
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2017

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: 001-36687

XENON PHARMACEUTICALS INC.

(Exact name of Registrant as Specified in its Charter)

Canada

(State or other jurisdiction of
incorporation or organization)

200-3650 Gilmore Way

Burnaby, British Columbia, Canada

(Address of principal executive offices)

98-0661854

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

V5G 4W8

(Zip Code)

Registrant's telephone number, including area code: (604) 484-3300

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or 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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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 July 31, 2017, the registrant had 17,998,420 common shares, without par value, outstanding.

**XENON PHARMACEUTICALS INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2017**

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In this Quarterly Report on Form 10-Q, "we," "our," "us," "Xenon," and "the Company" refer to Xenon Pharmaceuticals Inc. and its subsidiary. "Xenon," the Xenon logo and "Extreme Genetics" are the property of Xenon Pharmaceuticals Inc. and are registered in the United States and used or registered in various other jurisdictions. This report contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this report may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

XENON PHARMACEUTICALS INC.

Consolidated Balance Sheets

(Unaudited)

(Expressed in thousands of U.S. dollars except share amounts)

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 23,090	\$ 17,095
Marketable securities	28,606	47,051
Accounts receivable	198	200
Prepaid expenses and other current assets	739	1,329
	52,633	65,675
Prepaid expenses, long term	285	408
Property, plant and equipment, net	1,308	1,404
Total assets	\$ 54,226	\$ 67,487
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued expenses (note 6)	3,774	3,586
	\$ 3,774	\$ 3,586
Shareholders' equity:		
Common shares, without par value; unlimited shares authorized; issued and outstanding: 17,998,420 (December 31, 2016 - 17,930,590) (note 7a)	173,841	173,246
Additional paid-in capital	35,182	34,326
Accumulated deficit	(157,581)	(142,681)
Accumulated other comprehensive loss	(990)	(990)
	\$ 50,452	\$ 63,901
Total liabilities and shareholders' equity	\$ 54,226	\$ 67,487
Collaboration agreements (note 8)		
Commitments and contingencies (note 9)		
Subsequent event (note 11)		

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

XENON PHARMACEUTICALS INC.

Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(Expressed in thousands of U.S. dollars except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenue:				
Collaboration revenue (note 8)	\$ 15	\$ 412	\$ 30	\$ 981
Royalties	—	1	1	33
	15	413	31	1,014
Operating expenses:				
Research and development	6,109	5,103	12,012	9,467
General and administrative	1,799	1,676	3,899	3,571
	7,908	6,779	15,911	13,038
Loss from operations	(7,893)	(6,366)	(15,880)	(12,024)
Other income:				
Interest income	109	123	258	222
Foreign exchange gain	404	227	725	2,523
Net loss and comprehensive loss	(7,380)	(6,016)	(14,897)	(9,279)
Net loss per common share (note 4):				
Basic	\$ (0.41)	\$ (0.42)	\$ (0.83)	\$ (0.64)
Diluted	\$ (0.41)	\$ (0.42)	\$ (0.84)	\$ (0.65)
Weighted-average common shares outstanding (note 4):				
Basic	17,997,194	14,408,108	17,971,702	14,401,054
Diluted	18,015,748	14,434,602	17,995,109	14,428,160

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

XENON PHARMACEUTICALS INC.

Consolidated Statement of Shareholders' Equity

(Unaudited)

(Expressed in thousands of U.S. dollars except share amounts)

	Common shares		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss (1)	Total shareholders' equity
	Shares	Amount				
Balance as of						
December 31, 2015	14,385,336	\$ 148,634	\$ 33,083	\$ (119,693)	\$ (990)	\$ 61,034
Net loss for the year				(22,997)		(22,997)
Issuance of common shares, net of issuance costs	3,450,000	23,832				23,832
Stock-based compensation expense			2,186			2,186
Issued pursuant to exercise of stock options	95,254	780	(657)	9		132
Fair value adjustment upon reclassification of stock options			(286)			(286)
Balance as of						
December 31, 2016	17,930,590	\$ 173,246	\$ 34,326	\$ (142,681)	\$ (990)	\$ 63,901
Net loss for the period				(14,897)		(14,897)
Stock-based compensation expense			1,271			1,271
Issued pursuant to exercise of stock options	67,830	595	(415)	(3)		177
Balance as of						
June 30, 2017	17,998,420	\$ 173,841	\$ 35,182	\$ (157,581)	\$ (990)	\$ 50,452

(1) Our accumulated other comprehensive loss is entirely related to historical cumulative translation adjustments from the application of U.S. dollar reporting when the functional currency of the Company was the Canadian dollar.

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

XENON PHARMACEUTICALS INC.
Consolidated Statements of Cash Flows
(Unaudited)
(Expressed in thousands of U.S. dollars)

	Six Months Ended June 30,	
	2017	2016
Operating activities:		
Net loss	\$ (14,897)	\$ (9,279)
Items not involving cash:		
Depreciation and amortization	334	531
Stock-based compensation	1,076	1,006
Unrealized foreign exchange gain	(819)	(2,508)
Changes in operating assets and liabilities:		
Accounts receivable	5	(333)
Prepaid expenses, and other current assets	590	(96)
Prepaid expenses, long term	123	462
Accounts payable and accrued expenses	326	1
Deferred revenue	—	(157)
Net cash used in operating activities	(13,262)	(10,373)
Investing activities:		
Purchases of property, plant and equipment	(238)	(205)
Purchase of marketable securities	(22,281)	(15,300)
Proceeds from marketable securities	41,099	—
Net cash provided by (used in) investing activities	18,580	(15,505)
Financing activities:		
Issuance of common shares pursuant to exercise of stock options	177	82
Net cash provided by financing activities	177	82
Effect of exchange rate changes on cash and cash equivalents	500	2,355
Increase (decrease) in cash and cash equivalents	5,995	(23,441)
Cash and cash equivalents, beginning of period	17,095	58,651
Cash and cash equivalents, end of period	\$ 23,090	\$ 35,210
Supplemental disclosures:		
Interest received	\$ 457	\$ 204
Supplemental disclosures of non-cash transactions:		
Fair value of options exercised on a cashless basis	25	4

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

XENON PHARMACEUTICALS INC.

Notes to Consolidated Financial Statements

(Unaudited)

(Expressed in thousands of U.S. dollars except share and per share amounts)

1. Nature of the business:

Xenon Pharmaceuticals Inc. (the "Company"), incorporated in 1996 under the British Columbia Business Corporations Act and continued federally in 2000 under the Canada Business Corporation Act, is a clinical-stage biopharmaceutical company discovering and developing a pipeline of differentiated therapeutics for orphan indications that it intends to commercialize on its own, and for larger market indications that it intends to partner with global pharmaceutical companies.

2. Basis of presentation:

These consolidated financial statements are presented in U.S. dollars.

The Company has one wholly-owned subsidiary as at June 30, 2017, Xenon Pharmaceuticals USA Inc., which was incorporated in Delaware on December 2, 2016.

These unaudited interim consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All intercompany transactions and balances have been eliminated on consolidation.

