer of the manufacturing process to us or our designee for production of vibegron and URO-902, respectively. Although Merck and ICI have already transferred the manufacturing process of vibegron and URO-902 to us, respectively, we may still need additional assistance if we experience any setbacks with the manufacturing on the larger scale. If Merck or ICI fail to fulfill their respective continuing obligations, as applicable, or if we require additional assistance after their obligation to assist us expires, our development of our product candidates could be significantly delayed or otherwise adversely affected.

Pursuant to our agreement with Merck, Merck provided us with a supply of vibegron, which we may only utilize in preclinical and clinical work. We expect that the vibegron drug substance transferred to us under our agreement with Merck will be sufficient for us to complete our currently planned clinical trials for the treatment of OAB in men with BPH and abdominal pain due to IBS. Additionally, supplies from our planned commercial manufacturers have become available and may be used in on-going and future clinical studies. We also expect that the URO-902 drug substance transferred to us under our license agreement with ICI will be sufficient for us to complete our Phase 2a study if materials continue to meet all specifications. We have recently contracted with a third-party vendor for the manufacturing of URO-902 for future preclinical studies and clinical trials, but the vendor has not yet manufactured any URO-902. We intend to contract with third-party vendors for commercialization if and when URO-902 receives marketing approval.

If we are unable to initiate or continue our relationship with one or more of these third-party manufacturers, we could experience delays in our development efforts and subsequent commercialization if any of our product candidates are approved, as we locate and qualify new or additional manufacturers.

Third-party vendors may be difficult to identify for process and formulation development and manufacturing for our product candidates due to special capabilities required, and they may not be able to meet our quality standards. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of our product candidates.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted prior to FDA approval of our NDA for vibegron. We are currently contracted with one contract manufacturer for our supply of vibegron. Such contract manufacturer has begun commercial manufacturing of vibegron. If the completion of commercial manufacturing is delayed, FDA approval of vibegron may be delayed as well. Any such delays in the approval process would impact our expected timing for the commercial launch for vibegron, if approved, and could harm our business, operating results and prospects.

Further, if we are not able to identify additional contract manufacturers for the commercial supply of vibegron and are not able to produce a sufficient commercial supply of vibegron to support its commercial launch, it may jeopardize our ability to successfully commercialize vibegron and generate any revenue. Also, if additional contract manufacturers are identified but are ultimately not approved by the FDA, we would have unnecessarily incurred additional manufacturing costs. This may be costly, and our investment would be lost if we could not utilize these additional contract manufacturers in the future.

In addition, we do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP requirements for manufacture of drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, they will not be able to supply us with sufficient product or secure or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If these facilities are unable to supply us with sufficient product or if FDA or comparable foreign regulatory authorities do not approve these facilities for the manufacture of our product candidates or if they withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates, if approved. Further, our reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including:

- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- failure to comply with applicable laws, regulations and standards, including cGMP and similar foreign standards;
- deficient or improper record-keeping;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell our product candidates, if approved, or any future product candidate in a timely fashion, in sufficient quantities or under acceptable terms;
- lack of and cost to identify and partner with qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or other regulatory sanctions related to the manufacture of another company’s products;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our products under specified storage conditions and in a timely manner.

In addition, the process for manufacturing gene therapy product candidates, such as URO-902, is more complex than those required for most chemical pharmaceuticals. Moreover, unlike chemical pharmaceuticals, characterization and testing of a gene therapy product candidate such as ours generally can be challenging. The complexity of these processes, as well as strict government standards for the manufacture and storage of gene therapy product candidates, subjects us to increased manufacturing risks for URO-902. If supply from a third-party manufacturing facility is interrupted, there could be a significant disruption in supply of URO-902.

Any of these events could lead to clinical trial delays, cost overruns, delay or failure to obtain regulatory approval or impact our ability to successfully commercialize our product candidates, if approved, as well as potential product liability litigation, product recalls or product withdrawals. Some of these events could be the basis for FDA or other regulatory authority action, including injunction, recall, seizure, or total or partial suspension of production of our product candidates.

We currently rely on a single supplier for the enzyme used to manufacture vibegron, and if we encounter any difficulties in procuring such enzyme, it may harm our business.

Currently, we rely on a single supplier, Codexis, for its proprietary enzyme that we use to manufacture vibegron, and we have agreed to purchase from Codexis all of our requirements for such enzyme for use in our clinical and commercial production of vibegron for the first six years after the first approval in either the United States, Europe or Canada. However, if following the first six years after such approval, if any, we are unable to continue to obtain the proprietary enzyme from Codexis, or make arrangements for an alternative source for such enzyme, we may encounter difficulties or delays in continuing to produce vibegron on a commercial scale.

Furthermore, there can be no assurance that Codexis will be able to meet our commercial needs, if any, for the enzyme used to manufacture vibegron. Any business or economic challenges our supplier faces, including compliance with regulatory authorities, whether in the ordinary course or not, could impair its ability to meet our needs. Accordingly, there is a risk that supplies of our product may be significantly delayed by or may become unavailable as a result of any issues affecting our supplier’s production of its proprietary enzyme.

Changes in methods of product manufacturing or formulation may result in additional costs or delays.

It is common that various aspects of the development program, such as manufacturing methods and formulation, are altered in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our products to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates and generate any revenue.

We are reliant on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We currently do not have the ability to independently conduct nonclinical studies that comply with Good Laboratory Practice, or GLP, requirements. We also do not currently have the ability to independently conduct any clinical trials. We rely exclusively on CROs and clinical trial sites, which need to comply with GCP, to ensure the proper and timely conduct of our clinical trials, and we have limited influence over their actual performance.

We rely upon CROs to monitor and manage data for our clinical programs, as well as for the execution of nonclinical studies. We control only certain aspects of our CROs’ activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with GLP and GCP regulations and guidelines enforced by the FDA, and are also required by the competent authorities of the member states of the European Economic Area and other comparable foreign regulatory authorities to comply with the International Council for Harmonization guidelines for any of our product candidates that are in nonclinical and clinical development. The regulatory authorities enforce GCP regulations through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we rely on CROs to conduct our GLP-compliant nonclinical studies and GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP nonclinical studies and GCP clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. If we or our CROs fail to comply with GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may reject our marketing applications or require us to perform additional clinical trials before approving our marketing applications. Accordingly, if we or our CROs fail to comply with these regulations or other applicable laws, regulations or standards, or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the relevant regulatory approval process. Failure by our CROs to properly execute study protocols in accordance with applicable law could also create product liability and healthcare regulatory risks for us as sponsors of those studies.

While we will have agreements governing their activities, our CROs are not our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs, including their ability to work during the COVID-19 pandemic. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities, which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret and intellectual property protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our (or their own) clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop could be harmed, our costs could increase and our ability to generate revenue could be delayed.

If our relationships with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms or in a timely manner. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can adversely impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future, including effects due to the COVID-19 pandemic, or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely, and will continue to rely, upon a combination of patents, trademarks, trade secret protection and confidentiality agreements with employees, consultants, collaborators, advisors and other third parties to protect the intellectual property related to our current and future drug development programs and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our current and any future product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our current and future drug development programs and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our current and any future product candidates in the United States or in other foreign countries. We may also inadvertently make statements to regulatory agencies during the regulatory approval process that may be inconsistent with positions that have been taken during prosecution of our patents, which may result in such patents being narrowed, invalidated or held unenforceable.

The patents and patent applications that we own or in-license may fail to result in issued patents with claims that protect our current and any future product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application, or be used to invalidate a patent. The examination process may require us to narrow our claims, which may limit the scope of patent protection that we may obtain. Even if patents do successfully issue based on our patent applications, and even if such patents cover vibegron and URO-902, uses of vibegron and URO-902, or other aspects related to vibegron, URO-902 or any future product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us in the future could deprive us of rights necessary for the successful commercialization of any of our current or future product candidates, if approved. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

If the patent applications we hold or have in-licensed with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for any of our current or future product candidates, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize, future drugs. Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Any such outcome could have an adverse effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being

issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act made a number of significant changes to United States patent laws. These include provisions that affect the way patent applications are prosecuted and challenged at the U.S. Patent and Trademark Office, or the USPTO, and may also affect patent litigation. The USPTO has developed and continues to develop new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act, subsequent rulemaking, and judicial interpretation of the Leahy-Smith Act and regulations will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business and financial condition.

The inventorship and ownership rights for patents that we own or in-license may be challenged by third parties. Such challenges could result in loss of exclusive rights to such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or require us to obtain a license from such third parties on commercially reasonable terms to secure exclusive rights. If any such challenges to inventorship or ownership were asserted, there is no assurance that a court would find in our favor or that, if we choose to seek a license, such license would be available to us on acceptable terms or at all.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain protection under the Hatch-Waxman Amendments by extending the patent term and obtaining data exclusivity for our product candidates, our business may be harmed.

Our commercial success will largely depend on our ability to obtain and maintain patent and other intellectual property in the United States and other countries with respect to our proprietary technology, product candidates and our target indications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after such candidates begin to be commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during development and the FDA regulatory review process, which is limited to the approved indication (or any additional indications approved during the period of extension). This extension is limited to only one patent that covers the approved product, the approved use of the product, or a method of manufacturing the product. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time-period or the scope of patent protection afforded could be less than we request.

If we are unable to extend the expiration date of our existing patents or obtain new patents with longer expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products following our patent expiration and launch their product earlier than might otherwise be the case.

The validity, scope and enforceability of any patents listed in the Orange Book that cover our product candidates can be challenged by third parties.

If one of our product candidates is approved by the FDA, one or more third parties may challenge the current patents, or patents that may issue in the future, within our portfolio, which could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or a finding of non-infringement. For example, if a third party files an Abbreviated New Drug Application, or ANDA, for a generic drug containing vibegron, and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA for the applicable approved product candidate; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third party's generic drug. A certification that the new drug will not infringe the Orange Book-listed patents for the applicable approved product candidate, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third party's ANDA will not be subject to the 30-month stay of FDA approval.

Moreover, a third party may challenge the current patents, or patents that may issue in the future, within our portfolio, which could result in the invalidation of some or all of the patents that might otherwise be eligible for listing in the Orange Book for one of our products. If a third party successfully challenges all of the patents that might otherwise be eligible for listing in the Orange Book for one of our products, we will not be entitled to the 30-month stay of FDA approval upon the filing of an ANDA for a generic drug containing, for example, vibegron, and relies in whole or in part on studies conducted by or for us. Also, if competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could limit our ability to prevent third parties from competing with our product candidates.

The validity, scope and enforceability of any patents that cover our biologic product candidates can be challenged by third parties.

For biologics, such as URO-902, the Biologics Price Competition and Innovation Act of 2009, or BPCIA provides a mechanism for one or more third parties to seek FDA approval to manufacture or sell a biosimilar or interchangeable versions of brand name biological products. Due to the large size and complexity of biological products, as compared to small molecules, a biosimilar must be "highly similar" to the reference product with "no clinically meaningful differences between the two." The BPCIA also provides reference product sponsors with 12 years of market exclusivity, but unlike the Hatch-Waxman Act, it does not require reference product sponsors to list patents in an Orange Book and does not include an automatic 30-month stay of FDA approval upon the timely filing of a lawsuit. The BPCIA, however, does require a formal pre-litigation process which includes the exchange of information between a biosimilar applicant and a reference biologic sponsor that includes the identification of relevant patents and each parties' basis for infringement and invalidity. After the exchange of this information, we may then initiate a lawsuit within 30 days to defend the patents identified in the exchange. If the biosimilar applicant successfully challenges the asserted patent claims it could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or result in a finding of non-infringement.

There is a risk that our current or any future gene therapy product candidate approved as a biological product under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated.

Moreover, the extent to which a biosimilar, once approved, will be substituted for our current or any future reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In addition, the biosimilar regulatory framework is still being implemented by the FDA and is subject to ongoing litigation disputes to interpret the laws and implementing regulations. Depending on actions by the United States Congress, the federal courts and the USPTO, the laws and regulations governing biosimilars could change in unpredictable ways that would weaken our ability to obtain or maintain approval as a biologic and 12 years of market exclusivity.

If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidate.

We have licensed certain intellectual property rights covering vibegron from Merck and URO-902 from ICI. If, for any reason, our license agreement with either of these licensors is terminated or we otherwise lose those rights, it could adversely affect our business. These license agreements impose, and any future collaboration agreements or license agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology, or having to negotiate new or reinstated licenses on less favorable terms, or enable a competitor to gain access to the licensed technology.

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

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

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights that are important or necessary to the development of our product candidates. It may be necessary for us to use the patented or proprietary technology of one or more third parties to commercialize our product candidates, including for example, use of a patented or proprietary DNA delivery-related technology to manufacture and commercialize URO-902. If we are unable to obtain licenses from such third parties when needed or on commercially reasonable terms, our ability to commercialize our product candidates, if approved, would likely be delayed.

The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we in-license, and any failure by us or our licensors to obtain, maintain, defend and enforce these rights could have an adverse effect on our business. In some cases we may not have control over the prosecution, maintenance or enforcement of the patents that we license, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents.

Third-party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate patents or other proprietary rights, may delay or prevent the development and commercialization of any of our current or future product candidates.

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter partes review and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization. For example, we have conducted searches for information in support of patent protection and otherwise evaluating the patent landscape for vibegron, and based on these searches and evaluations to date, we do not believe that there are valid patents that contain granted claims that could be asserted with respect to vibegron. However, we may be incorrect.

There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent was to be held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We cannot provide any assurances that third-party patents do not exist which might be enforced against our drugs or product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

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

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

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

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal

assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to detect or prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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 an adverse effect on the price of our common shares.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our shareholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

Changes in United States patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

The United States has recently enacted and implemented wide-ranging patent reform legislation. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the United States 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 licensed or that we might obtain in the future. Similarly, changes in patent law 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 have licensed or that we may obtain in the future.

The United States federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for its own benefit. The Bayh-Dole Act also provides federal agencies with “march-in rights”. March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive, or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the government may grant the license itself.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Filing, prosecuting and defending patents covering our current and any future product candidates throughout the world would be prohibitively expensive. 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 may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Many countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our 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.

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

Because we expect to rely on third parties to manufacture our current and any future product candidates, and we expect to continue to collaborate with third parties on the development of our current and any future product candidates, we must, at times, share trade secrets with them. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our collaboration or similar agreements. For example, under our collaboration agreement with Kyorin, we are obligated to share with Kyorin certain information relating to the development of vibegron including reports from nonclinical studies and clinical trials. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Further, adequate remedies may not exist in the event of unauthorized use or disclosure. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Policing unauthorized use of our or our licensors' intellectual property is difficult, expensive and time-consuming, and we may be unable to determine the extent of any unauthorized use. Moreover, enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

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

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and 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.

Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we or our licensors fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we and our licensors are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials and internal research programs, or in-license needed technology or other product candidates. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us commercialize our product candidates, if approved.

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

In addition to seeking patents for our current and any future product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Any trademarks we have obtained or may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. Once we select new trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our drugs, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks. If we attempt to enforce our trademarks and assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

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

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

- others may be able to make formulations or compositions that are the same as or similar to our product candidates, but that are not covered by the claims of the patents that we own;
- others may be able to make product that is similar to product candidates we intend to commercialize that is not covered by the patents that we exclusively licensed and have the right to enforce;
- we, our licensor or any collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own;
- we or our licensor might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;

- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; and
- we may not develop additional proprietary technologies that are patentable.

Risks Related to Ownership of Our Common Shares

An active public market for our common shares may not be sustained or be liquid enough for you to sell your shares quickly or at market price.

Prior to the listing of our common shares on Nasdaq in connection with our IPO in October 2018, no public market for our common shares existed. If an active trading market for our common shares is not sustained, you may not be able to sell your shares quickly or at or above the market price. An inactive market may also impair our ability to raise capital to continue to fund operations by selling common shares and may impair our ability to acquire other companies or technologies by using our common shares as consideration.

In addition, our common shares are held by a relatively small number of holders. Sumitovant owns approximately 74% of our outstanding common shares as of August 12, 2020. Moreover, our officers and directors have the right to acquire our common shares through any equity awards granted to them, subject to vesting conditions. Consequently, our common shares may have a limited public float and low average daily trading volume, which could affect a holder's ability to sell common shares or the price at which they can be sold.

In addition, future sales of substantial amounts of our common shares in the public market by those larger holders, or the perception that these sales could occur, may adversely impact the market price of our common shares and our shares could be difficult for a holder to liquidate.

The market price of our common shares has been and is likely to continue to be highly volatile.