The accompanying unaudited interim consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") and pursuant to the rules and regulations of the United States Securities and Exchange Commission ("SEC") for interim financial information. Accordingly, these consolidated financial statements do not include all of the information and footnotes required for complete consolidated financial statements and should be read in conjunction with the audited consolidated financial statements and notes for the year ended December 31, 2016 and included in the Company's 2016 Annual Report on Form 10-K filed with the SEC and with the securities commissions in British Columbia, Alberta and Ontario on March 8, 2017.

These unaudited interim consolidated financial statements reflect all adjustments, consisting of normal recurring adjustments, which, in the opinion of management, are necessary for a fair presentation of results for the interim periods presented. The results of operations for the three and six month periods ended June 30, 2017 and 2016 are not necessarily indicative of results that can be expected for a full year. These unaudited interim consolidated financial statements follow the same significant accounting policies as those described in the notes to the audited consolidated financial statements of the Company included in the Company's 2016 Annual Report on Form 10-K for the year ended December 31, 2016. Certain comparative figures have been reclassified to conform to the consolidated financial statement presentation adopted for the current period.

3. Future changes in accounting policies:

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers (ASC 606) to clarify the principles of recognizing revenue and to develop a common revenue standard that would remove inconsistencies in revenue requirements, leading to improved comparability of revenue recognition practices across entities and industries. The standard, as subsequently amended, stipulates that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The new guidance will be effective for public entities for fiscal years and interim periods within those years, beginning after December 15, 2017. The Company has begun its evaluation and identified two significant collaboration agreements with respect to revenue, the collaborative development and license agreements with Teva Pharmaceutical Industries, Ltd. and Genentech, a member of the Roche Group, described in notes 9(a) and (b), respectively, to the audited consolidated financial statements of the Company included in the Company's 2016 Annual Report on Form 10-K for the year ended December 31, 2016. The Company is evaluating the new guidance as it applies to revenue previously recognized as well as milestone payments the Company is eligible to receive in future periods under these agreements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842): Recognition and Measurement of Financial Assets and Financial Liabilities. The update requires the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous U.S. GAAP. The new guidance retains a distinction between finance leases and operating leases, with cash payments from operating leases classified within operating activities in the statement of cash flows. These amendments will be effective for public entities for fiscal years and interim periods within those years, beginning after December 15, 2018. The Company is currently evaluating the new guidance to determine the impact it will have on the Company's consolidated financial statements.

4. Net income (loss) per common share:

Basic net income (loss) per common share is computed by dividing the net income (loss) by the weighted average number of common shares outstanding for the period. Diluted net income (loss) per common share is computed by adjusting the numerator and denominator of the basic net income (loss) per share calculation for the potential impact of dilutive securities.

For the three and six month periods ended June 30, 2017, 2,228,637 and 2,086,072 stock options, respectively, were excluded from the calculation of diluted net income per common share as their inclusion would be anti-dilutive (three and six months ended June 30, 2016 – 1,934,452 and 1,841,096, respectively).

The following is a reconciliation of the numerators and denominators of basic and diluted net loss per common share:

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Numerator:				
Net loss used to compute net loss per common share:				
Basic	\$ (7,380)	\$ (6,016)	\$ (14,897)	\$ (9,279)
Adjustment for change in fair value of liability classified stock options	(30)	(58)	(162)	(100)
Diluted	\$ (7,410)	\$ (6,074)	\$ (15,059)	\$ (9,379)
Denominator:				
Weighted average number of common shares:				
Basic	17,997,194	14,408,108	17,971,702	14,401,054
Adjustment for dilutive effect of stock options	18,554	26,494	23,407	27,106
Diluted	18,015,748	14,434,602	17,995,109	14,428,160
Net loss per common share - basic	\$ (0.41)	\$ (0.42)	\$ (0.83)	\$ (0.64)
Net loss per common share - diluted	\$ (0.41)	\$ (0.42)	\$ (0.84)	\$ (0.65)

5. Fair value of financial instruments:

We measure certain financial instruments and other items at fair value.

To determine the fair value, we use the fair value hierarchy for inputs used to measure fair value of financial assets and liabilities. This hierarchy prioritizes the inputs to valuation techniques used to measure fair value into three levels: Level 1 (highest priority), Level 2, and Level 3 (lowest priority).

- *Level 1* - Unadjusted quoted prices in active markets for identical instruments.
- *Level 2* - Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (i.e., interest rates, yield curves, etc.), and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).
- *Level 3* - Inputs are unobservable and reflect the Company's assumptions as to what market participants would use in pricing the asset or liability. The Company develops these inputs based on the best information available.

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. Changes in the observability of valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy.

The Company's Level 1 assets include cash and cash equivalents and marketable securities with quoted prices in active markets. The carrying amount of accounts receivables, accounts payable and accrued expenses approximates fair value due to the nature and short-term of those instruments. As quoted prices for the liability classified stock options, included in the consolidated balance sheet as accounts payable and accrued expenses, are not readily available, the Company has used a Black-Scholes pricing model to estimate fair value using Level 3 inputs as defined above.

6. Accounts payable and accrued expenses:

Accounts payable and accrued expenses consisted of the following:

	June 30, 2017	December 31, 2016
Trade payables	\$ 1,314	\$ 1,463
Employee compensation, benefits, and related accruals	975	872
Consulting and contracted research	1,061	1,029
Professional fees	358	93
Other	66	129
Total	<u>\$ 3,774</u>	<u>\$ 3,586</u>

7. Share Capital

(a) Financing:

On September 13, 2016, the Company completed an underwritten public offering of 3,450,000 of its common shares at a public offering price of \$7.50 per common share. The Company received approximately \$24.3 million of proceeds, net of underwriting discounts and commissions but before offering expenses.

(b) Stock-based compensation:

The following table presents stock option activity for the period:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Outstanding, beginning of period	2,258,237	1,934,734	1,910,823	1,721,472
Granted	29,750	65,450	446,500	299,400
Exercised ⁽¹⁾	(3,085)	(14,283)	(71,006)	(30,529)
Forfeited and expired	(8,005)	(2,227)	(9,420)	(6,669)
Outstanding, end of period	<u>2,276,897</u>	<u>1,983,674</u>	<u>2,276,897</u>	<u>1,983,674</u>
Exercisable, end of period	<u>1,374,535</u>	<u>1,195,883</u>	<u>1,374,535</u>	<u>1,195,883</u>

- (1) During the six months ended June 30, 2017, 63,425 stock options were exercised for the same number of common shares for cash (six months ended June 30, 2016 – 29,270). In the same period, the Company issued 4,405 common shares (six months ended June 30, 2016 – 741) for the cashless exercise of 7,581 stock options (six months ended June 30, 2016 – 1,259).

The fair value of each option granted to employees and non-employees is estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Average risk-free interest rate	2.05%	1.44%	2.41%	1.60%
Expected volatility	81%	74%	81%	75%
Average expected term (in years)	7.68	6.14	7.49	6.23
Expected dividend yield	<u>0.00%</u>	<u>0.00%</u>	<u>0.00%</u>	<u>0.00%</u>

The weighted-average fair value of options granted during the six months ended June 30, 2017 was \$6.11 (six months ended June 30, 2016 – \$4.90) per option.

8. Collaboration agreements:

The Company has entered into a number of collaboration agreements with multiple deliverables under which it may have received non-refundable upfront payments. The Company generally recognizes revenue from non-refundable upfront payments ratably over the term of its estimated period of performance of research under its collaboration agreements in the event that such arrangements represent a single unit of accounting.