The market price of our common shares has been and is likely to continue to be highly volatile and may be subject to wide fluctuations in response to a variety of factors, including the following:

- any delay in the commencement, enrollment and ultimate completion of our clinical trials;
- results of clinical trials of our product candidates or those of our competitors;
- any delay in future NDA filings or similar applications for vibegron and any other product candidates and any adverse development or perceived adverse development with respect to the FDA or other regulatory authority's review of our submitted NDA for vibegron or future NDA submissions or similar applications, as the case may be;
- failure to successfully develop and commercialize our current or any future product candidates;
- failure to maintain our relationships with Merck and ICI or to comply with the terms of our license agreements with these licensors;
- inability to obtain additional funding;
- regulatory or legal developments in the United States or other countries or jurisdictions applicable to our current and any future product candidates;
- adverse regulatory decisions;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for our current or any future product candidates, or the inability to do so at acceptable prices;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- changes in the market valuations of similar companies;
- market conditions in the pharmaceutical and biotechnology sectors and the issuance of new or changed securities analysts' reports or recommendations;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- variations in our financial results or the financial results of companies that are perceived to be similar to us;
- changes in estimates of financial results or investment recommendations by securities analysts;

- significant lawsuits, including patent or shareholder litigation and disputes or other developments relating to our proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- short sales of our common shares;
- sales of a substantial number of shares of our common shares in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares;
- sales or purchases of our common shares by our officers who are subject to beneficial ownership reporting requirements under Section 16 of the Exchange Act;
- sales of our common shares by us or our shareholders in the future;
- negative coverage in the media or analyst reports, whether accurate or not;
- issuance of subpoenas or investigative demands, or the public fact of an investigation by a government agency, whether meritorious or not;
- size of our public float;
- trading liquidity of our common shares;
- investors' general perception of our company and our business;
- general economic, industry and market conditions;
- global health concerns, such as the COVID-19 pandemic; and
- the other factors described in this "Risk Factors" section.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, as well as general economic, political, regulatory and market conditions and global health concerns, such as the COVID-19 pandemic, may negatively affect the market price of our common shares, regardless of our actual operating performance.

Volatility in our share price could subject us to securities class action litigation.

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

We are a "controlled company" within the meaning of the applicable Nasdaq listing rules and, as a result, qualify for exemptions from certain corporate governance requirements. As long as we rely on these exemptions, you will not have the same protections afforded to shareholders of companies that are subject to such requirements.

As of August 12, 2020, Sumitovant controls a majority of the voting power of our outstanding common shares. As a result, we are a "controlled company" within the meaning of applicable Nasdaq listing rules. Under these rules, a company is a "controlled company" if more than 50% of the voting power for the election of its directors is held by an individual, group or another company. In addition, Sumitovant has the right to designate two directors to our board of directors, each of whom have three votes on all matters presented to the board. Together, the Sumitovant designated directors can control all matters presented to our board of directors for a vote. For so long as the Sumitovant designated directors control all such matters presented, we will be a "controlled company" and may elect not to comply with certain corporate governance requirements in accordance with the Nasdaq listing rules, including the requirements:

- that a majority of the board of directors consists of independent directors;
- that we annually evaluate the performance of the nominating and corporate governance and compensation committees;
- that we have a nominating and corporate governance committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities; and
- that we have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibility.

We have elected to use certain of these exemptions, and we may continue to use all or some of these exemptions in the future. As a result, you may not have the same protections as those afforded to shareholders of companies that are not exempt from such Nasdaq corporate governance requirements.

Sumitovant owns a significant percentage of our common shares and is our primary lender and will be able to exert significant control over matters subject to shareholder approval.

Sumitovant beneficially owns approximately 74% of the voting power of our outstanding common shares as of August 12, 2020. This majority ownership position, in combination with it acting as our primary lender, gives Sumitovant the ability to exert substantial influence and control over us and our operations. For example, Sumitovant and its lone shareholder, Sumitomo Dainippon Pharma, will be able to control elections of directors, issuance of equity, including to our employees under equity incentive plans, amendments of our organizational documents, or approval of any merger, amalgamation, sale of assets or other major corporate transaction.

Sumitovant and Sumitomo Dainippon Pharma's ability to control such decisions is subject to the terms of the investor rights agreement we entered into with Sumitovant and Sumitomo Dainippon Pharma on December 27, 2019, or the Investor Rights Agreement. The Investor Rights Agreement provides that for so long as Sumitomo Dainippon Pharma or certain of its affiliates beneficially own between 50% and 90% of the total number of votes entitled to be cast at elections of our directors, any transaction that would increase Sumitomo Dainippon Pharma's beneficial ownership to over 80% of our outstanding voting power must be approved by the holders of a majority of our outstanding voting shares that are not beneficially owned by Sumitovant or its affiliates, or the Minority Shares. In addition the audit committee of our board of directors, or the Audit Committee, must approve any transaction that would increase Sumitomo Dainippon Pharma's beneficial ownership to over 76% of our outstanding voting power (if occurring prior to December 27, 2021) and any other related person transactions between Sumitomo Dainippon Pharma or certain of its affiliates and us, consistent with our existing related person transactions policy.

As a strategic investor, Sumitovant's interests may not always coincide with our corporate interests or the interests of other shareholders, and it may exercise its voting and other rights in a manner with which our other shareholders may not agree or that may not be in the best interests of our other shareholders. For example, Sumitovant may oppose a merger, amalgamation, sale of assets or other major corporate transaction involving one of its competitors for reasons independent of its ownership of our common shares. As a result of Sumitovant's voting power, it has the ability to block matters submitted for shareholder approval. Further, Sumitovant is a privately held company whose ownership and governance structure is not transparent to our other shareholders. There may be changes to the management or ownership of Sumitovant, or to Sumitovant's business model, that could impact Sumitovant's interests in a way that may not coincide with our corporate interests or the interests of other shareholders. Any such changes may diminish, or eliminate entirely, any benefits we expect to derive from our affiliation with Sumitovant. So long as Sumitovant or a successor to Sumitovant continues to own a significant amount of our equity, it will continue to be able to strongly influence and effectively control our decisions.

Sumitovant has the right to appoint two directors to our board of directors, each of whom has three votes.

Sumitovant is entitled to appoint two directors to our board of directors, each of whom has three votes on all matters presented to the board of directors. All other directors have one vote on all matters presented to the board of directors. While the directors appointed by Sumitovant are obligated to act in accordance with their fiduciary duty, they may have equity or other interests in Sumitovant and, accordingly, their interests may be aligned with Sumitovant's interests, which may not always coincide with our corporate interests or the interests of our other shareholders. The two directors appointed by Sumitovant and who currently serve on our board of directors, acting together, are able to determine the outcome of all matters presented to the board of directors.

Any shareholder or group of shareholders who own a majority of our Minority Shares can control the approval of certain transactions with Sumitovant and the elections of our independent directors.

Pursuant to the Investor Rights Agreement, for so long as Sumitomo Dainippon Pharma or certain of its affiliates beneficially own between 50% and 90% of the total number of votes entitled to be cast at elections of our directors, the holders of a majority of our Minority Shares, must approve any of the following actions before they can be taken:

- removal of any of our independent directors who comprise our Audit Committee;
- removal of Mr. Pierre Legault as our lead independent director; and
- any transaction that would increase Sumitomo Dainippon Pharma's beneficial ownership to over 80% of our outstanding voting power.

In addition, during the same period, the Investor Rights Agreement requires Sumitovant to vote its common shares in connection with the election of our independent directors in direct proportion to how the Minority Shares are voted.

As a result, any investor or group of investors who acquire a majority of our Minority Shares will have the right to control the election and terms of our independent directors and the approval of any transactions that would increase Sumitomo Dainippon Pharma's beneficial ownership above 80%. The interests of the holders of the majority of the Minority Shares may not always coincide with our corporate interests or the interests of our other shareholders, and such holder may exercise their voting and other rights in a manner with which our other shareholders may not agree or that may not be in the best interests of our other shareholders. For example, such holders of a majority of the Minority Shares could refuse to approve a covered transaction with Sumitomo Dainippon Pharma, even if our board of directors and the Audit Committee has approved such transaction, or block the removal of an independent director serving on our Audit Committee, even if the remainder of our shareholders desire to remove such director.

If any investor or group of investors acquire a majority of our Minority Shares, our other shareholders may not have access to information about such investors beyond any information such investors would be required to file with the SEC.

Our organizational and ownership structure may create significant conflicts of interests.

Our organizational and ownership structure involves a number of relationships that may give rise to certain conflicts of interest between us and holders of our Minority Shares, on the one hand, and Sumitovant and its sole shareholder, Sumitomo Dainippon Pharma, on the other hand. Certain of our directors have indirect equity interests in Sumitovant and, accordingly, their interests may be aligned with Sumitovant's interests, which may not always coincide with our corporate interests or the interests of our other shareholders. Further, our other shareholders may not have access to such information regarding our directors' equity interest in Sumitovant, Sumitomo Dainippon Pharma or their respective affiliates, which may change at any time through acquisition, disposition, dilution, or otherwise. Any change in our directors' equity interest in Sumitovant or Sumitomo Dainippon Pharma could impact the interests of those holders.

We are party to various related party agreements with Sumitovant and its affiliates, including the Sumitomo Loan Agreement, the Investor Rights Agreement, the Information Sharing Agreement, and the Market Access Services Agreement, and we may enter into other related party agreements with Sumitovant or its affiliates in the future. These entities and their shareholders, including certain of our directors and employees, may have interests which differ from our interests or those of the holders of our Minority Shares. Any material transaction between us and Sumitovant or its affiliates is subject to our related party transaction policy, which requires prior approval of such transaction by our audit committee. Because Sumitomo Dainippon Pharma beneficially owns more than 10% of the voting interests of RSL, Sumitomo Dainippon Pharma is considered a "principal owner" of RSL under applicable accounting standards. For so long as Sumitomo Dainippon Pharma maintains a 10% or more ownership stake in RSL, transactions between us and RSL will be deemed related party transactions. The Investor Rights Agreement also requires that any related person transactions between us and Sumitomo Dainippon Pharma or its affiliates must be approved by the Audit Committee, consistent with our related person transactions policy, for so long as Sumitomo Dainippon Pharma or certain of its affiliates beneficially own between 50% and 90% of the total number of votes entitled to be cast at elections of our directors.

To the extent we fail to appropriately deal with any such conflicts of interests, it could negatively impact our reputation and ability to raise additional funds and the willingness of counterparties to do business with us, all of which could have an adverse effect on our business, financial condition, results of operations, and cash flows.

The Sumitomo Transaction may cause disruptions that could have an adverse effect on our business and stock price.

The Sumitomo Transaction closed on December 27, 2019. Accordingly, Sumitovant now controls a majority of the voting power of our outstanding common shares. A number of factors could adversely affect our business or our stock price following the closing of the Sumitomo Transaction as we begin working with Sumitovant and undergo certain transitions following the closing, including:

- Sumitovant now controls certain matters requiring our shareholders' approval, including the election of non-independent directors and approval of transactions that are not related person transactions.
- Sumitovant may implement changes to our business or take other corporate actions that our other shareholders may not view as beneficial.
- The anticipated benefits of our affiliation with Sumitomo Dainippon Pharma may not occur or may occur in a less pronounced way than currently expected.
- The vesting of equity awards under the 2017 Plan accelerated upon the closing of the Sumitomo Transaction in accordance with its terms, which could adversely affect the market price of our common shares in the event that the holders of those equity awards elect to exercise their vested awards and sell the underlying common shares.
- The change in ownership of a majority of our outstanding common shares creates uncertainty for our employees, which could make it difficult to attract and retain qualified management and commercial, scientific and clinical personnel.
- In connection with the closing of the Sumitomo Transaction and the Sumitomo Loan Agreement, we agreed to abide by certain covenants, and the restrictions imposed by these covenants on our operations could impair our management's ability to respond to changing circumstances and exploit business opportunities that may arise in the future.

- The Sumitomo Transaction may increase the risk of litigation, which could distract management and negatively impact our business.
- We are now party to the Sumitomo Loan Agreement, which restricts us from taking certain actions without the consent of Sumitomo Dainippon Pharma, thereby giving Sumitomo Dainippon Pharma and Sumitovant additional control over our business.
- While Sumitomo Dainippon Pharma or Sumitovant also owns or is the majority shareholder of certain business service providers, we may not realize the benefits of this broader commercial network and may not enter into arrangements with these other providers.

In addition to these risks, the Sumitomo Transaction may result in unanticipated risks or other unintended consequences that could have an adverse effect on our business and stock price.

If securities or industry analysts cease to publish research or reports about our business, or publish negative reports about our business, our share price and trading volume could decline.

The trading market for our common shares depends, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If our financial performance fails to meet analyst estimates or one or more of the analysts who cover us downgrade our common shares or change their opinion of our common shares, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

If we fail to meet the listing standards of Nasdaq, our common shares may be delisted, which could have a material adverse effect on the liquidity of our common shares.

Our common shares are currently listed on Nasdaq. The Nasdaq Stock Market LLC has requirements that a company must meet in order to remain listed on Nasdaq. For example, we are required to maintain minimum levels of shareholders' equity, market values of our common shares, or bid prices. We are also required to meet certain minimum corporate governance requirements, including related to a majority independent board of directors and independent board committees, although we are exempt from many of these requirements because we are a controlled company. Under Nasdaq rules, even though we are a controlled company, we are not exempt from the requirement that we have three independent members of our Audit Committee, however.

If we are unable to meet applicable Nasdaq listing requirements in the future, including following any applicable cure period, our common shares could be delisted. If our common shares were delisted, the liquidity of our common shares would be materially adversely affected and the market price of our common shares could decrease.

We do not anticipate paying any cash dividends on our common shares in the foreseeable future.

We have never declared or paid any cash dividends on our common shares. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Additionally, we are subject to Bermuda legal constraints that may affect our ability to pay dividends on our common shares and make other payments. In addition, the terms of our Sumitomo Loan Agreement restrict our ability to pay dividends to limited circumstances. As a result, investors in our common shares may only receive a return if the market price of our common shares increases.

Future sales of our common shares may depress our share price.

Sales of a substantial number of our common shares in the public market, or the perception by investors that our shareholders intend to sell substantial amounts of our common shares in the public market, could depress the market price of our common shares even if our business is doing well. A decrease in our share price could in turn impair our ability to raise capital through the sale of additional equity securities.

All of the common shares sold in our IPO, as well as shares issued upon the exercise of options granted to persons other than our officers and directors and shares held by our non-affiliated shareholders, are freely transferable without restrictions or further registration under the Securities Act. If our major shareholders, including Sumitovant, or any of our executive officers or directors were to sell a substantial portion of our common shares, or if the market perceived that Sumitovant or any of our executive officers or directors intends to sell our common shares, it could negatively affect our common share price and could cause our share price to fall.

As of June 30, 2020, there were an aggregate of 6,624,189 common shares subject to outstanding options, stock appreciation rights, and restricted stock units. We have filed a registration statement on Form S-8 under the Securities Act to register the total number of our common shares that may be issued under our equity incentive plans, including these outstanding options, stock appreciation rights, restricted stock units and any equity awards we may grant in the future. Accordingly, these shares may be freely sold in the public market upon issuance as permitted by any applicable vesting requirements, subject to the contractual restrictions described above. Sales of these common shares may have an adverse effect on the trading price of our common shares. In addition, in the future we may issue common shares or other securities if we need to raise additional capital. We have filed a registration statement on Form S-3 under the Securities Act to register the offer and sale of up to an aggregate of $200.0 million of our securities, which includes $50.0 million of our common shares under our "at-the-market" equity offering program. As of August 12, 2020, we have not sold any common shares pursuant to this "at-the-market" equity offering program. The number of our new common shares issued in connection with raising additional capital could constitute a material portion of our then outstanding common shares, and the issuance of our common shares in an equity offering, or the perception that such sales may occur, could have the effect of depressing the market price of our common shares.

We have incurred, and will continue to incur, increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance with our public company responsibilities and corporate governance practices.

As a public company, and particularly after we are no longer an "emerging growth company" and no longer qualify as a "non-accelerated filer," we will incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002, or the Sarbanes Oxley Act, 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 public companies. Our management and other personnel will need to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For as long as we are an emerging growth company and a non-accelerated filer, we will not be required to comply with certain requirements applicable to other public companies, including an auditor attestation of the effectiveness of our internal control over financial reporting, and may be permitted to provide reduced disclosures under applicable SEC rules after we no long qualify as an emerging growth company or a non-accelerated filer as long as we then qualify as a smaller reporting company under applicable SEC rules. Our legal and financial compliance costs will increase once we are no longer able to benefit from the exemptions and reduced disclosure requirements currently available to us as an emerging growth company and non-accelerated filer. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs.

As a result of becoming a public company, we are obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common shares.

We are required, pursuant to Section 404 of the Sarbanes Oxley Act, or Section 404, to furnish an annual report by management on, among other things, the effectiveness of our internal controls over financial reporting as of the end of our fiscal year. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal controls over financial reporting. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting until our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company, as defined in the JOBS Act, or such time as we no longer qualify as a non-accelerated filer, whichever occurs later. At such time as we are required to obtain an auditor attestation of our internal control over financial reporting, if we then have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered public accounting firm. We are required to disclose significant changes made in our internal controls procedures on a quarterly basis.