The collaborations may also include contractual milestone payments, which relate to the achievement of pre-specified research, development, regulatory and commercialization events. The milestone events coincide with the progression of product candidates from research and development, to regulatory approval and through to commercialization. The process of successfully discovering a new product candidate, having it selected by the collaborator for development and having it approved and ultimately sold for a profit is highly uncertain. As such, the milestone payments that the Company may earn from its collaborators involve a significant degree of risk to achieve.

The following table is a summary of the revenue recognized from the Company's collaborations for the three and six months ended June 30, 2017 and 2016:

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Teva:				
Research funding	\$ 15	\$ 29	\$ 30	\$ 58
Genentech:				
Recognition of upfront payment	—	—	—	157
Research funding	—	383	—	766
Total collaboration revenue	<u>\$ 15</u>	<u>\$ 412</u>	<u>\$ 30</u>	<u>\$ 981</u>

9. Commitments and contingencies:

(a) Priority access agreement with Medpace Inc. ("Medpace"):

In August 2015, the Company entered into a priority access agreement with Medpace for the provision of certain clinical development services. Under the terms of the agreement, the Company has committed to using Medpace non-exclusively for clinical development services over the five year term of the agreement. In consideration for priority access to Medpace resources and preferred service rates, the Company has committed to \$7,000 of services over the term of the agreement, \$3,000 of which was paid in the year ended December 31, 2015. Of the amounts paid by the Company in 2015 in connection with the priority access agreement, an aggregate of \$2,715 has been recorded as expenses to date for services rendered, and no amount has been classified as current prepaid expenses (December 31, 2016 – \$392) and \$285 has been classified as long-term prepaid expenses (December 31, 2016 – \$408) for the provision of future services as at June 30, 2017.

(b) License, manufacture and supply agreement:

In March 2017, the Company entered into a license, manufacture and supply agreement with a pharmaceutical contract manufacturing organization for the access and use of certain regulatory documents as well as for the manufacture and supply of clinical and commercial drug product. Under the terms of the agreement, the Company paid an upfront fee of \$500 CAD and will be required to pay a low single-digit percentage royalty on net sales of any products developed and commercialized under the agreement.

(c) Asset purchase agreement with 1st Order Pharmaceuticals, Inc. ("1st Order"):

In April 2017, the Company acquired XEN1101 (previously known as IOP2198) from 1st Order pursuant to an asset purchase agreement. 1st Order previously acquired IOP2198 from an affiliate of Valeant Pharmaceuticals International, Inc. ("Valeant"), and the Company has assumed certain financial responsibilities under that agreement. Under the terms of the agreement, the Company paid an upfront fee of \$350 and expects to pay an additional \$700 in milestones in 2017. Future potential payments to both 1st Order and Valeant include \$1,000 in clinical development milestones, up to \$13,000 in regulatory milestones, and up to approximately \$33,600 in sales-based and other milestones, which includes a \$1,500 milestone that may be payable pre-commercially, plus a mid-to-high single-digit percentage royalty on commercial sales.

(d) **Guarantees and indemnifications:**

The Company has entered into license and research agreements with third parties that include indemnification provisions that are customary in the industry. These indemnification provisions generally require the Company to compensate the other party for certain damages and costs incurred as a result of third party claims or damages arising from these transactions.

The maximum amount of potential future indemnification is unlimited; however, the Company currently holds commercial and product liability insurance. This insurance limits the Company's exposure and may enable it to recover a portion of any future amounts paid. Historically, the Company has not made any indemnification payments under such agreements and the Company believes that the fair value of these indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations for any period presented.

10. Related Parties:

Dr. August J. Troendle, an officer and director of Medpace, which provided clinical development services to the Company, was a beneficial owner of more than 5% of the Company's common shares during 2016. The Company incurred \$332 and \$764 of clinical development service fees under its priority access agreement and a master services agreement with Medpace for the three and six months ended June 30, 2017, respectively (three and six months ended June 30, 2016 – \$568 and \$941, respectively.)

11. Subsequent Event:

In July 2017, the Company entered into a license agreement with a pharmaceutical company for the access and use of certain regulatory documents to support the development of a potential product candidate. Under the terms of the agreement, the Company is required to pay an upfront fee of \$1,000. Future potential payments include \$2,000 in clinical development milestones, up to \$7,000 in regulatory milestones, which includes \$1,000 expected to be paid in 2017, plus a low-to-mid single-digit percentage royalty on net sales of any products developed and commercialized under the agreement.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This section should be read in conjunction with our unaudited interim consolidated financial statements and related notes included in Part I, Item 1 of this report and our audited consolidated financial statements and related notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2016 included in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission on March 8, 2017 and with the securities commissions in British Columbia, Alberta and Ontario on March 8, 2017.

Forward-Looking Statements

Certain statements contained in this Quarterly Report on Form 10-Q may constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and Canadian securities laws. The words or phrases "would be," "will allow," "intends to," "may," "believe," "plan," "will likely result," "are expected to," "will continue," "is anticipated," "estimate," "project," or similar expressions, or the negative of such words or phrases, are intended to identify "forward-looking statements." You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements include, but are not limited to:

- our ability to identify additional products or product candidates either from our internal research efforts or through acquiring or in-licensing other product candidates or technologies;
- the initiation, timing, cost, progress and success of our research and development programs, preclinical studies, and clinical trials;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- our ability to recruit sufficient numbers of patients for our current and future clinical trials for orphan or more common indications;
- our ability to achieve profitability;
- our ability to obtain funding for our operations, including research funding;
- our ability to receive milestones, royalties and sublicensing fees under our collaborations, and the timing of such payments;
- the timing and magnitude of potential milestone payments under our product acquisition and in-licensing agreements;
- the implementation of our business model and strategic plans;
- our ability to develop and commercialize product candidates for orphan and niche indications independently;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our ability to find families to support our Extreme Genetics discovery platform;
- our ability to discover genes and drug targets;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- our expectations regarding federal, state and foreign regulatory requirements;
- the therapeutic benefits, effectiveness and safety of our product candidates;
- the accuracy of our estimates of the size and characteristics of the markets that may be addressed by our products and product candidates;
- the rate and degree of market acceptance and clinical utility of any future products;
- the timing of, and our and our collaborators' ability to obtain and maintain, regulatory approvals for our product candidates;
- our ability to maintain and establish collaborations;
- our expectations regarding market risk, including interest rate changes and foreign currency fluctuations;

- our belief in the sufficiency of our cash flows to meet our needs for at least the next 12 months;
- our ability to engage and retain the employees required to grow our business;
- our future financial performance and projected expenditures;
- developments relating to our competitors and our industry, including the success of competing therapies that are or become available; and
- estimates of our expenses, future revenue, capital requirements and our needs for additional financing.

These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this report in Part I, Item 1A — “Risk Factors,” and elsewhere in this report. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments, except as required by law. In this report, “we,” “our,” “us,” “Xenon,” and “the Company” refer to Xenon Pharmaceuticals Inc. and its subsidiary. Unless otherwise noted, all dollar amounts in this report are expressed in United States dollars.