We have completed the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluations needed to comply with Section 404. Our compliance with Section 404 has required us to incur substantial legal, accounting and other compliance expense and expend significant management efforts. We currently do not have an internal audit group, but we have engaged consultants with appropriate public company experience and technical accounting knowledge to assist in compiling the system and process documentation necessary to perform the evaluations needed to comply with Section 404.

During the evaluation and testing process of our internal controls, if we identify one or more material weaknesses in our internal controls over financial reporting, we will be unable to assert that our internal controls over financial reporting are effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain effective internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common shares could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also negatively impact our ability to access to the capital markets.

In addition, effective disclosure controls and procedures enable us to make timely and accurate disclosure of financial and non-financial information that we are required to disclose. As a public company, if our disclosure controls and procedures are ineffective, we may be unable to report our financial results or make other disclosures accurately on a timely basis, which could cause our reported financial results or other disclosures to be materially misstated and result in the loss of investor confidence and cause the market price of our common shares to decline.

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

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including exemption from compliance with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earlier of (1) the date (a) that is March 31, 2024, (b) on which we have total annual gross revenue of at least $1.07 billion or (c) on which we are deemed to be a large accelerated filer, which means the market value of our common shares that are held by non-affiliates exceeds $700 million as of the prior September 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the

prior three-year period. In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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

We cannot predict if investors will find our common shares less attractive because we may rely on these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and our share price may be more volatile.

We are a Bermuda company and it may be difficult for shareholders to enforce judgments against us or our directors and executive officers.

We are a Bermuda exempted company. As a result, the rights of our shareholders are governed by Bermuda law and our memorandum of association and bye-laws. The rights of shareholders under Bermuda law may differ from the rights of shareholders of companies incorporated in another jurisdiction. It may be difficult for investors to enforce in the U.S. judgments obtained in U.S. courts against us based on the civil liability provisions of the U.S. securities laws. As we are incorporated under the laws of Bermuda and all or a substantial portion of our assets are located outside the United States, a shareholder may need to effect service of process upon us in Bermuda. There is no treaty in force between the United States and Bermuda providing for the reciprocal recognition and enforcement of judgments in civil and commercial matters. As a result, whether a U.S. judgment would be enforceable in Bermuda against us or our directors and officers depends on whether the U.S. court that entered the judgment is recognized by a Bermuda court as having jurisdiction over us or our directors and officers, as determined by reference to Bermuda conflict of law rules. The courts of Bermuda would recognize as a valid judgment, a final and conclusive judgment *in personam* obtained in a U.S. court pursuant to which a sum of money is payable (other than a sum of money payable in respect of multiple damages, taxes or other charges of a like nature or in respect of a fine or other penalty). The courts of Bermuda would give a judgment based on such a U.S. judgment as long as (1) the U.S. court had proper jurisdiction over the parties subject to the judgment; (2) the U.S. court did not contravene the rules of natural justice of Bermuda; (3) the U.S. judgment was not obtained by fraud; (4) the enforcement of the U.S. judgment would not be contrary to the public policy of Bermuda; (5) no new admissible evidence relevant to the action is submitted prior to the rendering of the judgment by the courts of Bermuda; (6) there is due compliance with the correct procedures under the laws of Bermuda; and (7) the U.S. judgment is not inconsistent with any judgment of the courts of Bermuda in respect of the same matter.

In addition, and irrespective of jurisdictional issues, the Bermuda courts will not enforce a U.S. federal securities law that is either penal or contrary to Bermuda public policy. We have been advised that an action brought pursuant to a public or penal law, the purpose of which is the enforcement of a sanction, power or right at the instance of the state in its sovereign capacity, is unlikely to be entertained by a Bermuda court. Certain remedies available under the laws of U.S. jurisdictions, including certain remedies under U.S. federal securities laws, would not be available under Bermuda law or enforceable in a Bermuda court, as they are likely to be contrary to Bermuda public policy. Further, it may not be possible to pursue direct claims in Bermuda against us or our directors and officers for alleged violations of U.S. federal securities laws because these laws are unlikely to have extraterritorial effect and do not have force of law in Bermuda. A Bermuda court may, however, impose civil liability on us or our directors and officers if the facts alleged and proved in the Bermuda proceedings constitute or give rise to a cause of action under the applicable governing law, not being a foreign public, penal or revenue law.

Bermuda law differs from the laws in effect in the United States and may afford less protection to our shareholders.

We are incorporated under the laws of Bermuda. As a result, our corporate affairs are governed by the Bermuda Companies Act 1981, as amended, or the Companies Act, which differs in some material respects from laws typically applicable to U.S. corporations and shareholders, including the provisions relating to interested directors, amalgamations, mergers and acquisitions, takeovers, shareholder lawsuits and indemnification of directors. Generally, the duties of directors and officers of a Bermuda company are owed to the company only. Shareholders of Bermuda companies typically do not have rights to take action against directors or officers of the company and may only do so in limited circumstances. Shareholder class actions are not available under Bermuda law. The circumstances in which shareholder derivative actions may be available under Bermuda law are substantially more proscribed and less clear than they would be to shareholders of U.S. corporations. The Bermuda courts, however, would ordinarily be expected to permit a shareholder to commence an action in the name of a company to remedy a wrong to the company where the act complained of is alleged to be beyond the corporate power of the company or illegal, or would result in the violation of the company's memorandum of association or bye-laws. Furthermore, consideration would be given by a Bermuda court to acts that are alleged to constitute a fraud against the minority shareholders or, for instance, where an act requires the approval of a greater percentage of the company's shareholders than those who actually approved it.

When the affairs of a company are being conducted in a manner that is oppressive or prejudicial to the interests of some shareholders, one or more shareholders may apply to the Supreme Court of Bermuda, which may make such order as it sees fit, including an order regulating the conduct of the company's affairs in the future or ordering the purchase of the shares of any shareholders by other shareholders or by the company. Additionally, under our bye-laws and as permitted by Bermuda law, each shareholder has waived any claim or right of action against our directors or officers for any action taken by directors or officers in the performance of their duties, except for actions involving fraud or dishonesty. In addition, the rights of our shareholders and the fiduciary responsibilities of our directors under Bermuda law are not as clearly established as under statutes or judicial precedent in existence in jurisdictions in the United States, particularly the State of Delaware. Therefore, our shareholders may have more difficulty protecting their interests than would shareholders of a corporation incorporated in a jurisdiction within the United States.

There are regulatory limitations on the ownership and transfer of our common shares.

Common shares may be offered or sold in Bermuda only in compliance with the provisions of the Companies Act and the Bermuda Investment Business Act 2003, which regulates the sale of securities in Bermuda. In addition, the Bermuda Monetary Authority must approve all issues and transfers of shares of a Bermuda exempted company. However, the Bermuda Monetary Authority has, pursuant to its statement of June 1, 2005, given its general permission under the Exchange Control Act 1972 and related regulations for the issue and free transfer of our common shares to and among persons who are non-residents of Bermuda for exchange control purposes as long as the shares are listed on an appointed stock exchange, which includes Nasdaq. Additionally, we have sought and have obtained a specific permission from the Bermuda Monetary Authority for the issue and transfer of our common shares up to the amount of our authorized capital from time to time, and options, warrants, depository receipts, rights, loan notes, debt instruments and our other securities to persons resident and non-resident for exchange control purposes with the need for prior approval of such issue or transfer. The general permission or the specific permission would cease to apply if we were to cease to be listed on Nasdaq or another appointed stock exchange.

Legislation enacted in Bermuda in response to the European Union's review of harmful tax competition could be harmful to our business.

During 2017, the European Union Economic and Financial Affairs Council, or ECOFIN, released a list of non-cooperative jurisdictions for tax purposes. The stated aim of this list, and accompanying report, was to promote good governance worldwide in order to maximize efforts to prevent tax fraud and tax evasion. In an effort to remain off this list, Bermuda committed to address concerns relating to economic substance by December 31, 2018. In accordance with that commitment, Bermuda enacted legislation that requires certain entities in Bermuda engaged in "relevant activities" to maintain a substantial economic presence in Bermuda and to satisfy economic substance requirements. In June 2019, Bermuda exempted entities which are resident for tax purposes outside of Bermuda (and which are not resident in a jurisdiction listed by the EU as non-cooperative for tax purposes) from satisfying these economic substance requirements. The Company would be exempt as it is regarded as resident in the U.K. for tax purposes.

To the extent the Company ceases to be exempt from the economic substance requirements and is required to increase its substance in Bermuda to satisfy such requirements, it could result in additional costs that could adversely affect the Company's financial condition or results of operations. If the Company were required to satisfy economic substance requirements in Bermuda but failed to do so, it could face automatic disclosure to competent authorities in the EU of the information filed by the Company with the Bermuda Registrar of Companies in connection with the economic substance requirements and may also face financial penalties, restriction or regulation of our business activities and/or may be struck off as a registered entity in Bermuda.

Our amended and restated bye-laws enable our board of directors to issue preference shares, which may discourage a change of control.

Our amended and restated bye-laws contain provisions that enable our board of directors to determine the powers, preferences and rights of our preference shares and to issue the preference shares without shareholder approval.

This could discourage, delay or prevent a transaction involving a change in control of our company and may prevent our shareholders from receiving the benefit from any premium to the market price of our common shares offered by a bidder in a takeover context. Even in the absence of a takeover attempt, the existence of this provision may adversely affect the prevailing market price of our common shares if it is viewed as discouraging takeover attempts in the future.

We may become subject to unanticipated tax liabilities and higher effective tax rates.

We are incorporated under the laws of Bermuda, where we are not subject to any income or withholding taxes. We are centrally managed and controlled in the United Kingdom, and, under current U.K. tax law, a company which is centrally managed and controlled in the United Kingdom is regarded as resident in the United Kingdom for taxation purposes. Accordingly, we expect to be subject to U.K. taxation on our income and gains and subject to U.K.'s controlled foreign company rules, except where an exemption applies. We may be treated as a dual resident company for U.K. tax purposes. As a result, our right to claim certain reliefs from U.K. tax may be restricted, and changes in law or practice in the United Kingdom could result in the imposition of further restrictions on our right to claim U.K. tax reliefs. We may also become subject to income, withholding or other taxes in certain jurisdictions by reason of our activities and operations, and it is also possible that taxing authorities in any such jurisdictions could assert that we are subject to greater taxation than we currently anticipate. Any such additional tax liability could adversely affect our results of operations.

The intended tax effects of our corporate structure and intercompany arrangements depend on the application of the tax laws of various jurisdictions and on how we operate our business.

We and Sumitovant, our majority shareholder, are incorporated under the laws of Bermuda. We currently have subsidiaries in the United Kingdom, Switzerland and the United States. If we succeed in growing our business, we expect to conduct increased operations through our subsidiaries in various countries and tax jurisdictions, in part through intercompany service agreements between us and our subsidiaries. In that case, our corporate structure and intercompany transactions, including the manner in which we develop and use our intellectual property, will be organized so that we can achieve our business objectives in a tax-efficient manner and in compliance with applicable transfer pricing rules and regulations. If two or more affiliated companies are located in different countries or tax jurisdictions, the tax laws and regulations of each country generally will require that transfer prices be the same as those between unrelated companies dealing at arm's length and that appropriate documentation be maintained to support the transfer prices. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable taxing authorities.

Significant judgment is required in evaluating our tax positions and determining our provision for income taxes. During the ordinary course of business, there are many transactions and calculations for which the ultimate tax determination is uncertain. For example, our effective tax rates could be adversely affected by changes in foreign currency exchange rates or by changes in the relevant tax, accounting and other laws, regulations, principles and interpretations. In addition, our effective tax rate and the availability of any tax holidays could be adversely affected if we do not obtain favorable tax rulings from certain taxing authorities. As we intend to operate in numerous countries and taxing jurisdictions, the application of tax laws can be subject to diverging and sometimes conflicting interpretations by taxing authorities of these jurisdictions. It is not uncommon for taxing authorities in different countries to have conflicting views, for instance, with respect to, among other things, the manner in which the arm's length standard is applied for transfer pricing purposes, or with respect to the valuation of intellectual property.

In addition, tax laws are dynamic and subject to change as new laws are passed and new interpretations of the law are issued or applied. We continue to assess the impact of such changes in tax laws and interpretations on our business and may determine that changes to our structure, practice, tax positions or the manner in which we conduct our business are necessary in light of such changes and developments in the tax laws of the jurisdictions in which we operate. Such changes may nevertheless be ineffective in avoiding an increase in our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

If taxing authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arm's length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, potentially resulting in double taxation. If taxing authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

Changes in our effective tax rate may reduce our net income in future periods.

Our tax position could be adversely impacted by changes in tax rates, tax laws, tax practice, tax treaties or tax regulations or changes in the interpretation thereof by the taxing authorities in Europe (including the United Kingdom and Switzerland), the United States, Bermuda and other jurisdictions as well as being affected by certain changes currently proposed by the Organisation for Economic Co-operation and Development and their action plan on Base Erosion and Profit Shifting. Such changes may become more likely as a result of recent economic trends in the jurisdictions in which we operate, particularly if such trends continue. If such a situation were to arise, it could adversely impact our tax position and our effective tax rate. Failure to manage the risks associated with such changes, or misinterpretation of the laws providing such changes, could result in costly audits, interest, penalties and reputational damage, which could adversely affect our business, results of our operations and our financial condition.

Our actual effective tax rate may vary from our expectation and that variance may be material. A number of factors may increase our future effective tax rates, including: (1) the jurisdictions in which profits are determined to be earned and taxed; (2) the resolution of issues arising from any future tax audits with various taxing authorities; (3) changes in the valuation of our deferred tax assets and liabilities; (4) increases in expenses not deductible for tax purposes, including transaction costs and impairments of goodwill in connection with acquisitions; (5) changes in the taxation of share-based compensation; (6) changes in tax laws or the interpretation of such tax laws, and changes in generally accepted accounting principles; and (7) challenges to the transfer pricing policies related to our structure.

U.S. holders that own 10% or more of the combined voting power or value of our common shares may suffer adverse tax consequences because we and/or any of our non-U.S. subsidiaries are expected to be characterized as a "controlled foreign corporation," or a CFC, under Section 957(a) of the U.S. Internal Revenue Code of 1986, as amended, or the Code.

A non-U.S. corporation is considered a CFC if more than 50% of (1) the total combined voting power of all classes of stock of such corporation entitled to vote, or (2) the total value of the stock of such corporation, is owned, or is considered as owned by applying certain constructive ownership rules, by United States shareholders (U.S. persons who own stock representing 10% or more of the combined voting power or value of all outstanding stock of such non-U.S. corporation) on any day during the taxable year of such non-U.S. corporation. Certain United States shareholders of a CFC generally are required to include currently in gross income such shareholders' share of the CFC's "Subpart F income," a portion of the CFC's earnings to the extent the CFC holds certain U.S. property, and a portion of the CFC's "global intangible low-taxed income" (as defined under Section 951A of the Code). Such United States shareholders are subject to current U.S. federal income tax with respect to such items, even if the CFC has not made an actual distribution to such shareholders. "Subpart F income" includes, among other things, certain passive income (such as income from dividends, interests, royalties, rents and annuities or gain from the sale of property that produces such types of income) and certain sales and services income arising in connection with transactions between the CFC and a person related to the CFC. "Global intangible low-taxed income" may include most of the remainder of a CFC's income over a deemed return on its tangible assets.

We believe that we and our non-U.S. subsidiaries were classified as CFCs in the prior taxable year that ended on March 31, 2020. For U.S. holders who hold 10% or more of the combined voting power or value of our common shares, this may result in adverse U.S. federal income tax consequences, such as current U.S. taxation of Subpart F income and of any such shareholder's share of our accumulated non-U.S. earnings and profits (regardless of whether we make any distributions), taxation of amounts treated as global intangible low-taxed income under Section 951A of the Code with respect to such shareholder, and being subject to certain reporting requirements with the U.S. Internal Revenue Service, or the IRS. Any such U.S. holder who is an individual generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a U.S. corporation. If you are a U.S. holder who holds 10% or more of the combined voting power or value of our common shares, you should consult your own tax advisors regarding the U.S. tax consequences of acquiring, owning, or disposing of our common shares.

U.S. holders of our common shares may suffer adverse tax consequences if we are characterized as a passive foreign investment company.

Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the average quarterly value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a passive foreign investment company, or a PFIC, for U.S. federal income tax purposes. For purposes of these tests, passive income generally includes dividends, interest, gains from the sale or exchange of investment property and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. Additionally, a look-through rule generally applies with respect to 25% or more owned subsidiaries. If we are characterized as a PFIC, U.S. holders of our common shares may suffer adverse tax consequences, including having gains realized on the sale of our common shares treated as ordinary income, rather than capital gain, the loss of the preferential tax rate applicable to dividends received on our common shares by individuals who are U.S. holders, and having interest charges apply to certain distributions by us and the proceeds of sales or other dispositions of our common shares. In addition, special information reporting may be required.

Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets from time to time. The 50% passive asset test described above is generally based on the fair market value of each asset, with the value of goodwill and going concern value determined in large part by reference to the market value of our common shares, which may be volatile. Our status may also depend, in part, on how quickly we utilize the cash on hand and cash from future financings, including the cash proceeds from the Sumitomo Loan Agreement, in our business and whether we earned or earn primarily passive income (such as interest income) in the prior, current or future taxable years. With respect to the prior taxable year that ended on March 31, 2020, the current taxable year and foreseeable future taxable years, we believe that we were not a PFIC and presently do not anticipate that we will be a PFIC based upon the expected value of our assets, including any goodwill, and the expected nature and composition of our income and assets. However, our status as a PFIC is a fact-intensive determination made on an annual basis and we cannot provide any assurances regarding our PFIC status for the prior, current or future taxable years. Our U.S. counsel expresses no opinion with respect to our PFIC status for our prior, current or future taxable years. We will determine whether we were a PFIC or not for each taxable year and make such determination available to U.S. holders.

We have implemented structures and arrangements intended to mitigate the possibility that we will be classified as a PFIC. There can be no assurance that the IRS will not successfully challenge these structures and arrangements, which may result in an adverse impact on the determination of whether we were or are classified as a PFIC in the prior, current and future taxable years. In addition, recently proposed U.S. Treasury Regulations, of which we are continuing to assess the impact, may also adversely affect the treatment of these structures and arrangements with respect to our PFIC status.

The tax consequences that would apply if we are classified as a PFIC may be different from those described above if a U.S. holder were able to make a valid "qualified electing fund," or QEF, election. At this time, we do not expect to provide U.S. shareholders with the information necessary for a U.S. holder to make a QEF election. Prospective investors should assume that a QEF election will not be available.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

On April 2, 2020 and July 2, 2020, Sumitomo Dainippon Pharma funded an additional amount of $41.0 million and $43.0 million, respectively, to us under the Sumitomo Loan Agreement. As of August 12, 2020, $171.5 million was outstanding under the Sumitomo Loan Agreement and approximately $128.5 million remained available, which may be drawn down by us no more than once in any calendar quarter, subject to funding requests made by the Company in accordance with the Company's Board approved operating budget. The loans mature and are payable in full on the five-year anniversary of the closing date of the Sumitomo Loan Agreement or December 27, 2024. See Note 4-Related-party long-term debt for additional information regarding loans under the Sumitomo Loan Agreement, including our obligations thereunder and the interest rate on loans under such agreement.

Item 6. Exhibits.

Exhibit Number	Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Certificate of Incorporation.	S-1	333-226169	3.1	7/13/18	
3.2	Memorandum of Association.	S-1	333-226169	3.2	7/13/18	
3.3	Second Amended and Restated Bye-laws.	10-Q	001-38667	3.3	2/13/20	
10.1*	Market Access Services Agreement, dated June 17, 2020, by and between the Company and Sunovion Pharmaceuticals Inc.					X
31.1	Certification of Principal Executive Officer Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	XBRL Instance Document					
101.SCH	XBRL Taxonomy Extension Schema Document					
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					

* Certain portions of this document that constitute confidential information have been redacted in accordance with Item 601(b)(10) of Regulation S-K.

** These certifications are being furnished solely to accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Exchange Act, and are not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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.

UROVANT SCIENCES LTD.

Date: August 13, 2020 By: /s/ James Robinson
James Robinson
Principal Executive Officer

Date: August 13, 2020 By: /s/ Ajay Bansal
Ajay Bansal
Principal Financial Officer

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

MARKET ACCESS SERVICES AGREEMENT

This Market Access Services Agreement (this "Agreement") is entered into as of June 17, 2020 (the "Effective Date") by and between Sunovion Pharmaceuticals Inc., a Delaware corporation, having a principle place of business at 84 Waterford Drive, Marlborough, MA 01752 ("Sunovion") and Urovant Sciences GmbH, a Swiss corporation, having a principle place of business at Aeschenvorstadt 4, CH-4010, Viaduktstrasse 8, 4051 Basel, Switzerland ("Urovant"). Sunovion and Urovant may individually be referred to as a "Party" and collectively as the "Parties".

A. Sunovion has certain capabilities with regards to the marketing of pharmaceutical products and Urovant is a pharmaceutical company; and

B. Sunovion and Urovant desire to enter into this Agreement in which Urovant would engage Sunovion to provide the Services (as defined below) for the Products (as defined below) to Urovant.

THEREFORE, in consideration of the mutual covenants and promises contained herein, and for good and valuable consideration the receipt and sufficiency of which is hereby acknowledged, intending to be legally bound hereby, it is understood and agreed upon by and between the Parties as follows:

1. DEFINITIONS

The capitalized terms used in this Agreement shall have the meanings as defined below:

1.1 "3PL Contract" means the contract by and between Sunovion and a 3PL Provider to which a Product has been added by written agreement between Sunovion and such 3PL Provider.

1.2 "3PL Provider" means a Third Party that provides logistics services.

1.3 "3PL Services" mean the activities required in connection with Sunovion's facilitation of Urovant's use of Sunovion's 3PL Provider, as further described on Exhibit A.

1.4 "AAA" has the meaning set forth in Section 15.12.2.

1.5 "Affiliate" means, with respect to either Urovant or Sunovion, any corporation, company, partnership, joint venture or firm which controls, is controlled by or is under common control with Sunovion or Urovant, as the case may be. As used in the definition of Affiliate, "control" means (i) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors (or such lesser percentage that is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction), and (ii) in the case of non-corporate entities, the direct or indirect power to manage, direct or cause the direction of the management and policies of the non-corporate entity or the power to elect at least fifty percent (50%) of the members of the governing body of such non-corporate entity. Notwithstanding the foregoing, for purposes of this Agreement, Urovant shall not be an Affiliate of Sunovion and Sunovion shall not be an Affiliate of Urovant.

1.6 "Agreement" has the meaning set forth in the introductory paragraph.

1.7 "Alliance Manager" has the meaning set forth in Section 2.10.

1.8 "AMP" means the average manufacturer price, as defined in 42 U.S.C. § 1396r-8(k)(1) and any regulations and guidance promulgated thereunder, including 42 C.F.R. § 447.500 et seq.

1.9 "Applicable Law" means any federal, state, or local law, rule or regulation that may exist from time to time that applies to the obligations of the Parties under this Agreement. Applicable Law includes (i) the Prescription Drug Marketing Act of 1987, (ii) the federal health care program Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)) and related implementing regulations, and any similar state law; (iii) the federal False Claims Act (31 U.S.C. §§ 3729 et seq.); (iv) the Federal Civil Monetary Penalty statute and any similar state law; (v) the Foreign Corrupt Practices Act, (vi) anti-corruption and improper payments regulations; (vii) the Federal Food, Drug and Cosmetic Act; (viii) the DSCSA, and any associated implementing FDA regulations and guidance; and (ix) state product distribution licensing and pedigree laws (to the extent not preempted by federal law).

1.10 "ASP" means the manufacturer's average sales price as defined in 42 U.S.C. § 1395w-3a(c) and 42 C.F.R. § 414.800, et seq.

1.11 "Best Price" means the "best price" as defined in 42 U.S.C. § 1396r-8(c)(1)(C) and any regulations and guidance promulgated thereunder, including 42 C.F.R. § 447.500 et seq.

1.12 "Break-Up Fee" has the meaning set forth in Section 14.6.2.

1.13 "Business Day" means a day (other than a Saturday, Sunday or a public holiday) on which the banks are generally open for the transaction of general banking in Marlborough, Massachusetts, USA.

1.14 "cGMP" means the applicable regulatory standards and requirements for current good manufacturing practices promulgated by the FDA under and in accordance with the Food Drug & Cosmetic Act, Title 21, Parts 210, 211 and 600 of the U.S. Code of Federal Regulations, including any applicable and binding guidance documents published, as all such standards, requirements and guidance may be updated or amended from time to time.

1.15 "Change of Control" means any of the following events: (a) any Third Party (or group of Third Parties acting in concert) becomes the beneficial owner, directly or indirectly, of more than fifty percent (50%) of the total voting power of the stock then outstanding of a Party normally entitled to vote in elections of directors; (b) a Party consolidates with or merges into another corporation or entity, or any corporation or entity consolidates with or merges into such Party, in either event pursuant to a transaction (or series of transactions) in which more than fifty percent (50%) of the total voting power of the stock outstanding of the surviving entity normally entitled to vote in elections of directors is not held by the same parties as held at least fifty percent (50%) of the outstanding shares of voting stock of the Party immediately preceding such consolidation or merger; or (c) such Party conveys, transfers, assigns or leases to any Third Party, or otherwise disposes of, all or substantially all of its assets.

1.16 "Chargeback Offsets" has the meaning set forth in Section 3 of Exhibit D.

1.17 "Claims" means any complaints, charges, demands, claims, hearings, investigations, actions, inquiries, proceedings, arbitrations or suits.

1.18 "Commercially Reasonable Efforts" means, with respect to the efforts to be expended by a Party with respect to its performance of its obligations under this Agreement, including the Services, reasonable, diligent, good-faith efforts to perform such obligations as a similarly situated pharmaceutical company would normally use to accomplish activities that are similar to such obligations, but not less than the efforts a Party would perform on behalf of itself under similar circumstances while exercising reasonable business judgment. With respect to a Party's obligations, Commercially Reasonable Efforts requires that the Party: (i) promptly assign responsibility for such obligations to specific employee(s) who are held accountable for progress and monitor such progress on an on-going basis; (ii) set and consistently seek to achieve specific and meaningful objectives for carrying out such obligations; and (iii) consistently make and implement decisions and allocate resources designed to advance progress with respect to such objectives. Notwithstanding the foregoing, if the performance of a Party's obligations hereunder is impaired by the other Party's failure to perform its obligations hereunder, the determination of whether such first Party has used Commercially Reasonable Efforts in performing a given obligation will be determined in the context of such other Party's failure.

1.19 "Confidential Information" means all non-public business financial, scientific or technical information in whatever form (oral, visual or written) furnished or made available to, or otherwise acquired by, a Party from the other Party in connection with this Agreement. Confidential Information shall also include (i) subject to Section 9.7, the terms and conditions of this Agreement, (ii) all derivative information prepared by or on behalf of Receiving Party (such as notes, drawings, plans, projections, analyses, records and materials) that incorporates or reflects Confidential Information, and (iii) with respect to Urovant, the Government Pricing Report.

1.20 "Contracting Services" mean the activities required in connection with supporting new and existing Urovant Market Access Contracts, as further described on Exhibit C.

1.21 "Disclosing Party" means the Party that receives Confidential Information from the other Party.

1.22 "Dispute" has the meaning set forth in Section 15.12.1.

1.23 "DS Fees" has the meaning set forth in Section 3 of Exhibit D.

1.24 "DSCSA" means the Drug Supply Chain Security Act.

1.25 "DSP" means Sumitomo Dainippon Pharma Ltd., a Japanese company with its principal place of business at 6-8 Doshomachi 2-Chome, Chuo-ku, Osaka, 541-0045, Japan.

1.26 "Effective Date" has the meaning set forth in the introductory paragraph.

1.27 "Escrow Fund" means the escrow fund established by the Parties, which shall be funded by Urovant, to provide Sunovion with the necessary funds to fulfil Sunovion's payment obligations that are required in connection with the Services.

1.28 "Escrow Fund Minimum Amount" has the meaning set forth in Section 8.1.3.

1.29 "FDA" means the United States Food and Drug Administration and any successor entity thereto

1.30 "FSS" means the Federal Supply Schedule administered by the VA.

1.31 "FTE" means full time employee equivalent over a twelve (12) month period (including normal vacations, sick days and holidays). The portion of an FTE year devoted by an employee to a particular activity or Service shall be determined by dividing the number of full working days during any twelve (12) month period devoted by such employee to such activity or Service by the total number of working days during such twelve (12) month period.

1.32 "FTE Rate for Regulatory Services" means fully burdened cost of a Sunovion FTE dedicated to performing the Regulatory Services as needed, and as agreed upon by the Parties from time to time.

1.33 "Government Contracts" means the following contracts between Urovant and Government Entities: (i) any Medicaid Rebate Program agreement, PHS 340B Program agreement, or VA Master Agreement (including the pharmaceutical pricing agreement attached thereto), in each case, as described in Section 1927(a) of the Social Security Act, (ii) any Medicare Part D Coverage Gap Discount Program agreement as described in Section 1860D-43(a) of the Social Security Act, (iii) any FSS contract with the Secretary of Veterans Affairs, and any TriCare Rebate Program agreement with the Secretary of Defense, (iv) state supplemental Medicaid rebate agreements, and (v) to the extent mutually agreed by the Parties, other agreements comparable to the agreements described in (i) or (ii) that are with state or local government agencies or authorities.

1.34 "Government Entities" mean the government entities that are a party to a Urovant Government Contract.

1.35 "Government Pricing Programs" has the meaning set forth in Section 1 of Exhibit E.

1.36 "Government Pricing Report" has the meaning set forth in Section 1 of Exhibit E.

1.37 "Governmental Contact" has the meaning set forth in Section 15.2.

1.38 "GPO" means a group purchasing organization.

1.39 "GPO/IDN Contract" means contracts by and between Sunovion and a GPO or IDN to which a Product has been added by written agreement between Sunovion and such GPO or IDN.

1.40 "GPO/IDN Fees" has the meaning set forth in Section 3 of Exhibit D.

1.41 "GPR Services" mean the activities required in connection government price reporting, as further described on Exhibit E.

1.42 "IDN" means an integrated delivery network.

1.43 "Initial Term" has the meaning set forth in Section 14.1.

1.44 "JGC" has the meaning set forth in Section 2.1.

1.45 "Losses" means liabilities, losses, damages, awards, settlements, judgments, interest, costs, fines and expenses (including all reasonable attorneys' fees and expenses).

1.46 "Market Access Customers" means any Payor or other Third Party as agreed upon by the Parties in writing.

1.47 "Material Wholesaler Contracts" mean certain contracts by and between Sunovion and the Material Wholesalers.

1.48 "Material Wholesalers" mean those certain Wholesalers, comprising of the contracts to which AmerisourceBergen Corporation, Cardinal Health, Inc., or McKesson Corporation, or their respective Affiliates.

1.49 "Medicaid Rebate Program" means the rebate program established pursuant to 42 U.S.C. §1396r-8.

1.50 "Medicare Program" means the program established pursuant to 42 U.S.C. 1395 et seq (title XVIII of the Social Security Act).

1.51 "Monthly Flat Service Charge" means, subject to Section 8.2.2, (i) [* * *] per calendar month for the first year of the Term, (ii) [* * *] for the second year of the Term, and (iii) an adjusted amount for each year after the second year of the Term consistent with Section 8.2.2; provided that, (i) if the Term begins after the first day of a calendar month, such amount shall be multiplied by a fraction where the numerator is the number of days in such calendar month that are on or after the Effective Date and the denominator is the number of days in such calendar month, and (ii) if the Term ends before the last day of a calendar month, such amount shall be multiplied by a fraction where the numerator is the number of days in such calendar month that are on or before the effective date of the termination or expiration of this Agreement and the denominator is the number of days in such calendar month.

1.52 "NDA" means new drug application filed with the FDA for authorization to market any and each of the Products.

1.53 "Non-FAMP" means the non-federal average manufacturer price as defined in 38 U.S.C. § 8126, the VA Master Agreement, and any regulations and guidance promulgated thereunder.

1.54 "Party" and "Parties" the meaning set forth in the introductory paragraph.

1.55 "Pass-Through Expenses" means (a) the Payor Fees, (b) the DS Fees, (c) the GPO/IDN Fees, (d) the out-of-pocket costs and expenses incurred by or on behalf of Sunovion in connection with Sunovion's provision to Urovant of the Sunovion Reports that are specific to the Products, (e) the costs and expenses owed to a third-party recall vendor that arise in connection with the Regulatory Services, (f) reasonable travel expenses that are incurred by Sunovion, its Affiliates or a third-party service provider in connection with the performance of the Services that are incurred in accordance with a travel policy to be agreed upon in writing by the Parties, (g) software license fees, costs and expenses reasonably incurred by Sunovion or its Affiliates in connection with modification of the information technology systems reasonable necessary or useful for Sunovion to perform the Services and that have been pre-approved by Urovant in writing; provided that any costs set forth in herein shall be deemed to be approved by Urovant, and (h) any additional costs and expenses incurred by Sunovion in connection with the Services as agreed by the Parties in writing.

1.56 "Payor" means any health maintenance organization, preferred provider organization, self-insured employer, employee group, exclusive provider or similarly funded (directly or indirectly) health benefits program, administrator, managed care organization, pharmacy benefit manager, or other health organization.

1.57 "Payor Fees" has the meaning set forth in Section 2 of Exhibit D.

1.58 "Pedigree Information" means, with respect to a Product, at least the information (which includes the Product Identifiers, Transaction History and Transaction Information (as such terms are defined in the DSCSA)) that Sunovion is required to provide to its down-stream authorized trading partners pursuant to the DSCSA.

1.59 "Person" means any individual, partnership, limited liability company, firm, corporation, association, trust, unincorporated organization or other entity.