Overview

We are a clinical stage biopharmaceutical company focused on developing innovative therapeutics to improve the lives of patients with neurological disorders. Building upon our vast knowledge of human genetics and diseases caused by mutations in ion channels, known as channelopathies, we are advancing a novel neurology-focused product pipeline of ion channel modulators to address therapeutic areas of high unmet medical need, such as pain and epilepsy.

Our pharmaceutical partners include Teva Pharmaceutical Industries, Ltd., or Teva (through its subsidiary, Ivax International GmbH), Genentech, a member of the Roche Group, and Merck & Co., Inc. (through its affiliate, Essex Chemie AG). Our pharmaceutical collaborations have generated in aggregate over \$160.0 million in non-equity funding to date with the potential to provide us with over \$1.0 billion in future milestone payments, as well as royalties and co-promotion income on product sales.

Our proprietary development pipeline and pharmaceutical partnerships include:

- XEN1101 is a next-generation Kv7 potassium channel opener for the treatment of epilepsy. Pre-clinically, XEN1101 has demonstrated improved pharmacokinetics, selectivity, potency and efficacy over first-generation potassium channel modulators, such as ezogabine. Xenon anticipates filing an investigational new drug, or IND, or IND equivalent, application to initiate a Phase 1 first-in-man clinical trial in the fourth quarter of 2017, and Phase 2 development is anticipated to begin by mid-2018;
- XEN901 is a potent, selective Nav1.6 sodium channel inhibitor for the treatment of rare infantile epileptic encephalopathies and other forms of epilepsy. XEN901 has demonstrated efficacy against seizures in an animal model of Nav1.6 gain-of-function SCN8A epilepsy as well as animal models that support the treatment of adult partial onset epilepsy. Xenon expects to file an IND, or IND equivalent, application in the fourth quarter of 2017;
- Our collaborator, Teva, is responsible for the development of TV-45070, which is a topical sodium channel inhibitor for the treatment of neuropathic pain. In June 2017, we, along with Teva, announced topline results from a Phase 2b clinical trial that evaluated the efficacy and safety of TV-45070 in patients with post-herpetic neuralgia. TV-45070 did not meet the primary endpoint of a statistically significant change in pain from baseline to week four as assessed by the numeric rating scale, and secondary endpoints were also not met in the study. There were no safety concerns in the study. We and Teva plan to further analyze the data from this study to determine the next steps for TV-45070;
- Our collaborator, Genentech, has completed a Phase 1 clinical trial for GDC-0310, which is an oral, selective Nav1.7 small-molecule inhibitor. Pending completion and assessment of ongoing preclinical studies, Genentech anticipates initiating a Phase 2 clinical trial for the potential treatment of pain in the first quarter of 2018.
- In July 2017, we achieved a milestone in our pain genetics discovery collaboration with Genentech triggering a milestone payment. We and Genentech have successfully discovered and identified a novel pain target by leveraging our Extreme Genetics platform based on the study of rare phenotypes of individuals who have either an inability to perceive pain or have non-precipitated spontaneous severe pain; and

- Our licensee uniQure Biopharma B.V., or uniQure, has developed Glybera for the treatment of the orphan disorder lipoprotein lipase deficiency. Glybera was the first gene therapy product approved in the European Union, or the EU. In November 2015, the first patient treated with Glybera as a commercially available gene therapy was announced by uniQure and enabled by its commercialization partner in the EU, Chiesi Farmaceutici S.p.A., which has sole control over commercialization in the EU. In April 2017, uniQure announced that it will not pursue the renewal of the Glybera marketing authorization in Europe, which is scheduled to expire on October 25, 2017.

We have funded our operations through the sale of equity securities, funding received from our licensees and collaborators and, to a lesser extent, government funding. For the six months ended June 30, 2017, we recognized revenue, consisting primarily of funding from our collaborators of approximately \$0.03 million. This compares to \$1.0 million for the six months ended June 30, 2016.

We had a net loss of \$14.9 million for the six months ended June 30, 2017 and an accumulated deficit of \$157.6 million as of June 30, 2017, from expenses incurred in connection with our research programs and from general and administrative costs associated with our operations and we do not expect to have sustained profitability for the foreseeable future.

Other than royalties we are eligible to receive from sales of Glybera under our license to uniQure, which have not been significant to date and which we expect to cease in October 2017 following expiration of Glybera's marketing authorization, we have not generated any royalty revenue from product sales, and do not otherwise anticipate generating revenue from product sales for the foreseeable future, if ever. We expect that our revenue in the near term will be substantially dependent on our collaboration agreements. Given the uncertain nature of clinical development of our current and future product candidates and the commercialization of current and future products, we cannot predict when or whether we will receive further milestone payments under our current or future collaboration agreements or whether we will be able to report either revenue or net income in future years.

We expect to continue to incur significant expenses and operating losses for at least the next 12 to 24 months. We anticipate that our expenses will increase as we:

- continue our research and preclinical and clinical development of our product candidates either from our internal research efforts or through acquiring or in-licensing other product candidates or technologies;
- seek regulatory and marketing approvals for any of our product candidates that successfully complete clinical trials;
- make milestone and other payments under our product acquisition and in-license agreements;
- maintain, protect and expand our intellectual property portfolio;
- attract, hire and retain skilled personnel; and
- create additional infrastructure to support our operations and otherwise.

Financial Operations Overview

Revenue

To date, our revenue has been primarily derived from collaboration and licensing agreements as well as, to a lesser extent, government funding. In addition, we have received nominal royalties from a diagnostic license and from sales of Glybera. Other than royalties we are eligible to receive from sales of Glybera under our license to uniQure, which have not been significant to date and which we expect to cease in October 2017 following expiration of Glybera's marketing authorization, we have not generated any royalty revenue from product sales, and do not otherwise anticipate generating revenue from product sales for the foreseeable future, if ever.

The following table is a summary of revenue recognized from our current collaboration agreements for the three and six months ended June 30, 2017 and 2016 (in thousands):

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Teva:				
Research funding	\$ 15	\$ 29	\$ 30	\$ 58
Genentech:				
Recognition of upfront payment	—	—	—	157
Research funding	—	383	—	766
Total collaboration revenue	<u>\$ 15</u>	<u>\$ 412</u>	<u>\$ 30</u>	<u>\$ 981</u>

Pursuant to the terms of our March 2014 genetics collaborative agreement with Genentech, we received an upfront payment of \$1.5 million. We determined that the various deliverables under this agreement should be considered as a single unit of accounting. As such, the \$1.5 million upfront payment was recognized as revenue ratably over the expected period of research performance, which was the two-year period from March 2014 to March 2016.

As our other internal and partnered products are in various stages of clinical and preclinical development, we do not expect to generate any revenue from product sales other than from royalties related to our agreement with uniQure, which have not been significant to date and which we expect will cease in October 2017 following expiration of Glybera's marketing authorization, for at least the next several years. We expect that revenue for the next several years will be derived from milestone payments under our current collaboration agreements and any additional collaboration agreements that we may enter into in the future. We cannot provide any assurance as to the extent or timing of future milestone payments or royalty payments or that we will receive any future payments at all.

We expect that any revenue we generate will fluctuate quarter to quarter as a function of the timing and amount of milestones and other payments from our existing collaborations and any future collaborations.

As of June 30, 2017, we have recognized all deferred revenue from upfront payments received under our existing collaboration and licensing agreements.

Operating Expenses

The following table summarizes our operating expenses for the three and six months ended June 30, 2017 and 2016 (in thousands):

	Three Months Ended		Six Months Ended June 30,	
	June 30,			
	2017	2016	2017	2016
Research and development	\$ 6,109	\$ 5,103	\$ 12,012	\$ 9,467
General and administrative	1,799	1,676	3,899	3,571
Total operating expenses	<u>\$ 7,908</u>	<u>\$ 6,779</u>	<u>\$ 15,911</u>	<u>\$ 13,038</u>

Research and Development Expenses

Research and development expenses represent costs incurred to conduct research and development of our proprietary product candidates including any acquired or in-licensed product candidates or technology, as well as to support research and development of our product candidates in collaboration with Teva and Genentech.

Research and development expenses consist of costs incurred in performing research and development activities, including salary, related benefits and stock-based compensation for employees engaged in scientific research and development, third-party contract costs relating to research, formulation, manufacturing, preclinical studies and clinical trial activities, third-party acquisition, license and collaboration fees, laboratory consumables and allocated facility-related and information technology costs.

Project-specific expenses reflect costs directly attributable to our clinical development candidates and our preclinical candidates once nominated and selected for further development including preclinical and discovery costs supporting a development candidate. All remaining research and development expenses are reflected in preclinical and discovery program expenses. At any given time, we have several active early-stage research and drug discovery programs. Our personnel and infrastructure are typically deployed over multiple projects and are not directly linked to any individual internal early-stage research or drug discovery program. Therefore, we do not maintain financial information for our internal early-stage research and internal drug discovery programs on a project-specific basis.

We expense all research and development costs as incurred. We expect that our research and development expenses will increase in the future as we advance our proprietary product candidates through clinical development, advance our internal drug discovery programs into preclinical development and continue our early-stage research. The increase in expense will likely include added personnel and third-party contracts related to research, formulation, manufacturing, preclinical studies and clinical trial activities as well as third-party acquisition, license and collaboration fees and laboratory consumables.

Clinical development timelines, likelihood of regulatory approval and commercialization and associated costs are uncertain and difficult to estimate and can vary significantly. We anticipate determining which research and development projects to pursue as well as the level of funding available for each project based on the scientific research and preclinical and clinical results of each product candidate and related regulatory action. We expect our research and development expenses to continue to represent our largest category of operating expense for at least the next 12 to 24 months.

General and Administrative Expenses

General and administrative expenses consist primarily of salary, related benefits and stock-based compensation of our executive, finance, legal, business development and administrative functions, travel expenses, allocated facility-related and information technology costs not otherwise included in research and development expenses, director compensation, director's and officer's insurance premiums, investor relations costs and professional fees for auditing, tax and legal services, including legal expenses for intellectual property protection. General and administrative expenses also include fair value adjustments of certain liability classified stock option awards.

We expect that general and administrative expenses will increase in the future as we expand our operating activities to support increased research and development activities, and the potential build of commercial infrastructure for our option for co-promotion of TV-45070 in the U.S., if and when regulatory approval is received.

Other Income (Expense)

Interest Income. Interest income consists of income earned on our cash and investment balances. Our interest income has not been significant due to the levels of cash and investment balances and low interest earned on such balances. We anticipate that our interest income will continue to fluctuate depending on timing of payments from collaborative partners, our cash and investment balances, and interest rates.

Foreign Exchange Gain (Loss). Net foreign exchange gains and losses consist of gains and losses from the impact of foreign exchange fluctuations on our monetary assets and liabilities that are denominated in currencies other than the U.S. dollar (principally the Canadian dollar). See "Quantitative and Qualitative Disclosures About Market Risk – Foreign Currency Exchange Risk" below for additional information.

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 conformity with generally accepted accounting principles in the U.S., or U.S. GAAP. The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the revenue and expenses incurred during the reported periods. We base estimates on our historical experience, known trends and 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 apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Critical accounting policies and significant judgments and estimates are those that we consider the most important to the portrayal of our financial condition and results of operations because they require our most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Our critical accounting policies and significant estimates include those related to:

- revenue recognition;
- research and development costs; and
- stock-based compensation.

There have been no material changes in our critical accounting policies and significant judgements and estimates during the six months ended June 30, 2017, as compared to those disclosed in "Management's Discussion and Analysis of Financial Conditions and Results of Operations - Critical Accounting Policies and Significant Judgments and Estimates" included in our 2016 Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission, or SEC, and with the securities commissions in British Columbia, Alberta and Ontario, or the Canadian Securities Commissions, on March 8, 2017. We believe that the accounting policies discussed in the Annual Report are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Results of Operations

Comparison of Three and Six Months Ended June 30, 2017 and 2016

The following table summarizes the results of our operations for the three and six months ended June 30, 2017 and 2016 together with changes in those items (in thousands):

	Three Months Ended June 30,		Change	Six Months Ended June 30,		Change
	2017	2016	2017 vs. 2016 Increase/(Decrease)	2017	2016	2017 vs. 2016 Increase/(Decrease)
Collaboration revenue	\$ 15	\$ 412	\$ (397)	\$ 30	\$ 981	\$ (951)
Royalties	—	1	(1)	1	33	(32)
Research and development expenses	6,109	5,103	1,006	12,012	9,467	2,545
General and administrative expenses	1,799	1,676	123	3,899	3,571	328
Other:						
Interest income	109	123	(14)	258	222	36
Foreign exchange gain	404	227	177	725	2,523	(1,798)
Net loss	<u>\$ (7,380)</u>	<u>\$ (6,016)</u>	<u>\$ (1,364)</u>	<u>\$ (14,897)</u>	<u>\$ (9,279)</u>	<u>\$ (5,618)</u>

Revenue

Revenue decreased by \$0.4 million and \$1.0 million in the three and six months ended June 30, 2017 as compared to the three and six months ended June 30, 2016, respectively. In 2016, we recognized revenue related to the upfront payment from the March 2014 genetics collaborative agreement with Genentech which was fully recognized by March 2016. The remaining decrease as compared to the same periods in 2016 was mainly due to the expiration of FTE funding from Genentech in 2017 as we shifted resources from supporting our collaborations to our proprietary programs.

Research and Development Expenses

The following table summarizes research and development expenses for the three and six months ended June 30, 2017 and 2016 together with changes in those items (in thousands):

	Three Months Ended June 30,		Change	Six Months Ended June 30,		Change
	2017	2016	2017 vs. 2016 Increase/(Decrease)	2017	2016	2017 vs. 2016 Increase/(Decrease)
Collaboration expenses	\$ 51	\$ 342	\$ (291)	\$ 121	\$ 631	\$ (510)
XEN801 expenses	101	1,173	(1,072)	1,550	2,333	(783)
XEN901 and Nav1.6 preclinical and discovery expenses	3,281	2,546	735	5,795	4,667	1,128
XEN1101 expenses	1,025	—	1,025	1,151	—	1,151
Preclinical and discovery program expenses	1,651	1,042	609	3,395	1,836	1,559
Total research and development expenses	<u>\$ 6,109</u>	<u>\$ 5,103</u>	<u>\$ 1,006</u>	<u>\$ 12,012</u>	<u>\$ 9,467</u>	<u>\$ 2,545</u>

Research and development expenses increased by \$1.0 million and \$2.5 million in the three and six months ended June 30, 2017 as compared to the three and six months ended June 30, 2016, respectively. These increases were primarily attributable to increased spending on our internal preclinical and discovery programs, our XEN1101 product candidate which was acquired in April 2017, and our XEN901 product candidate. These increases were partially offset by a decrease in XEN801 expenses, a product candidate which is no longer being developed, and a decrease in collaboration expenses.