1.60 "PHS 340B Program" means the drug discount program, available to "covered entities", that is administered by the Health Resources and Services Administration pursuant to 42 U.S.C. § 256b.

1.61 "Product Contracts" means any Wholesaler Contracts, 3PL Contracts, and GPO/IDN Contracts, and any other contracts to which Sunovion is a party, in each case, that is a contract to which a Product has been added in fulfillment of Sunovion's obligations under this Agreement.

1.62 "Product Inventions" has the meaning set forth in Section 10.1.

1.63 "Products" means pharmaceutical products owned by Urovant, consisting of Vibegron.

1.64 "RCP Payments" means Rebate Payments, Payor Fees, Chargeback Offsets, DS Fees, and GPO/IDN Fees.

1.65 "RCP Services" mean the activities required in connection with the validation, processing and payment of the RCP Payments, as further described on Exhibit D.

1.66 "Rebate Payment" has the meaning set forth in Section 2 of Exhibit D.

1.67 "Receiving Party" means the Party that receives Confidential Information from the other Party.

1.68 "Records" has the meaning set forth in Section 6.5.

1.69 "Regulatory Service Charge" has the meaning set forth in Section 4.7.

1.70 "Regulatory Services" mean regulatory-related activities, as further described on Exhibit F.

1.71 "Renewal Term" has the meaning set forth in Section 14.1.

1.72 "Service Charge" has the meaning set forth in Section 8.2.1.

1.73 "Services" means the 3PL Services, Wholesaler, GPO, and IDN Services, Contracting Services, GPR Services, RCP Services, and Regulatory Services.

1.74 "Subcommittee" has the meaning set forth in Section 2.7.

1.75 "Sunovion" has the meaning set forth in the introductory paragraph.

1.76 "Sunovion GPOs" means any GPO that is a party to a GPO/IDN Contract.

1.77 "Sunovion IDNs" means any IDN that is a party to a GPO/IDN Contract.

1.78 "Sunovion Indemnitees" has the meaning set forth in Section 12.2.

1.79 "Sunovion Property" has the meaning set forth in Section 10.3.

1.80 "Sunovion Reports" has the meaning set forth in Section 6.3.

1.81 "Term" has the meaning set forth in Section 14.1.

1.82 "Territory" means the United States, the District of Columbia, and all of the United States' territories and possessions.

1.83 "Third Party" means any Person other than a Party or an Affiliate of a Party.

1.84 "TriCare Rebate Program" means the rebate program described in the final rule published by the Department of Defense at 74 Fed. Reg. 11,279 to implement Section 703 of the National Defense Authorization Act of 2008, and includes rebates pursuant to any voluntary rebate agreement described therein.

1.85 "Urovant" has the meaning set forth in the introductory paragraph.

1.86 "Urovant Government Contract" means a Government Contract covering a Product to which Urovant is a party.

1.87 "Urovant GPO/IDN Contract" means a contract covering a Product between Urovant and a GPO or IDN that is not a Sunovion GPO or Sunovion IDN.

1.88 "Urovant Indemnitees" has the meaning set forth in Section 12.1.

1.89 "Urovant Market Access Contract" means a contract by and between Urovant and a Market Access Customer covering a Product.

1.90 "VA" means the United States Department of Veterans Affairs.

1.91 "VA Master Agreement" means an agreement between a pharmaceutical manufacturer and the VA to implement the provisions of the Veterans Health Care Act of 1992, 38 U.S.C. § 8126.

1.92 "Wholesaler" means any wholesaler of pharmaceutical products or similar trade partner.

1.93 "Wholesaler Contract" means contracts by and between Sunovion and a Wholesaler to which a Product has been added by written agreement between Sunovion and such Wholesaler.

1.94 "Wholesaler, GPO, and IDN Services" mean the activities required in connection with the performance of Sunovion's obligations under the Wholesaler Contracts and GPO/IDN Contracts, as further described on Exhibit B.

1.95 "Work Product" has the meaning set forth in Section 10.1.

2. JOINT GOVERNANCE COMMITTEE

2.1 Joint Governance Committee. Within thirty (30) days after the Effective Date, the Parties shall establish a joint governance committee (the "JGC"), which shall consist of three (3) representatives from each Party, each with the requisite experience and seniority to enable such representative to make decisions on behalf of the Party it represents with respect to the issues falling within the jurisdiction of the JGC. From time to time, each Party may substitute one (1) or more of its representatives to the JGC on written notice to the other Party. Each individual appointed by a Party as a representative to the JGC shall be an employee of such Party or of such Party's Affiliate. The Parties shall each select a chairperson for the JGC which shall serve as joint-chairpersons during the Term unless a Party determines to replace its chairperson.

2.2 Responsibilities. The JGC shall:

2.2.1 review disputes escalated to the JGC pursuant to Section 7.1;

2.2.2 review and approve changes to the Escrow Fund Minimum Amount in accordance with Section 8.1.2;

2.2.3 establish an efficient and secure method of transmission for the Records, including the Government Pricing Report;

2.2.4 review and suggest any amendments to the Services; provided that any such amendments or updates shall be memorialized in a separate writing signed by each Party;

2.2.5 review the activities of any Subcommittees established by the JGC, and resolve any disagreement between the designees of Sunovion and Urovant on any Subcommittee;

2.2.6 provide a forum for discussing and recommending consensus resolution of any disputes within the jurisdiction of the JGC; and

2.2.7 perform such other functions as are set forth herein, if and as applicable, or as the Parties may mutually agree in writing.

2.3 Meetings. The JGC shall meet quarterly until its disbandment, or as otherwise agreed to by the Parties, with the location of in-person meetings alternating between a location designated by Sunovion and a location designated by Urovant, with Sunovion designating the place of the first meeting. The chairpersons of the JGC shall be responsible for calling meetings of the JGC on no less than ten (10) days' notice unless exigent circumstances require shorter notice. Each Party shall make all proposals for agenda items at least ten (10) days in advance of the applicable meeting and shall provide all appropriate information with respect to such proposed items at least five (5) days in advance of the applicable meeting*;* provided, that under exigent circumstances requiring input by the JGC, a Party may provide its agenda items to the other Party within a shorter period of time in advance of the meeting or may propose that there not be a specific agenda for a particular meeting, so long as the other Party consents to such later addition of such agenda items or the absence of a specific agenda for such meeting (which consent shall not be unreasonably conditioned, withheld or delayed). The chairpersons of the JGC shall prepare and circulate, or cause to be prepared and circulated, for review and approval of the Parties minutes of each meeting within thirty (30) days after the meeting. The Parties shall agree on the minutes of each meeting promptly, but in no event later than the next meeting of the JGC.

2.4 Procedural Rules. Within sixty (60) days after the Effective Date, the JGC shall adopt standing rules as shall be necessary for the JGC to conduct business; provided that that such rules are not inconsistent with this Agreement. A quorum of the JGC shall exist whenever there is present at a meeting at least one (1) representative appointed by each Party. Representatives of the Parties on the JGC may attend a meeting either in person or by telephone, video conference or similar means in which each participant can hear what is said by and be heard by, the other participants; provided, that each Calendar Year at least one (1) meeting of the JGC will be in-person. Representation by proxy shall be allowed.

2.5 Decision-Making. The JGC shall take action by consensus of the representatives present at a meeting at which a quorum exists, with each Party having a single vote irrespective of the number of representatives of such Party in attendance, or by a written resolution signed by at least one (1) representative of each Party. Except for matters outside the jurisdiction and authority of the JGC, as applicable (including as set forth in Section 2.6), if the JGC cannot, or does not, reach consensus on an issue within fifteen (15) Business Days after such issue is first presented to the JGC for consideration, then either Party shall have the right to refer such issue to the Chief Executive Officers of the Parties for attempted resolution by good faith negotiations during a period of at least thirty (30) days in accordance with Section 15.12. Any final decision mutually agreed to by the Chief Executive Officers of the Parties in writing shall be conclusive and binding on the Parties.

2.6 Limitations on Authority. Without limitation to the foregoing, the Parties hereby agree that matters explicitly reserved to the consent, approval, discretion or other decision-making authority of one or both Parties, as expressly provided in this Agreement, are outside the jurisdiction and decision-making authority of the JGC or any Subcommittee, including: (i) amendment, modification or waiver of compliance with this Agreement; (ii) requiring a Party to breach any obligation or agreement that such other Party may have with or to a Third Party prior to the Effective Date; or (iii) require the other Party to perform any activities that are materially different or greater in scope than those expressly set forth under the Agreement. Furthermore, no decision of the JGC or any Subcommittee shall be in contravention of any terms and conditions of this Agreement. It is understood and agreed that issues to be decided by the JGC or any Subcommittee, as applicable, are only those specific issues within such committee's duties.

2.7 Subcommittees. From time to time, the JGC may establish and delegate duties to sub-committees or directed teams (each, a "Subcommittee") on an "as-needed" basis to oversee specific Services. Each such Subcommittee shall be constituted and shall operate as the JGC determines; provided that each Subcommittee shall have equal representation from each Party, unless otherwise mutually agreed. Subcommittees may be established on an ad hoc basis for purposes of a specific Service or on such other basis as the JGC may determine. Each Subcommittee and its activities shall be subject to the oversight, review and approval of, and shall report to, the JGC. In no event shall the authority of the Subcommittee exceed that specified for the JGC. All decisions of a Subcommittee shall be by consensus. Any disagreement between the designees of Sunovion and Urovant on a Subcommittee shall be referred to the JGC for resolution.

2.8 Expenses. Each Party shall be responsible for all travel and related costs and expenses for its members and other representatives to attend meetings of, and otherwise participate on, the JGC or any Subcommittee. For purposes of clarity, the foregoing travel and related costs and expenses shall not be Pass-Through Expenses.

2.9 Disbandment. Unless otherwise agreed to in writing by the Parties, the JGC shall disband three (3) months after the launch of the first Product.

2.10 Alliance Manager. Each Party shall appoint a person(s) who shall oversee contact between the Parties for all matters between meetings of the JGC and shall have such other responsibilities as the Parties may agree in writing after the Effective Date (each, an "Alliance Manager"). Each Party shall be responsible for all travel and related costs and expenses for its Alliance Manager. For purposes of clarity, the foregoing travel and related costs and expenses shall not be Pass-Through Expenses. Each Party may replace its Alliance Manager at any time by notice in writing to the other Party.

3. APPOINTMENT

Subject to the terms and conditions of this Agreement, Urovant hereby appoints Sunovion, and Sunovion hereby accepts such appointment, to be Urovant's: (a) co-licensed partner (for the purposes of the DSCSA) with regard to the Products; and (b) an exclusive distributor of the Products in the Territory.

4. SUNOVION OBLIGATIONS

4.1 Generally; Efforts; Product Contracts.

4.1.1 During the Term, Sunovion shall use Commercially Reasonable Efforts to perform, or cause to be performed by an Affiliate of Sunovion (as applicable), its obligations under this Agreement, including those in Sections 4.2 through 4.7.

4.1.2 Sunovion shall provide copies of Product Contracts to support Urovant's compliance with Applicable Law, Government Contracts, and for Urovant's review and validation of Sunovion's Government Pricing Report and underlying government pricing calculation methodologies (including ensuring that such methodologies align with Urovant's reasonable assumptions). Sunovion may redact certain provisions of the Product Contracts that (i) are related to a Sunovion product, or (ii) are required to maintain an obligation of confidentiality to the counterparty to such Product Contract and are not related to the applicable Product.

4.2 3PL Services.

4.2.1 Sunovion shall: (i) add the Products to the contract(s) by and between Sunovion and its 3PL Provider(s), (ii) negotiate rates under the applicable 3PL Contract [* * *] and (iii) provide reasonable evidence to Urovant that the obligations under (i) and (ii) have been fulfilled.

4.2.2 After Sunovion's fulfilment of Sunovion's obligations pursuant to Section 4.2.1, unless this Agreement is earlier terminated by Urovant pursuant to Section 14.5.1, Sunovion shall provide the 3PL Services. In the performance of the 3PL Services, Sunovion shall ensure that neither Sunovion nor a 3PL Provider takes title to the Products.

4.3 Wholesaler, GPO, and IDN Services.

4.3.1 Sunovion shall: (i) add the Products to the contracts by and between Sunovion and its Wholesalers, the Sunovion GPOs, and the Sunovion IDNs, (ii) negotiate rates under such contracts [* * *]; provided that, subject to Section 5.3.2, [* * *], and (iii) provide reasonable evidence to Urovant that the obligations under (i) and (ii) have been fulfilled.

4.3.2 After Sunovion's fulfilment of Sunovion's obligations pursuant to Section 4.3.1, unless this Agreement is earlier terminated by Urovant pursuant to Section 14.5.2, Sunovion shall provide the Wholesaler, GPO, and IDN Services.

4.4 Contracting Services.

4.4.1 At least ninety (90) days prior to the anticipated date on which FDA will complete its review of the NDA for the first Product to be approved by FDA, which is currently anticipated to be December 26, 2020, Sunovion shall configure, or cause to be configured, the Model N software to enable Sunovion to perform its obligations under this Agreement; provided that the costs and expenses incurred by or on behalf of Sunovion in connection therewith shall be deemed to be a Pass-Through Expense.

4.4.2 Sunovion shall provide the Contracting Services.

4.5 RCP Services. Sunovion shall provide the RCP Services.

4.6 GPR Services. Sunovion shall provide the GPR Services.

4.7 Regulatory Services.

4.7.1 In connection with the Regulatory Services, Sunovion shall provide the necessary number of FTEs as agreed upon by the Parties from time to time at the FTE Rate for Regulatory Services (the "Regulatory Service Charge").

4.7.2 Sunovion shall provide the Regulatory Services.

5. UROVANT OBLIGATIONS

5.1 Generally; Efforts. During the Term, Urovant shall use Commercially Reasonable Efforts to perform its obligations under this Agreement, including those in Sections 5.2 through 5.6.

5.2 3PL Services.

5.2.1 In connection with the 3PL Services, Urovant shall provide to Sunovion in writing information necessary or reasonably useful for Sunovion to perform the 3PL Services within thirty (30) days after the Effective Date.

5.2.2 Prior to consignment of the Product to a 3PL Provider pursuant to the terms of a 3PL Contract: (i) Urovant shall: (a) release the Products in accordance with (1) cGMP, and (2) any serialization requirements under the DSCSA and policies and procedures to be agreed upon by the Parties in writing, and (b) transmit all Pedigree Information related to the Products to Sunovion; and (ii) Sunovion shall have received and verified such Pedigree Information.

5.2.3 In connection with the 3PL Services, Urovant shall: (i) coordinate shipment of the Products, at Urovant's cost and expense, to the 3PL Provider designated by Sunovion; (ii) cause the Products to be consigned to Sunovion; (iii) enter into a quality agreement with each 3PL Provider and Sunovion prior to consignment of any Product to Sunovion; (iv) refrain from actions which would cause Sunovion to be in material breach of any covenant, representation, or warranty contained in any agreement by and between Sunovion and a 3PL Provider to which a Product has been consigned; and (v) ensure that the Products do not include any hazardous materials.

5.3 Wholesaler, GPO, and IDN Services.

5.3.1 In connection with the Wholesaler, GPO, and IDN Services, Urovant shall: (i) provide to Sunovion in writing information that is reasonably necessary for Sunovion to perform the Wholesaler, GPO, and IDN Services within fifteen (15) days after the Effective Date; (ii) comply with the terms and conditions of the applicable Wholesaler Contract or GPO/IDN Contract as if Urovant were a party, including with regard to any dispute resolution mechanisms set forth therein, and any policies and procedures agreed upon in writing by the Parties regarding returns of Products, (iii) promptly provide Sunovion with any information requested by Sunovion that is necessary for Sunovion to properly complete returns of Products, and (iv) upon the reasonable request by Sunovion, cooperate with Sunovion in the conduct of any investigation regarding orders of the Products by a Wholesaler, GPO, or IDN.

5.3.2 Urovant shall ensure that (i) its directors, officers, employees, contractors and agents, as applicable, use best efforts to confer with Sunovion at least five (5) Business Days in advance of any first-time communication with a Sunovion GPO or Sunovion IDN relating to a GPO/IDN Contract to align on a meeting strategy to employ in connection with the Wholesaler, GPO and IDN Services, and (ii) a Sunovion representative participates in any such communication with such Sunovion GPO or Sunovion IDN in connection with the Contracting Services unless Sunovion elects in writing not to participate.

5.4 Contracting Services.

5.4.1 In connection with the Contracting Services, Urovant shall: (i) provide un-redacted copies of each Urovant Market Access Contract, Urovant Government Contract and Urovant GPO/IDN Contract entered into by Urovant to Sunovion to the extent not already provided, provided that Sunovion shall not use such Urovant Market Access Contracts, Urovant Government Contracts or Urovant GPO/IDN Contracts for any purpose other than in furtherance of Sunovion's obligations under this Agreement, and (ii) identify a Urovant employee to be a dedicated liaison that will communicate with Sunovion from time to time as reasonably requested by Sunovion to complete the Contracting Services.