General and Administrative Expenses

The following table summarizes general and administrative expenses for the three and six months ended June 30, 2017 and 2016 together with changes in those items (in thousands):

	Three Months Ended June 30,		Change	Six Months Ended June 30,		Change
	2017	2016	2017 vs. 2016 Increase/(Decrease)	2017	2016	2017 vs. 2016 Increase/(Decrease)
General and administrative expenses	<u>\$ 1,799</u>	<u>\$ 1,676</u>	<u>\$ 123</u>	<u>\$ 3,899</u>	<u>\$ 3,571</u>	<u>\$ 328</u>

General and administrative expenses increased by \$0.1 million and \$0.3 million in the three and six months ended June 30, 2017 as compared to the three and six months ended June 30, 2016, respectively. These increases were primarily attributable to increased costs for business development activities and salaries and benefits, partially offset by the fair value adjustment on our liability classified stock options.

Other Income

The following table summarizes our other income for the three and six months ended June 30, 2017 and 2016 together with changes in those items (in thousands):

	Three Months Ended June 30,		Change	Six Months Ended June 30,		Change
	2017	2016	2017 vs. 2016 Increase/(Decrease)	2017	2016	2017 vs. 2016 Increase/(Decrease)
Other income:	\$ 513	\$ 350	\$ 163	\$ 983	\$ 2,745	\$ (1,762)

Other income changed by \$0.2 million and \$1.8 million in the three and six months ended June 30, 2017 as compared to the three and six months ended June 30, 2016, respectively. The change in other income was primarily driven by the change in foreign exchange gains arising largely from the translation of cash and cash equivalents and marketable securities denominated in Canadian dollars to U.S. dollars. We recorded foreign exchange gains of \$0.4 million and \$0.2 million due to a 2% and 1% increase in the value of the Canadian dollar during the three months ended June 30, 2017 and 2016, respectively. During the six month periods ended June 30, 2017 and 2016, we recorded foreign exchange gains of \$0.7 million and \$2.5 million due to a 3% and 7% increase in the value of the Canadian dollar, respectively.

Liquidity and Capital Resources

To date, we have financed our operations primarily through funding received from collaboration and license agreements, private placements of our common and preferred shares and public offerings of our common shares and, to a lesser extent, through the receipt of government funding. As of June 30, 2017, we had cash and cash equivalents and marketable securities of \$51.7 million. In September 2016, we completed an underwritten public offering of 3,450,000 of our common shares at a public offering price of \$7.50 per common share. We received approximately \$24.3 million of proceeds, net of underwriting discounts and commissions but before offering expenses.

We have incurred significant operating losses since inception. We had a \$14.9 million net loss for the six months ended June 30, 2017 and an accumulated deficit of \$157.6 million from inception through June 30, 2017. We expect to continue to incur significant expenses in excess of our revenue and expect to incur operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we continue our research and preclinical and clinical development of our product candidates; expand the scope of our current studies for our product candidates; initiate additional preclinical, clinical or other studies for our product candidates, including under our collaboration agreements; change or add additional manufacturers or suppliers; seek regulatory and marketing approvals for any of our product candidates that successfully complete clinical studies; seek to identify, evaluate and validate additional product candidates; acquire or in-license other product candidates and technologies; make milestone or other payments under our product acquisition and in-license agreements including, without limitation, our agreements with the University of British Columbia, the Memorial University of Newfoundland, 1st Order Pharmaceuticals, Inc., or 1st Order, Valeant Pharmaceuticals International, Inc., or Valeant, and other third parties; maintain, protect and expand our intellectual property portfolio; attract and retain skilled personnel; establish a sales, marketing and distribution infrastructure to commercialize any products for which we or one of our collaborators may obtain marketing approval, and maintain commercial rights; create additional infrastructure to support our operations and our product development and planned future commercialization efforts; and experience any delays or encounter issues with any of the above.

Until such time as we can generate substantial product revenue, if ever, we expect to finance our cash needs through a combination of collaboration agreements and equity or debt financings. Except for any obligations of our collaborators to reimburse us for research and development expenses or to make milestone payments under our agreements with them, we do not have any committed external sources of capital. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common shareholders. If we raise additional funds through collaboration agreements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our future capital requirements are difficult to forecast and will depend on many factors, including:

- the number and characteristics of the future product candidates we pursue either from our internal research efforts or through acquiring or in-licensing other product candidates or technologies;
- the scope, progress, results and costs of independently researching and developing any of our future product candidates, including conducting preclinical research and clinical trials;
- whether our existing collaborations continue to generate substantial milestone payments and, ultimately, royalties on future approved products for us;
- the timing of, and the costs involved in, obtaining regulatory approvals for any future product candidates we develop independently;
- the cost of future commercialization activities, if any, including activities required pursuant to our option to co-promote TV-45070, if exercised by us, and the cost of commercializing any future products we develop independently that are approved for sale;
- the cost of manufacturing our future product candidates and products, if any;
- our ability to maintain existing collaborations and to establish new collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the costs of preparing, filing, prosecuting, maintaining, defending and enforcing patents, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, Glybera or our collaborators' product candidates, and our future products, if any.

Based on our research and development plans and our timing expectations related to the progress of our programs, we expect that our existing cash and cash equivalents and marketable securities as of the date of this report and research funding that we expect to receive under our existing collaborations, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect. Additionally, the process of testing drug candidates in clinical trials is costly, and the timing of progress in these trials remains uncertain.

Cash Flows

The following table shows a summary of our cash flows for the six months ended June 30, 2017 and 2016 (in thousands):

	Six Months Ended June 30,	
	2017	2016
Net cash used in operating activities	\$ (13,262)	\$ (10,373)
Net cash provided by (used in) investing activities	18,580	(15,505)
Net cash provided by financing activities	177	82

Operating Activities

For the six months ended June 30, 2017, net cash used in operating activities totaled \$13.3 million, compared to \$10.4 million for the same period in 2016. The change was primarily related to a \$2.5 million increase in research and development expenses and a \$1.0 million decrease in revenue, partially offset by working capital changes.

Investing Activities

For the six months ended June 30, 2017, net cash provided by investing activities totaled \$18.6 million, compared to net cash used in investing activities of \$15.5 million for the same period in 2016. The change was driven by the maturity of marketable securities, net of purchases in the six months ended June 30, 2017 as compared to the purchase of marketable securities in the same period in 2016.

Financing Activities

For the six months ended June 30, 2017, net cash provided by financing activities did not change significantly as compared to the same period in 2016 and consisted exclusively of proceeds from the issuance of common shares from the exercise of stock options for both periods.

Contractual Obligations and Commitments

Our future significant contractual obligations as of December 31, 2016 were reported in our Annual Report on Form 10-K, filed with the SEC and the Canadian Securities Commissions on March 8, 2017.