5.4.2 Urovant shall be responsible for ensuring that the Urovant Market Access Contracts, Urovant Government Contract, and Urovant GPO/IDN Contracts permit Sunovion to perform the RCP Services and the GPR Services.

5.5 GPR Services. Urovant hereby acknowledges and agrees that it will: (i) [* * *], (ii) [* * *], and (iii) be solely responsible for: (a) entering the information contained in the Government Pricing Report into the Centers for Medicare & Medicaid Services Drug Data Reporting System (or other applicable system), and (b) certifying and submitting such government pricing data to the applicable government authority in accordance with Applicable Laws, in each case (a) and (b), as required under Applicable Law, including under the Government Pricing Programs, and applicable state laws, rules and regulations.

5.6 Regulatory Services.

5.6.1 Upon written notice from Sunovion to Urovant, Urovant shall permit Sunovion to conduct a for-cause audit of Urovant's quality systems that in any way relate to Sunovion's performance of the Services.

5.6.2 Urovant shall promptly, but in no event less than two (2) Business Days, notify Sunovion in the event that a recall is issued for any Product.

5.7 Training Services. Urovant shall, upon a reasonable request by Sunovion, provide to Sunovion's account directors certain training the enable Sunovion to perform the Services. Such training may, to the extent feasible, be administered virtually or as otherwise agreed upon by the Parties.

6. OPERATIONS

6.1 Title and Risk of Loss. At no time during the Term shall Sunovion have title to the Products. At all times during the Term, title to the Products shall either be with Urovant or an applicable Wholesaler, and, as between Urovant and Sunovion, risk of loss of Products shall be with Urovant at all times; provided that to the extent the risk of loss of the Products are contractually assigned to a Wholesaler pursuant to Wholesaler Contract, Sunovion shall, subject to Section 4.1, enforce any rights of such contractual assignment of risk of loss for the benefit of Urovant.

6.2 Regulatory Responsibility. Except as expressly set forth in this Agreement or where required by Applicable Law for Sunovion to fulfill its obligations under this Agreement, Urovant (as the owner and applicant of the NDA for each Product) shall be solely responsible, at Urovant's sole cost and expense, for all regulatory obligations related to the Products, including annual product reports, drug listing updates, serious adverse event reports, field alerts, and DSCSA reporting and recordkeeping. Subject to Section 6.4 and Applicable Law, Urovant, not Sunovion, shall have the sole right to interact with FDA regarding the Products.

6.3 Sunovion Reporting Obligations. Sunovion shall provide the reports set forth on Exhibit G (the "Sunovion Reports") to Urovant at the frequency that corresponds to each such report.

6.4 Urovant Reporting Obligations. Urovant shall: (i) submit a report to Sunovion: (a) within thirty (30) days after the end of each calendar year describing the projected annual sales volume for the Products for the current calendar year, (b) within one hundred twenty (120) days prior to launch of a Product describing the volume requirements for such launch, and (c) within sixty (60) days prior to launch of a Product describing the volume requirements for a safety stock of such Product, (ii) within a reasonable period of time, provide to Sunovion any report or Product-related information that is reasonably requested by Sunovion or reasonably necessary for Sunovion to perform the Services, (iii) provide Sunovion with copies of all submissions to any regulatory authority that are reasonably requested by Sunovion or are reasonably necessary for Sunovion to perform the Services, and (iv) on a quarterly basis, prepare in good faith a forecast that projects sales demand for the Products for the following twelve (12) month period to enable Sunovion to adequately prepare for performance of the Services.

6.5 Records; Record Retention; Records Audits. Sunovion will maintain all Work Product generated by Sunovion in connection with the Services (collectively, the "Records") for a period of three (3) years. Following completion of the Services, Sunovion will, at the direction and written request of Urovant, promptly deliver Records to Urovant or its designee, or dispose of the Records.

7. DECISION-MAKING AUTHORITY; DISCRETION; REVIEW RIGHTS.

7.1 Wholesaler, GPO, and IDN Disputes. With regard to disputes under a Wholesaler Contract or GPO/IDN Contract that relate: (i) solely to a Sunovion product (and does not relate to a Product), Sunovion shall have final decision-making authority, (ii) to a Sunovion product and a Product, the JGC shall have final decision-making authority if the Parties cannot agree on a resolution to such dispute; and (iii) solely to a Product (and does not relate to a Sunovion product), Urovant shall have final decision-making authority.

7.2 Product Price Increases. [* * *]. Any dispute that arises in connection with the foregoing shall be escalated to the respective Chief Executive Officers of Urovant and Sunovion. If the Parties respective Chief Executive Officers are not able to resolve the dispute then the Parties' agree that the dispute shall be raised to the Parties' ultimate parent company, DSP, for further discussion. For clarity, if DSP is unable to resolve the dispute, Urovant will have final decision-making authority with respect to all pricing decisions relating to the Products.

8. FINANCIAL TERMS

8.1 Escrow Fund.

8.1.1 At least thirty (30) days prior to the launch of a Product, (i) the Parties shall establish the Escrow Fund at a reputable banking institution agreed upon by the Parties, and (ii) Urovant shall place [* * *] into the Escrow Fund for the first year of the Term. Any agreement by and among such banking institution, Sunovion and Urovant shall (a) not require Sunovion to seek approval from Urovant to withdraw funds from the Escrow Fund if such withdrawal is in connection with Sunovion's performance of the RCP Services, and (b) permit Sunovion to transfer funds from the Escrow Fund to an intermediate Sunovion bank account to enable Sunovion to complete RSP Payments in connection with Sunovion's performance of the RCP Services.

8.1.2 Notwithstanding the foregoing, during the first year of the Term, Urovant shall ensure that the Escrow Fund shall not have less than [* * *] (the "Escrow Fund Minimum Amount") for any period of time that is longer than ten (10) Business Days. The JGC shall discuss in good faith an adjustment to the Escrow Fund Minimum Amount six (6) months after the launch of such Product and every six (6) months thereafter. In the event that Urovant fails to timely fund the Escrow Fund, Sunovion may terminate this Agreement if such failure to fund the Escrow Fund is not cured within five (5) Business Days of receipt of notice of such failure from Sunovion.

8.1.3 Within ninety (90) days after the end of each calendar year in which there is an Escrow Fund, the Parties shall reconcile the amount remaining in Escrow Fund against all of the RCP Payments and other withdrawals initiated by Sunovion. After such completion reconciliation, in the event that the Escrow Fund has an amount that is less than the Escrow Fund Minimum Amount, or such other amount as determined by the JGC from time to time, Urovant shall reconcile any shortfall within five (5) Business Days.

8.2 Fees; Invoices; Payments.

8.2.1 In consideration for performance of the Services by Sunovion, Urovant shall: (i) pay to Sunovion an amount equal to the sum of: (a) the Monthly Flat Service Charge, and (b) any agreed to Regulatory Service Charge (the sum of (a) and (b), the "Service Charge"), and (ii) reimburse Sunovion for any Pass-Through Expenses.

8.2.2 Subject to the remainder of this Section 8.2.2, Sunovion reserves the right to adjust all fees on an annual basis beginning with the third (3rd) year of the Term, including the Monthly Flat Service Charge and Regulatory Service Charge, upon reasonable prior written approval of Urovant, such approval not to be unreasonably withheld, conditioned or delayed. Determination of the Monthly Flat Service Charge for the third (3rd) year of the Term and each year thereafter shall be subject to good faith negotiation between the Parties that will take into consideration any evidence that Sunovion provides in connection with cost increases by any vendor engaged by Sunovion on Urovant's behalf. All fees owed by a Party to the other Party under this Agreement shall comply with the federal health care program Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)), all applicable statutory "exceptions" and regulatory "safe harbors" related thereto, and related implementing regulations, and any similar state law, and shall comply with any bona fide service fee requirements.

8.2.3 At the end of each calendar month, Sunovion shall submit an invoice to Urovant for an amount equal to the sum of: (i) the Service Charges, and (ii) the Pass-Through Expenses incurred by Sunovion in connection with the Services during the prior calendar month. Urovant shall pay Sunovion all undisputed invoice amounts within thirty (30) days after receipt thereof. If payment of an undisputed invoice is not made by Urovant within thirty (30) days, then, upon five (5) days' written notice to Urovant, Sunovion may withdraw a certain amount from the Escrow Fund in lieu of a payment by Urovant of such invoice; provided that such payment has still not been made by Urovant.

8.3 Taxes. Urovant shall be responsible for all sales, use and excise taxes, and any other similar taxes, duties and charges of any kind imposed by any federal, state or local governmental entity: (i) on any amounts payable by Urovant hereunder, and (ii) related to the Products, including the branded prescription drug fee pursuant to 26 C.F.R. Parts 51 and 602; provided, that, in no event shall Urovant pay or be responsible for any taxes imposed on, or with respect to, Sunovion's income, revenues, gross receipts, personnel or real or personal property or other assets.

8.4 Financial Records; Financial Audits. Sunovion will keep reasonable financial records relating to its performance of the Services for a period of three (3) years after the end of performing such Services. Urovant, or its independent auditors or representatives, may, during normal business hours, and upon reasonable notice, review and inspect Sunovion's financial records of the Service Charges paid by Urovant and Pass-Through Expenses invoiced to Urovant for the purpose of determining if invoices submitted by Sunovion reflect the financial terms agreed to under this Agreement. Urovant or its representatives may conduct such financial audit no more than one time per calendar year during the Term and for a period of twelve (12) months thereafter. Urovant shall be responsible for the cost of any such audit, except that, if the auditor determines that Urovant has overpaid any amounts owed to Sunovion hereunder by five percent (5%) or more, Sunovion shall pay the costs and expenses of such audit, and any overpaid amounts that are discovered, together with reasonable interest on such overpaid amounts. The results of such audit shall be final and binding, absent manifest error.

8.5 Regulatory/Compliance Records; Regulatory/Compliance Audits. Sunovion shall keep reasonable regulatory and compliance records relating to its performance of the Services for a period of three (3) years after the end of performing such Services. Urovant, or its independent auditors or representatives, may, no more than one (1) time per calendar year, during normal business hours, and upon reasonable notice, review and inspect Sunovion's regulatory and compliance records relating to Sunovion's performance of the Services.

9. CONFIDENTIALITY

9.1 Obligations of Confidentiality. During the Term and thereafter, Receiving Party agrees to: (i) hold all Confidential Information in confidence and not, directly or indirectly, publish, disseminate or otherwise disclose, deliver or make available to any Third Party any Confidential Information, except as expressly permitted in this Agreement; (ii) use Confidential Information solely in furtherance of the purpose of this Agreement (i.e., the performance of a Party's obligations, or the exercise of a Party's rights, under this Agreement), (iii) treat Confidential Information with the same degree of care that Receiving Party uses to protect its own confidential information, but in no event with less than a reasonable degree of care, (iv) reproduce Confidential Information solely as necessary to further the purpose of this Agreement, and (v) notify Disclosing Party upon discovery of any unauthorized use or disclosure of any Confidential Information or any other breach of this Section 9 by Receiving Party and to cooperate with Disclosing Party in every reasonable way to help Disclosing Party regain possession of the Confidential Information and prevent its further unauthorized use.

9.2 Exceptions. Receiving Party shall have no obligations of confidentiality and non-use with respect to any Confidential Information which:

9.2.1 is, or later becomes, generally available to the public or trade by the use, publication or the like, through no fault of, or act, or failure to act on the part of Receiving Party, as evidenced by the then existing publication or other public dissemination of such information in written or other documentary form;

9.2.2 is obtained, after the Effective Date, by Receiving Party from a Third Party on a non-confidential basis and such Third Party had the legal right to disclose such Confidential Information to Receiving Party;

9.2.3 is independently developed by the Receiving Party without reliance on Disclosing Party's Confidential Information, as evidenced by the contemporaneous written records of Receiving Party that are maintained in the ordinary course of business; or

9.2.4 Receiving Party already knows prior to the date of any disclosure by Disclosing Party, as evidenced by the contemporaneous written records of Receiving Party that are maintained in the ordinary course of business.

9.3 Disclosures Required by Law. In the event that Receiving Party is: (i) requested in any judicial or administrative proceeding or by any governmental or regulatory authority to disclose any Confidential Information, Receiving Party shall give Sunovion prompt notice of such request so that Disclosing Party may seek an appropriate protective order; or (ii) compelled by a judicial or administrative proceeding or by any governmental or regulatory authority to disclose any Confidential Information, Receiving Party shall give Disclosing Party prompt prior written notice of such event and shall furnish only that portion of such Confidential Information that is legally required and shall exercise all reasonable efforts to obtain reliable assurance that confidential treatment will be afforded to such Confidential Information.

9.4 Work Product. Notwithstanding that Sunovion will be the Disclosing Party with respect to the Work Product or Product Inventions: (i) the Work Product (including the Government Pricing Reports) and Product Inventions shall be deemed to be the Confidential Information of Urovant, and (ii) Urovant shall be deemed to be the "Disclosing Party" and Sunovion shall be deemed to be the "Receiving Party" with respect thereto.

9.5 Ownership. All Confidential Information is and will remain the sole and exclusive property of Disclosing Party. Except for the limited right to use Confidential Information solely in accordance with this Agreement, no ownership interests, rights or licenses whatsoever, either express or implied, are granted hereunder by Disclosing Party to Receiving Party under any patents or patent applications, copyrights, trademarks, trade secrets, or other intellectual property rights now or hereafter acquired, developed, or controlled by Disclosing Party. Disclosing Party retains all rights and remedies afforded under all patent, copyright, trade secret, and other Applicable Law for protecting confidential, proprietary, or trade secret information.

9.6 Use of Name. Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo, or trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 9.6 shall not prohibit either Party from making any disclosure identifying the other Party that, in the opinion of the disclosing Party's counsel, is required by Applicable Law; provided, that such Party shall submit the proposed disclosure identifying the other Party in writing to the other Party as far in advance as reasonably practicable (and in no event less than three (3) Business Days prior to the anticipated date of disclosure) so as to provide a reasonable opportunity to comment thereon.

9.7 Publicity. Neither Party shall issue any other public announcement, press release, or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent, except for any such disclosure that is, in the opinion of the disclosing Party's counsel, required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed. In the event a Party is, in the opinion of its counsel, required by Applicable Law or the rules of a stock exchange on which its securities are listed to make such a public disclosure, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable so as to provide a reasonable opportunity to comment thereon.

9.8 Injunctive Relief. Each Party agrees that (a) the Disclosing Party may be irreparably injured by an impending or existing breach of this Section 9; (b) money damages would not be an adequate remedy for any such breach; and (c) the Disclosing Party will be entitled to seek equitable relief, including injunctive relief and specific performance, without proof of damages or having to post a bond, as a remedy for any such breach. Such injunctive relief shall be in addition to any other rights or remedies the Disclosing Party may otherwise be entitled to.

10. OWNERSHIP; INVENTIONS; LICENSE GRANT

10.1 Ownership. Urovant shall own all: (i) materials, data, analyses, reports and other work product related solely to a Product generated by Sunovion in connection with the Services, including the Government Price Report ("Work Product"); and (ii) all inventions (whether patentable or not), improvements, developments and intellectual property rights related thereto, that in each case: (a) are conceived, reduced to practice, made or authored by Sunovion (whether solely or jointly) under this Agreement, and (b) relate solely to a Product ("Product Inventions"). All other ownership rights shall be determined in accordance with United States patent laws.

10.2 Disclosure and Assignment. Sunovion shall disclose all Work Product and Product Inventions to Urovant promptly after they are conceived, reduced to practice, made or authored. Sunovion hereby assigns to Urovant all of Sunovion's right, title and interest in any and all Work Product and Product Inventions without any additional consideration, and Sunovion shall reasonably assist Urovant in the prosecution, maintenance and enforcement of such IP, at Urovant's sole expense.

10.3 Sunovion Property. Notwithstanding Section 10.1, Sunovion will retain all right, title and interest in and to: (i) all materials, data, analyses, reports and work product (other than Work Product) that do not solely relate to the Products and are generated by or on behalf of Sunovion (whether alone or jointly with others) under this Agreement without use of, or reliance upon, Urovant's Confidential Information or Work Product, (ii) all programs, methodologies, policies, processes, platforms, technologies and other materials developed or licensed by Sunovion prior to or apart from performing the Services or its obligations under this Agreement and without use of, or reliance upon, Urovant's Confidential Information or Work Product ((i) and (ii) collectively, the "Sunovion Property"), regardless of whether such Sunovion Property is used in connection with Sunovion's performance of the Services or its obligations under this Agreement, and (iii) any improvements and modifications made by Sunovion to Sunovion Property without use of, or reliance upon, Urovant's Confidential Information or Work Product.

10.4 License Grant. Urovant hereby grants to Sunovion a non-exclusive license, with the right to grant sublicenses, under any intellectual property rights owned or controlled by Urovant, including with respect to the Work Product, solely to enable Sunovion to perform the Services. Except as otherwise expressly provided herein, nothing in this Agreement is intended to grant to either Party any rights under any intellectual property right of the other Party.

11. REPRESENTATIONS, WARRANTIES AND COVENANTS

11.1 Mutual. Each of the Parties hereby represent, warrant and covenant to the other Party that:

11.1.1 it is and will remain a corporation duly organized, validly existing and in good standing under the laws of its jurisdiction of organization.

11.1.2 the execution and delivery of this Agreement has been authorized by all requisite corporate action;

11.1.3 this Agreement is and will remain a valid and binding obligation of it, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors;

11.1.4 it is under no contractual or other obligation or restriction that is inconsistent with its execution or performance of this Agreement;

11.1.5 during the Term, it will not, directly or indirectly, enter into any agreement, either written or oral, or take part in any activity, that would cause an actual or potential conflict with its responsibilities under this Agreement; and

11.1.6 it, its Affiliates, and each of their respective officers, directors, employees and subcontractors, as applicable: (i) have not been debarred and are not subject to a pending debarment, and will not use in any capacity in connection with the Services, any person who has been debarred or is subject to a pending debarment, pursuant to section 306 of the United States Food, Drug and Cosmetic Act, 21 U.S.C. §335a, (ii) are not ineligible to participate in any federal and/or state healthcare programs or federal procurement or non-procurement programs (as that term is defined in 42 U.S.C. 1320a-7b(f)), including Medicare, Medicaid and Civilian Health and Medical Program of the Uniformed Services, (iii) are not disqualified by any government or regulatory agencies from performing specific services, and are not subject to a pending disqualification proceeding, and (iv) have not been convicted of a criminal offense related to the provision of healthcare items or services, and are not subject to any such pending action.

Each Party will promptly notify the other Party if it, its Affiliates or any of their respective officers, directors, employees and subcontractors, as applicable, are or become subject to the foregoing, or if any Claim relating to the foregoing is pending, or to the best of such Party's knowledge, is threatened. The non-breaching Party shall have the right to immediately terminate this Agreement if the representation and warranties in Section 11.1.6 is or becomes untrue.

11.2 Sunovion. Sunovion hereby represents, warrants and covenants to Urovant that:

11.2.1 it will perform the Services in accordance with Applicable Law; and

11.2.2 it will ensure that any Product Contracts include obligations with respect to compliance with laws (or a right to indemnification for a counterparty's failure to comply with laws) and obligations of confidentiality no less restrictive than those included in this Agreement, subject to any customary qualifications ordinarily applied to such obligations;

11.2.3 it has obtained and will maintain, at all times during the Term, the required licenses, permits and authorizations necessary to provide the Services and commercialize the Products in the Territory; and

11.2.4 it will not employ or contract with any individual or entity to perform any of the Services under this Agreement who is debarred, disqualified, excluded, or otherwise sanctioned by any local, state, federal, or international governmental body, or is subject to an administrative, civil, or criminal proceeding which could result in such sanctions by a governmental body.

11.3 Urovant. Urovant hereby represents, warrants, and covenants to Sunovion that:

11.3.1 it will perform its obligations in furtherance of the Services in accordance with Applicable Law;

11.3.2 it will provide current, accurate and complete sales and pricing data under the Urovant Government Contracts, Urovant Market Access Contracts, or otherwise to Sunovion for purposes of Sunovion's performance of the Services;

11.3.3 it will obtain and maintain, at all times during the Term, the required licenses, permits and authorizations necessary to commercialize the Products in the Territory;

11.3.4 the Products (i) are free from defect in design, material and workmanship, (ii) manufactured and commercialized in compliance with Applicable Law, including in accordance with cGMP, (iii) have been approved by FDA prior to sale, (iv) are not articles which may not be introduced into interstate commerce, (v) are not infringing upon the patents, trademarks or other intellectual property rights of any Third Party, and (vi) comply with all traceability aspects of the DSCSA;

11.3.5 it will not, directly or indirectly, claim any payment in any form from a government program for any Product utilization for which rebates or chargebacks are payable under an existing Urovant Market Access Contract;

11.3.6 it will not, directly or indirectly, enter into any discount arrangement with any Market Access Customer or any other arrangement that could impact the Government Pricing Report without providing prior notice to Sunovion;

11.3.7 it will not during the Term, begin any negotiations with, engage, or enter into any agreement with, directly or indirectly, any Wholesaler that is a party to a Wholesaler Contract, Sunovion GPO or Sunovion IDN without the prior written consent of Sunovion;

11.3.8 except as expressly permitted by this Agreement, it will not, during the Term and or a period of two (2) years thereafter, meet, communicate or correspond with any Wholesaler that is a party to a Wholesaler Contract, Sunovion GPO or Sunovion IDN regarding any subject that relates to the Services without (i) a representative of Sunovion present at such meeting or as a participant in such communication, or (ii) Sunovion's prior written approval of such communication; and

11.3.9 it will not, during the Term and for a period of two (2) years thereafter, actively solicit, directly or indirectly, the employment of any employee of a 3PL Provider, subject to customary exceptions for general solicitations not directly targeted at such employees.

For clarity, nothing in Section 11.3.7 shall restrict Urovant from negotiating with, engaging or entering into any agreement with a GPO or IDN that is not a Sunovion GPO or Sunovion IDN.

12. INDEMNIFICATION; LIMITATION OF LIABILITY

12.1 Indemnification by Sunovion. Sunovion agrees to indemnify, defend and hold Urovant, its Affiliates, and its and their respective officers, directors, employees, subcontractors, and agents (collectively, the "Urovant Indemnitees") harmless from and against any and all Losses resulting from any Claims by a Third Party to the extent such Claim results from, arises from or out of, relates to, is in the nature of, or is caused by: (i) any non-compliance of any federal, state or local governmental laws, rules, regulations or statutes by a 3PL Provider that is a party to a 3PL Contract, where such non-compliance relates to such 3PL Provider's failure to hold all necessary licenses, permits, and authorizations necessary to provide the 3PL Services or otherwise damages Urovant, (ii) a breach of any representation, warranty or covenant of Sunovion set forth in this Agreement, and (iii) the negligence, gross negligence or willful misconduct of Sunovion in connection with this Agreement; except, in each case, to the extent that such Losses (or part thereof) results from a Claim that is an indemnifiable event pursuant to Section 12.2, in which case Urovant shall indemnify the Sunovion Indemnitees for such Losses (or part thereof) in accordance with Section 12.2.

12.2 Indemnification by Urovant. Urovant agrees to indemnify, defend and hold Sunovion, its Affiliates, and its and their respective officers, directors, employees, permitted subcontractors and permitted agents (collectively, the "Sunovion Indemnitees") harmless from and against any and all Losses resulting from any Claims by a Third Party to the extent such Claim results from, arises from or out of, relates to, is in the nature of, or is caused by: (i) death of, or bodily injury to, any person on account of the use of any Product, (ii) disputes that arise between Urovant and a Market Access Customer, Government Entity, or a GPO or IDN that is not a Sunovion GPO or Sunovion IDN that relate to a Urovant Market Access Contract, Urovant Government Contract, or a Urovant GPO/IDN Contract, respectively, (iii) disputes that arise between Sunovion or Urovant and a Wholesaler, Sunovion GPO, or Sunovion IDN that relate directly to a Product; provided that if such dispute does not solely relate to a Product, then the Parties shall negotiate in good faith an appropriate allocation of responsibility under the circumstances; (iv) any recall, quarantine, warning or withdrawal of any Product, (v) government pricing calculations performed by Sunovion on behalf of Urovant in connection with the GPR Services; provided that such calculations were performed by Sunovion in accordance with Sunovion's government price calculation methodologies approved by Urovant pursuant to Section 5.5, (vi) a breach of any representation, warranty or covenant of Urovant set forth in this Agreement, and (vii) the negligence, gross negligence or willful misconduct of Urovant in connection with this Agreement; except, in each case, to the extent that such Losses (or part thereof) results from a Claim that is an indemnifiable event pursuant to Section 12.1, in which case Urovant shall indemnify the Sunovion Indemnitees for such Losses (or part thereof) in accordance with Section 12.1.

12.3 Indemnification Procedure. The indemnifying party's agreement and obligation to indemnify, defend and hold the other harmless is conditioned on the indemnified party:

12.3.1 promptly providing written notice to the indemnifying party of any Claim resulting from, arising from or out of, relating to, in the nature of, or caused by the indemnified activities set forth in Section 12.1 and Section 12.2, at most within thirty (30) days after becoming aware of such Claim; provided that failure to provide prompt notice will relieve the indemnifying party of its indemnification obligations only to the extent that indemnifying party has been materially prejudiced as a result of such failure;

12.3.2 permitting the indemnifying party to assume full responsibility to select its choice of counsel, investigate, prepare for and defend against any such Claim; provided that the indemnified party shall have the right to retain separate legal counsel and participate in any defense of any Claim at its own expense;

12.3.3 reasonably assisting the indemnifying party, at the indemnifying party's reasonable expense, in the investigation of, preparation for, and defense of any such Claim; and

12.3.4 not compromising or settling such Claim without the indemnifying party's written consent.

The indemnifying party may not, without the indemnified party's written consent, compromise or settle any Claim resulting from, arising from or out of, relating to, in the nature of, or caused by the indemnified activities set forth in Section 12.1 and Section 12.2 if such compromise or settlement admits liability on behalf of or imposes any restrictions or obligations on the indemnified party. The indemnifying party shall make quarterly payments to the indemnified parties for any documented Losses resulting from such Claim.

12.4 Limitations of Liability.

12.4.1 EXCEPT WITH REGARD TO (A) OBLIGATIONS UNDER SECTION 12.1 AND SECTION 12.2 (INDEMNIFICATION), AND (B) DAMAGES ARISING FROM A PARTY'S GROSS NEGLIGENCE, WILLFUL MISCONDUCT OR FRAUD, IN NO EVENT SHALL A PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY CONSEQUENTIAL, INDIRECT, INCIDENTAL, EXEMPLARY, PUNITIVE, AND SPECIAL DAMAGES.

12.4.2 EXCEPT WITH REGARD TO LOSSES ARISING FROM A PARTY'S (A) A BREACH OF SECTION 9 (CONFIDENTIALITY), (B) OBLIGATIONS UNDER SECTION 12.1 AND SECTION 12.2 (INDEMNIFICATION), (C) FAILURE TO COMPLY WITH APPLICABLE LAW, (D) GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, AND (E) FRAUD, IN NO EVENT SHALL SUNOVION'S LIABILITY FOR LOSSES IN CONNECTION WITH THIS AGREEMENT EXCEED THREE (3) TIMES THE SERVICE CHARGES ACTUALLY PAID BY UROVANT TO SUNOVION UNDER THIS AGREEMENT DURING THE TWELVE (12) MONTH PERIOD PRECEDING THE EVENT GIVING RISE TO SUCH LOSSES.

12.4.3 NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, (I) SUNOVION SHALL HAVE NO LIABILITY FOR THIRD PARTY CLAIMS SOLELY ARISING OUT OF GOVERNMENT PRICING CALCULATIONS PERFORMED BY SUNOVION ON BEHALF OF UROVANT UNDER THIS AGREEMENT; PROVIDED THAT SUCH CALCULATIONS WERE PERFORMED BY SUNOVION IN ACCORDANCE WITH SUNOVION'S GOVERNMENT PRICE CALCULATION METHODOLOGIES APPROVED BY UROVANT PURSUANT TO SECTION 5.5, AND (II) TO THE EXTENT ANY PRODUCTS ARE LOST OR DAMAGED WHILE IN THE CUSTODY OF A 3PL PROVIDER, UROVANT HEREBY AGREES TO THE LOSS AND DAMAGE LIMITATIONS SET FORTH IN THE APPLICABLE CONTRACT BETWEEN SUNOVION AND SUCH 3PL PROVIDER AND SUNOVION SHALL HAVE NO LIABILITY WITH RESPECT THERETO OTHER THAN TO USE COMMERCIALLY REASONABLE EFFORTS TO ENFORCE SUCH CONTRACT.

13. INSURANCE

13.1 Urovant Insurance. Urovant shall (a) maintain (i) general liability insurance including premises and operations, broad form property damage, independent contractors, and contractual liability covering its obligations under this Agreement, with a combined single limit of not less than $2,000,000 on a per occurrence and aggregate basis, and (ii) product liability insurance including contractual liability for all products and completed operations and any work supplied pursuant to the terms and conditions of this Agreement, not less than $10,000,000 on a per occurrence and aggregate basis, and (b) add Sunovion as an additional insured to all of the above stated policies.

13.2 Sunovion Insurance. Sunovion shall (a) maintain (i) general liability insurance including premises and operations, broad form property damage, independent contractors, and contractual liability covering its obligations under this Agreement, with a combined single limit of not less than $2,000,000 on a per occurrence and aggregate basis, and (ii) product liability insurance including contractual liability for all products and completed operations and any work supplied pursuant to the terms and conditions of the Agreement, not less than $10,000,000 on a per occurrence and aggregate basis, and (b) add Urovant as an additional insured to all of the above stated policies.

13.3 Claims-Made Policies. If any of the above stated policies are on a claims-made basis, then the insured party shall maintain such policy in effect through a period of not less than one (1) year following the termination or expiration of this Agreement.

14. TERM; TERMINATION

14.1 Term. This Agreement shall become effective as of the Effective Date and, unless earlier terminated pursuant to the terms of this Agreement, shall continue in full force and effect for three (3) years (the "Initial Term"). Thereafter, this Agreement will automatically extend for additional one (1) year periods (each, a "Renewal Term", each Renewal Term collectively with the Initial Term, the "Term"), unless either Party provides the other Party written notice of termination of this Agreement not later than nine (9) months prior to the expiration of the Initial Term or any Renewal Term, in which case this Agreement shall terminate upon the expiration of the Initial Term or then current Renewal Term.

14.2 Termination by for Material Breach. Either Party may terminate this Agreement upon sixty (60) days prior written notice to the other Party if the other Party materially breaches this Agreement and fails to cure the breach during such notice period.

14.3 Termination for Insolvency. Subject to applicable bankruptcy laws, either Party may terminate this Agreement effective immediately in the event that the other Party: (i) has become insolvent (defined as such Party being subject to a voluntary or involuntary bankruptcy petition which is not dismissed) or has been dissolved or liquidated, has filed itself a petition, case or other proceeding under the applicable bankruptcy laws relating to bankruptcy, dissolution, liquidation, winding up or reorganization; (ii) makes a general assignment for the benefit of creditors; or (iii) has a receiver, custodian, trustee or other person exercising similar functions appointed for all or substantially all of its assets.

14.4 Termination by Sunovion. In the event of a Change of Control of Urovant, Sunovion may terminate this Agreement upon ten (10) days prior written notice to Urovant (or its successor).

14.5 Termination by Urovant.

14.5.1 Upon written notice to Sunovion, Urovant may terminate this Agreement if Sunovion has failed [* * *]; provided that prior to any such termination by Urovant, the Parties will cooperate in good faith to identify and negotiate in good faith the execution of alternative services that may be provided to Urovant by Sunovion in lieu of such termination; provided further that if Sunovion fulfils all of its obligations pursuant to Section 4.2.1 before Urovant terminates this Agreement pursuant to this Section 14.5.1, then Urovant shall no longer have the right to terminate this Agreement pursuant to this Section 14.5.1.

14.5.2 Urovant may terminate this Agreement if Sunovion has failed [* * *]; provided that prior to any such termination by Urovant, the Parties will cooperate in good faith to identify and negotiate in good faith the execution of alternative services that may be provided to Urovant by Sunovion in lieu of such termination; [* * *].

14.5.3 In the event of a Change of Control of Sunovion, Urovant may terminate this Agreement upon ten (10) days prior written notice to Sunovion (or its successor).

14.5.4 Urovant may terminate this Agreement for any reason upon ninety (90) days' prior written notice, provided that such termination shall only be effective upon the expiration of such ninety (90) day period if Sunovion has received the Break-Up Fee.

14.6 Effect of Termination or Expiration.

14.6.1 Upon expiration of this Agreement or termination of this Agreement for any reason, neither Urovant nor Sunovion will have any further obligations under this Agreement, except that:

(a) any liabilities that relate to the Services and that arise before, on, or after the termination or expiration this Agreement shall be the responsibility of Urovant even if claims for such liabilities are first made after the termination or expiration this Agreement;

(b) each Party will promptly return to the other Party all Confidential Information and all copies of Confidential Information associated with this Agreement, provided that each Party may retain one copy of Confidential Information to determine its obligations hereunder; and

(c) the terms and conditions under Sections 1 (Definitions), 8.2 (Fees; Invoices; Payments), 8.3 (Taxes), 9 (Confidentiality), 10 (Ownership; Inventions), 12 (Indemnification; Limitation of Liability), 14.6 (Effect of Termination or Expiration) and 15 (Miscellaneous) will survive any such termination or expiration of this Agreement.

14.6.2 Upon notice of termination of this Agreement pursuant to Section 14.5.4, Urovant shall pay to Sunovion, prior to the effective date of such termination, a break-up fee of (a) [* * *], if this Agreement is terminated within one (1) year of the Effective Date; and (b) [* * *], if this Agreement is terminated within two (2) years of the Effective Date (each, (a) and (b), a "Break-Up Fee").