As of June 30, 2017, there have been no material changes from the contractual commitments previously disclosed in the Annual Report on Form 10-K other than the following:

In March 2017, we entered into a license, manufacture and supply agreement with a pharmaceutical contract manufacturing organization for the access and use of certain regulatory documents as well as for the manufacture and supply of clinical and commercial drug product. Under the terms of the agreement, we paid an upfront fee of \$0.5 million CAD and will be required to pay a low single-digit percentage royalty on net sales of any products developed and commercialized under the agreement.

In April 2017, we acquired XEN1101 (previously known as IOP2198) from 1st Order pursuant to an asset purchase agreement. 1st Order previously acquired IOP2198 from an affiliate of Valeant, and we have assumed certain financial responsibilities under that agreement. Under the terms of the agreement, we paid an upfront fee of \$0.4 million and expect to pay an additional \$0.7 million in milestones in 2017. Future potential payments to both 1st Order and Valeant include \$1.0 million in clinical development milestones, up to \$13.0 million in regulatory milestones, and up to approximately \$33.6 million in sales-based and other milestones, which includes a \$1.5 million milestone that may be payable pre-commercially, plus a mid-to-high single-digit percentage royalty on commercial sales.

In July 2017, we entered into a license agreement with a pharmaceutical company for the access and use of certain regulatory documents to support the development of a potential product candidate. Under the terms of the agreement, we are required to pay an upfront fee of \$1.0 million. Future potential payments include \$2.0 million in clinical development milestones, up to \$7.0 million in regulatory milestones, which includes \$1.0 million expected to be paid in 2017, plus a low-to-mid single-digit percentage royalty on net sales of any products developed and commercialized under the agreement.

Inflation

We do not believe that inflation has had a material effect on our business, financial condition or results of operations in the last three fiscal years.

Off-Balance Sheet Arrangements

We do not engage in any off-balance sheet financing activities. We do not have any interest in entities referred to as variable interest entities, which include special purposes entities and other structured finance entities.

Outstanding Share Data

As of July 31, 2017, we had 17,998,420 common shares issued and outstanding and outstanding stock options to purchase an additional 2,276,897 common shares.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2014-09, Revenue from Contracts with Customers (ASC 606) to clarify the principles of recognizing revenue and to develop a common revenue standard that would remove inconsistencies in revenue requirements, leading to improved comparability of revenue recognition practices across entities and industries. The standard, as subsequently amended, stipulates that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The new guidance will be effective for public entities for fiscal years and interim periods within those years, beginning after December 15, 2017. We have begun our evaluation and identified two significant collaboration agreements with respect to revenue, the collaborative development and license agreements with Teva and Genentech, described in notes 9(a) and (b), respectively, to our audited consolidated financial statements included in our 2016 Annual Report on Form 10-K for the year ended December 31, 2016. We are evaluating the new guidance as it applies to revenue previously recognized as well as milestone payments we are eligible to receive in future periods under these agreements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842): Recognition and Measurement of Financial Assets and Financial Liabilities. The update requires the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous U.S. GAAP. The new guidance retains a distinction between finance leases and operating leases, with cash payments from operating leases classified within operating activities in the statement of cash flows. These amendments will be effective for public entities for fiscal years and interim periods within those years, beginning after December 15, 2018. We are currently evaluating the new guidance to determine the impact it will have on our consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to various market risks in the ordinary course of our business, including changes in interest rates and currency exchange rates. Market risk is the potential loss arising from adverse changes in interest rates and exchange rates.

Foreign Currency Exchange Risk

The principal market risk we face is foreign currency exchange rate risk. We face this risk, in part, as a result of entering into transactions denominated in currencies other than U.S. dollars, particularly those denominated in Canadian dollars. We also hold non-U.S. dollar denominated cash and cash equivalents, marketable securities, accounts receivable and accounts payable, which are denominated in Canadian dollars.

Changes in foreign currency exchange rates can create significant foreign exchange gains or losses to us. Our current foreign currency risk is with the Canadian dollar, as a majority of our non-U.S. dollar denominated expenses are denominated in Canadian dollars and a significant portion of our cash and cash equivalents and marketable securities are held in Canadian dollars. To limit our exposure to volatility in currency markets, we estimate our anticipated expenses that will be denominated in Canadian and U.S. dollars and then purchase a corresponding amount of Canadian or U.S. dollars at the current spot rate. Once these estimated expense amounts are acquired, we do not hedge our exposure and thus assume the risk of future gains or losses on the amounts of Canadian dollars held. At June 30, 2017, we held cash and cash equivalents and marketable securities of \$21.3 million denominated in Canadian dollars. A hypothetical 10% increase (decrease) in the value of the Canadian dollar would result in a foreign exchange gain (loss) of \$2.1 million being recorded in the Statement of Operations on the translation of these Canadian dollar cash and cash equivalent balances into the U.S. dollar functional currency.

Interest Rate Risk

An additional market risk we face is interest rate risk. We had cash and cash equivalents and marketable securities of \$51.7 million as of June 30, 2017. The goals of our investment policy are liquidity and capital preservation; we do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate exposure. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short term nature of our cash and cash equivalents and marketable securities. Declines in interest rates, however, would reduce future investment income. A 10% change in interest rates during any of the periods presented would not have had a material impact on our financial statements. Such interest-earning instruments carry a degree of interest rate risk. We had no outstanding debt as of June 30, 2017.

Item 4. Controls and Procedures

(a) Evaluation of disclosure controls and procedures. Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this quarterly report. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this quarterly report, our disclosure controls and procedures were effective, in design and operation, at the reasonable assurance level.

(b) Changes in internal control over financial reporting. There were no changes in our internal control over financial reporting during the period ended June 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent limitation on the effectiveness of internal control.

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, in the opinion of our management, would reasonably be expected to have a material adverse effect on our business, financial condition, operating results or cash flows if determined adversely to us. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors

You should carefully consider the following risk factors, in addition to the other information contained in this report, including the section of this report captioned "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes. 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. This 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 Financial Condition and Capital Requirements

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

We are a clinical-stage biotechnology company and, other than the years ended December 31, 2014 and 2013, we have recorded net losses in each annual reporting period since inception in 1996, and we do not expect to have sustained profitability for the foreseeable future. We had net losses of \$14.9 million for the six months ended June 30, 2017 and an accumulated deficit of \$157.6 million as of June 30, 2017, which were driven by expenses incurred in connection with our research programs and from general and administrative costs associated with our operations.

We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities. To date, we have financed our operations through the sale of equity securities, funding received from our licensees and collaborators and, to a lesser extent, government funding. Other than royalties we are eligible to receive from sales of Glybera under our license to uniQure Biopharma B.V., or uniQure, which have not been significant to date, we have not generated any royalty revenue from product sales and our product candidates will require substantial additional investment before they will provide us with any product royalty revenue. In April 2017, uniQure announced that it will not seek marketing authorization renewal for Glybera in Europe, which authorization is scheduled to expire in October 2017. As a result, we expect Glybera royalties to cease following the expiration of such marketing authorization.