15. MISCELLANEOUS

15.1 Publicity. Neither party may use the other Party's name or company artwork (for example, logo) on a website or in any form of advertising, promotion or publicity, including press releases, without the prior written consent of the other Party. This term does not restrict a Party's ability to use the other party's name in filings with the United States Securities and Exchange Commission or foreign equivalent, the United States Food and Drug Administration, or other governmental agencies, or when required by law to make a public disclosure.

15.2 Inspections; Other Proceedings. Each Party shall promptly notify the other Party upon receiving notice of an inspection, audit, enforcement action, or request for information by any regulatory or enforcement authority concerning this Agreement, the Services, or the Products ("Governmental Contact"). The Party in receipt of the Governmental Contact shall provide copies of any regulatory filings or formal communications concerning the other Party, this Agreement, the Services, or the Products to such other Party.

15.3 Notices. All notices must be in writing and sent to the address for the recipient set forth below or at such other address as the recipient may specify in writing under this procedure. All notices must be given (a) by personal delivery, with receipt acknowledged, or (b) by first class, prepaid certified or registered mail, return receipt requested, or (c) by prepaid national express delivery service. Notices will be effective upon receipt or at a later date stated in the notice.

If to SUNOVION:	If to UROVANT:
Sunovion Pharmaceuticals Inc. 84 Waterford Drive Marlborough, MA 01752 Attn: President and CEO	Urovant Sciences, Inc. Urovant Sciences GmbH 5281 California Avenue, Suite 100 Irvine, CA 92617 Attn: President and CEO
With a copy to:	With a copy to:
Sunovion Pharmaceuticals Inc. 84 Waterford Drive Marlborough, MA 01752 Attn: General Counsel	Urovant Sciences, Inc. 5281 California Avenue, Suite 100 Irvine, CA 92617 Attn: General Counsel
With a copy to (which shall not constitute notice):	With a copy to (which shall not constitute notice):
Reed Smith LLP 506 Carnegie Center, Suite 300 Princeton, NJ 08540-7839 Attn: Diane Frenier	O'Melveny & Myers LLP 610 Newport Center Drive, Suite 1700 Newport Beach, CA 92648 Attn: Mark Peterson

15.4 Assignment. Neither Party will assign, transfer or otherwise dispose of this Agreement in whole or in part to any Third Party without the prior written consent of the other Party; provided that each Party may assign this Agreement, in whole or in part, to any Affiliate; provided that such Affiliate remains an Affiliate of the initial Party during the Term. Any assignment in violation of this Section 15.4 shall be null and void. No assignment will relieve either Party of the performance of any accrued obligation that such Party may then have under this Agreement. This Agreement shall be binding upon, and inure to the benefit of the Parties and their respective legal representatives, heirs, successors and permitted assigns.

15.5 Change of Control.

15.5.1 Each Party (or its successor) shall provide the other Party with written notice of any Change of Control within five (5) days following the closing date of such transaction.

15.5.2 If: (a) Urovant undergoes a Change of Control and Sunovion does not terminate this Agreement pursuant to Section 14.4, or (b) Sunovion undergoes a Change of Control and Urovant does not terminate this Agreement pursuant to Section 14.5.4, then, in each case, the Party that undergoes a Change of Control shall: (x) ensure that all activities performed by or on behalf of such Party for the benefit of its successor are kept separate from the activities performed under or in connection with this Agreement; and (y) establish and cause its applicable Affiliates to establish reasonable internal safeguards that prevent any Confidential Information of the other Party from being utilized for the benefit of successor of the Party that undergoes a Change of Control.

15.6 Independent Contractor. All Services will be rendered by Sunovion as an independent contractor of Urovant for federal, state and local income tax purposes and for all other purposes. Neither Party will represent itself to be a partner or joint venturer of or with the other Party.

15.7 Severability; Reformation. If for any reason a court of competent jurisdiction finds any provision of this Agreement or any portion of such a provision to be invalid or unenforceable, such provision will be reformed to the extent required to make the provision valid and enforceable to the maximum extent permitted by Applicable Law.

15.8 Entire Agreement. This Agreement, including the attached Exhibits, each of which is incorporated herein, constitutes the entire agreement between the Parties with respect to the specific subject matter of this Agreement, and supersedes all negotiations, prior discussions, agreements or understandings, whether written or oral, with respect to the subject matter hereof.

15.9 Force Majeure. Nonperformance of either Party shall be excused to the extent that such performance is rendered impossible by fire, flood, earthquake, mass disaster, governmental acts, orders or restrictions (including shelter-in-place orders, quarantine orders or curfews), terrorism, epidemic, pandemic (including COVID-19) or any other reason where failure to perform is beyond the reasonable control of the non-performing Party and is not caused by the non-performing Party's negligence. If any condition contemplated by this Section 15.9 shall continue for a period of sixty (60) days, the non-breaching Party shall have the option of terminating this Agreement and, in such event, neither Party shall incur any liability for performance or payment other than for the Services satisfactorily provided up to and including the date of termination.

15.10 Waiver. No waiver of any term, provision or condition of this Agreement in any one or more instances will be deemed to be or construed as a further or continuing waiver or a waiver of any other term, provision or condition of this Agreement. Any such waiver must be evidenced by an instrument in writing executed by an officer authorized to execute such waivers.

15.11 Governing Law. The validity, interpretation and enforcement of this Agreement, matters arising out of or related to this Agreement or its making, performance or breach, and related matters shall be governed by the laws of the State of Delaware without reference to choice of law doctrine. The Parties expressly reject any application to this Agreement of (a) the United Nations Convention on Contracts for the International Sale of Goods, and (b) the 1974 Convention on the Limitation Period in the International Sale of Goods, as amended by that certain Protocol, done at Vienna on April 11, 1980.

15.12 Dispute Resolution.

15.12.1 Subject to Section 7.1 and 7.2, if a dispute arises between the Parties in connection with or relating to this Agreement, including disputes that arise within the scope of the JGC, or any document or instrument delivered in connection herewith (a "Dispute"), it shall be resolved pursuant to this Section 15.12. Any Dispute shall first be referred to the Chief Executive Officers of the Parties, who shall confer in good faith on the resolution of the issue. Any final decision mutually agreed to by the Chief Executive Officers shall be conclusive and binding on the Parties. If the Chief Executive Officers are not able to agree on the resolution of any such issue within thirty (30) days (or such other period of time as mutually agreed by the Chief Executive Officers) after such issue was first referred to them, then, either Party may, by written notice to the other Party, elect to escalate the Dispute to DSP. In the event that DSP is unable to resolve a Dispute, a Party may submit such Dispute to non-binding mediation. In the even that non-binding mediation is unable to resolve such Dispute, a Party shall submit such Dispute to binding arbitration in accordance with Section 15.12.2.

15.12.2 If any Dispute has not been resolved by good faith negotiations between the Parties pursuant to Section 15.12.1, then the Parties shall endeavor to settle the dispute by submitting the matter to binding arbitration by the American Arbitration Association ("AAA") in New York, New York. Such arbitration may be conducted under the commercial rules then in effect for the AAA except as provided herein. All such proceedings shall be held in English and a transcribed record prepared in English. Each Party shall choose one (1) arbitrator within thirty (30) days of receipt of notice of the intent to arbitrate. Such arbitrators shall thereafter choose a third arbitrator within thirty (30) days of their appointment. Any arbitrator chosen by the Parties or arbitrators will not have a material financial interest in any Party and will have significant experience with the arbitration of similar large, complex, commercial disputes between pharmaceutical companies. Each Party in any arbitration proceeding commenced hereunder shall bear such Party's own costs and expenses (including expert witness and attorneys' fees) of investigating, preparing and pursuing such arbitration claim. Nothing in this Agreement shall be deemed as preventing either Party from seeking injunctive relief (or any other provisional remedy) from any court having jurisdiction over the Parties and the subject matter of the dispute as necessary to protect either Party's name, intellectual property or Confidential Information. If the Dispute involves scientific or technical matters, any arbitrator chosen hereunder shall have educational training and/or experience sufficient to demonstrate a reasonable level of knowledge in the applicable field. The award rendered by the arbitrators with respect to such Dispute shall be written, final and non-appealable, and judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. The existence and contents of the arbitration shall be kept confidential by each Party except to the extent that disclosure may be required to fulfil a legal duty, protect or pursue a legal right, or enforce or challenge an award in legal proceedings.

15.13 Headings; Interpretation. This Agreement contains headings only for convenience and the headings do not constitute a form or part of this Agreement, and should not be used in the construction of this Agreement. Except where the context expressly requires otherwise: (i) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa); (ii) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation"; (iii) the word "will" shall be construed to have the same meaning and effect as the word "shall"; (iv) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein); (v) any reference herein to any Person shall be construed to include the Person's successors and assigns; (vi) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof; (vii) all references herein to Sections, or Exhibits shall be construed to refer to Sections, or Exhibits of this Agreement, and references to this Agreement include all Schedules hereto; (viii) the word "notice" means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (ix) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise, including by e-mail; (x) unless stated otherwise, references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof; (xi) the term "or" shall be interpreted in the inclusive sense commonly associated with the term "and/or"; and (xii) each Party has used its legal counsel in the negotiation of this Agreement, and the Agreement will not be construed against either Party as the drafter.

15.14 Counterparts. This Agreement may be executed in any number of counterparts, each of which will be deemed to be an original, and all of which together will constitute one and the same instrument.

[Signature Page to Follow]

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed in duplicate by their duly authorized representatives, effective as of the Effective Date.

Sunovion Pharmaceuticals Inc.		**Urovant Sciences GmbH**	
By:	/s/ Thomas Gibbs	By:	/s/ Sascha Bucher
Name:	Thomas E. Gibbs	Name:	Sascha Bucher
Title:	SVP, Chief Commercial Officer	Title:	Director

EXHIBIT A

3PL SERVICES

1. Upon request by a 3PL Provider, Sunovion shall facilitate communication between Urovant and such 3PL Provider to which a Product has been consigned; and

2. Any other services (which may result in additional fees being added to this Agreement, subject to customary, good faith negotiation) that are agreed upon in writing by the Parties from time to time.

EXHIBIT B

WHOLESALER, GPO, AND IDN SERVICES

1. Sunovion shall manage and process all orders (and adjustments thereto) for Products from Wholesalers and GPO/IDNs in accordance with the terms and conditions of the applicable Wholesaler Contract or GPO/IDN Contract, which shall consist of: (i) the necessary interaction with the applicable Wholesaler, GPO, or IDN to process orders of the Products, (ii) causing the shipment of the Products to the applicable Wholesaler via a 3PL Provider, and (iii) submission of invoices to an applicable Wholesaler or GPO/IDN for such Products;

2. Upon Sunovion's receipt of payment from a Wholesaler for an applicable invoice, Sunovion shall transfer such amount to the Escrow Fund, or a separate fund as agreed upon by the Parties in writing;

3. Sunovion shall process returns of the Products from Wholesalers in accordance with the terms and conditions of the applicable Wholesaler Contract;

4. Sunovion shall communicate all quality complaints and adverse event reports related to a Product received by Sunovion in connection with a Wholesaler Contract to Urovant or Urovant's designee in a timely manner consistent with Applicable Law and the policies and procedures agreed upon by the Parties; and

5. Any other services (which may result in additional fees being added to this Agreement, subject to customary, good faith negotiation) that are agreed upon in writing by the Parties from time to time.

EXHIBIT C

CONTRACTING SERVICES

1. Sunovion shall incorporate the necessary information from each of the Urovant Market Access Contracts, Urovant Government Contracts, and Urovant GPO/IDN Contracts into the necessary Sunovion systems to facilitate performance of the RCP Services and GPR Services; and

2. Any other services (which may result in additional fees being added to this Agreement, subject to customary, good faith negotiation) that are agreed upon in writing by the Parties from time to time.

EXHIBIT D

RCP SERVICES

1. Sunovion shall validate all invoices received from Market Access Customers, Sunovion GPOs, GPOs that are not Sunovion GPOs, Sunovion IDNs, IDNs that are not Sunovion IDNs, Wholesalers, 3PL Providers, or others for RCP Payments to ensure such invoices apply to eligible utilization of the applicable Products only, using a validation process agreed upon by the Parties;

2. Sunovion shall process and pay, using funds from the Escrow Fund, all: (i) validated rebate invoices and claim submissions received from a Payor or a Government Entity related to the applicable Products (such payment, the "Rebate Payment"), and (ii) applicable administrative fees on eligible utilization owed to the applicable Payor related to the applicable Products (such fees, the "Payor Fees"), in each case, pursuant to the terms of an applicable Urovant Market Access Contract or Urovant Government Contract;

3. Sunovion shall: (i) account for all chargeback submissions received from Wholesalers and Government Entities, in each case, for the Products (such amount, the "Chargeback Offsets"), and (ii) process and pay, using funds from the Escrow Fund: (a) all valid distribution fees or similar service fee claims received from a Wholesaler pursuant to an applicable Wholesaler Contract related to the Products (such fees, the "DS Fees"), and (b) applicable administrative fees owed to the applicable Sunovion GPO, GPOs that are not Sunovion GPOs, Sunovion IDNs, and IDNs that are not Sunovion IDNs related to the Products (such fees, the "GPO/IDN Fees"), in each case, pursuant to the terms of the Wholesaler Contract, GPO/IDN Contract or Urovant GPO/IDN Contract, as applicable;

4. Sunovion shall: (i) process adjustments to RCP Payments consistent with the applicable contract, and (ii) subject to Section 7.1, escalate contracts disputes related to the applicable Product that arise under the Wholesaler Contracts, GPO/IDN Contracts, Urovant GPO/IDN Contracts, Urovant Market Access Contracts and Urovant Government Contracts to Urovant; and

5. Any other services (which may result in additional fees being added to this Agreement, subject to customary, good faith negotiation) that are agreed upon in writing by the Parties from time to time.

EXHIBIT E

GPR SERVICES

1. Sunovion shall, solely with respect to the Products and to enable Urovant to comply with its submission requirements to Centers for Medicare and Medicaid Services, the Health Resources and Services Administration, and the VA, provide to Urovant the applicable price reporting metrics required under the Medicaid Rebate Program, the PHS 340B Program, Medicare Part B, the VA Federal Supply Schedule contract, and the VA Master Agreement ("Government Pricing Programs"), including : (i) the monthly AMP within twenty five (25) days after the end of each calendar month, and (ii) the ASP, Best Price, quarterly AMP, 340B Ceiling Price, the Non-FAMP, and other metrics required under the Government Pricing Programs within twenty five (25) days after the end of each calendar quarter or other applicable reporting period, in each case (i) and (ii), such metrics shall be determined in accordance with Applicable Law and [* * *] and shall be reported to Urovant in a form and format agreed to by the Parties (each, a "Government Pricing Report"). Sunovion acknowledges and agrees that each Government Pricing Report shall be delivered timely to Urovant.

2. Sunovion shall certify to Urovant that each such Government Pricing Report provided by Sunovion to Urovant is accurate and consistent with Sunovion's methodologies, policies and procedures.

3. [* * *].

4. Any other services, including any services related to state supplemental Medicaid rebate agreements (which may result in additional fees being added to this Agreement, subject to customary, good faith negotiation) that are agreed upon in writing by the Parties from time to time.

EXHIBIT F

REGULATORY SERVICES

1. Sunovion shall: (i) interface with the applicable Wholesalers, and (ii) cooperate with Urovant, in each case, in the event that a Product is recalled or is subject to an investigation under DSCSA for being a suspect or illegitimate product, or is otherwise subject to a product hold; and (iii) not, except as required by Applicable Law, provide any communication to any regulatory or other Third Party, including customers of the Products, without prior written consent of Urovant; and

2. Any other services (which may result in additional fees being added to this Agreement, subject to customary, good faith negotiation) that are agreed upon in writing by the Parties from time to time.

EXHIBIT G

SUNOVION REPORTS

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Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, James Robinson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Urovant Sciences Ltd.;

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

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

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

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

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

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

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

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

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

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

Date: August 13, 2020

By: /s/ James Robinson
James Robinson
Principal Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ajay Bansal, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Urovant Sciences Ltd.;

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

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

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

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

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

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

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

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

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

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

Date: August 13, 2020

By: /s/ Ajay Bansal
Ajay Bansal
Principal Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Urovant Sciences Ltd. (the "Company") for the period ended June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, James Robinson, Principal Executive Officer of the Company, hereby certifies, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and 18 U.S.C. Section 1350, that to the best of his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

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

Date: August 13, 2020

By: /s/ James Robinson
James Robinson
Principal Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Urovant Sciences Ltd. (the "Company") for the period ended June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Ajay Bansal, Principal Financial Officer of the Company, hereby certifies, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and 18 U.S.C. Section 1350, that to the best of his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

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

Date: August 13, 2020

By: /s/ Ajay Bansal
Ajay Bansal
Principal Financial Officer