We expect to incur significant expenses and increasing operating losses for the foreseeable future as we:

- continue our research and preclinical and clinical development of our product candidates;
- expand the scope of our clinical studies for our current and prospective product candidates;
- initiate additional preclinical, clinical or other studies for our product candidates, including under our collaboration agreements;
- change or add additional manufacturers or suppliers;
- seek regulatory and marketing approvals for any of our product candidates that successfully complete clinical studies;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- make milestone or other payments under our in-license agreements including, without limitation, our agreements with the University of British Columbia, the Memorial University of Newfoundland, 1st Order Pharmaceuticals, Inc., an affiliate of Valeant Pharmaceuticals International, Inc. and other third parties;
- maintain, protect and expand our intellectual property portfolio;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we or one of our collaborators may obtain marketing approval, and for which we have maintained commercial rights;
- create additional infrastructure to support our operations and our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with any of the above.

Our expenses could increase beyond expectations for a variety of reasons, including if we are required by the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, or other regulatory agencies, domestic or foreign, to perform clinical and other studies in addition to those that we currently anticipate. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our shareholders' equity.

Other than royalties we are eligible to receive from sales of Glybera, we have not generated any royalty revenue from product sales and may never become profitable on a U.S. GAAP basis.

Our ability to generate meaningful revenue and achieve profitability on a U.S. GAAP basis depends on our ability, alone or with strategic collaborators, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our product candidates. Substantially all of our revenue since inception has consisted of upfront and milestone payments associated with our collaboration and license agreements. Revenue from these agreements is dependent on successful development of our product candidates by us or our collaborators. Other than royalties we are eligible to receive from sales of Glybera under our license to uniQure, which have not been significant to date and which we expect to cease in October 2017 following expiration of Glybera's marketing authorization, we have not generated any royalty revenue from product sales, and do not otherwise anticipate generating revenue from product sales for the foreseeable future, if ever. If any of our product candidates fail in clinical trials or do not gain regulatory approval, or if any of our future products, if any, once approved, fail to achieve market acceptance or adequate market share, we may never become profitable. Although we were profitable for the years ended December 31, 2014 and 2013, we may not be able to sustain profitability in subsequent periods. Our ability to generate future revenue from product sales depends heavily on our success, and the success of our collaborators, in:

- completing research, preclinical and clinical development of our product candidates;
- seeking and obtaining regulatory and marketing approvals for product candidates for which we complete clinical studies;
- commercializing products for which we obtain regulatory and marketing approval, either with a collaborator or, if launched independently, by establishing sales, marketing and distribution infrastructure;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- obtaining market acceptance of products for which we obtain regulatory and marketing approval as therapies;
- addressing any competing technological and market developments;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate (in amount and quality) products and services to support clinical development and the market demand for any approved products in the future;
- developing sustainable, scalable, reproducible, and transferable manufacturing processes for any of our products approved in the future;
- maintaining, protecting, expanding and enforcing our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- implementing additional internal systems and infrastructure, as needed; and
- attracting, hiring and retaining qualified personnel.

The scope of our future revenue will also depend upon the size of any markets in which our product candidates receive approval and the availability of insurance coverage and the availability and amount of reimbursement from third-party payers for future products, if any. If we are unable to achieve sufficient revenue to become profitable and remain so, our financial condition and operating results will be negatively impacted, and the market price of our common shares might be adversely impacted.

We will likely need to raise additional funding, which may not be available on acceptable terms, if at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

Since our inception, we have dedicated most of our resources to the discovery and development of our proprietary preclinical and clinical product candidates, and we expect to continue to expend substantial resources doing so for the foreseeable future. These expenditures will include costs associated with research and development, potential milestone payments to third parties, manufacturing of product candidates and products approved for sale, conducting preclinical experiments and clinical trials and obtaining and maintaining regulatory approvals, as well as commercializing any products later approved for sale. During the six months ended June 30, 2017, we incurred approximately \$12.0 million of costs associated with research and development, exclusive of costs incurred by our collaborators in developing our product candidates.

Our current cash and cash equivalents and marketable securities are not expected to be sufficient to complete clinical development of any of our product candidates and prepare for commercializing any product candidate which receives regulatory approval. Accordingly, we will likely require substantial additional capital to continue our clinical development and potential commercialization activities. Our future capital requirements depend on many factors, including but not limited to:

- the number and characteristics of the future product candidates we pursue either from our internal research efforts or through acquiring or in-licensing other product candidates or technologies;
- the scope, progress, results and costs of independently researching and developing any of our future product candidates, including conducting preclinical research and clinical trials;
- whether our existing collaborations continue to generate substantial milestone payments and, ultimately, royalties on future approved products for us;
- the timing of, and the costs involved in, obtaining regulatory approvals for any future product candidates we develop independently;
- the timing and magnitude of potential milestone payments under our product acquisition and in-license agreements;
- the cost of future commercialization activities, including activities required pursuant to our option to co-promote TV-45070, if exercised by us, and the cost of commercializing any future products we develop independently that are approved for sale;
- the cost of manufacturing our future product candidates and products, if any;
- our ability to maintain existing collaborations and to establish new collaborations, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patents, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our future products, if any.

We are unable to estimate the funds we will actually require to complete research and development of our product candidates or the funds required to commercialize any resulting product in the future.

Based on our research and development plans and our timing expectations related to the progress of our programs, we expect that our existing cash and cash equivalents and marketable securities as of the date of this report and research funding that we expect to receive under our existing collaborations, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months.

Our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches. Raising funds in the future may present additional challenges and future financing may not be available in sufficient amounts or on terms acceptable to us, if at all.

Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

The terms of any financing arrangements we enter into may adversely affect the holdings or the rights of our shareholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common shares to decline. The sale of additional equity or convertible securities would dilute all of our shareholders. For example, in September 2016, we sold 3,450,000 of our common shares at a price to the public of \$7.50 per common share pursuant to our existing shelf registration statement on Form S-3 and corresponding Canadian base shelf prospectus. The incurrence of indebtedness would result in increased fixed payment obligations and, potentially, the imposition of restrictive covenants. Those covenants may include limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or otherwise at an earlier stage than otherwise would be desirable resulting in the loss of rights to some of our product candidates or other unfavorable terms, any of which may have a material adverse effect on our business, operating results and prospects. In addition, any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

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

Global credit and financial markets experienced extreme disruptions at various points over the last decade, characterized by diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. If another such disruption in credit and financial markets and deterioration of confidence in economic conditions occurs, our business may be adversely affected. If the equity and credit markets were to deteriorate significantly in the future, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and the market price of our common shares could require us to delay or abandon development or commercialization plans. In addition, there is a risk that one or more of our current collaborators, service providers, manufacturers and other partners would not survive or be able to meet their commitments to us under such circumstances, which could directly affect our ability to attain our operating goals on schedule and on budget.

We are subject to risks associated with currency fluctuations which could impact our results of operations.

As of June 30, 2017, approximately 41% of our cash and cash equivalents and marketable securities was denominated in Canadian dollars. Historically, the majority of our operating expenses have been denominated in Canadian dollars and the majority of our revenue has been denominated in U.S. dollars.

Prior to December 31, 2014, our functional currency was the Canadian dollar. On January 1, 2015, our functional currency changed from the Canadian dollar to the U.S. dollar based on our analysis of the changes in the primary economic environment in which we operate. As a result, changes in the exchange rate between the Canadian dollar and the U.S. dollar could materially impact our reported results of operations and distort period to period comparisons. In particular, to the extent that foreign currency-denominated (i.e., non-U.S. dollar) monetary assets do not equal the amount of our foreign currency denominated monetary liabilities, foreign currency gains or losses could arise and materially impact our financial statements. As a result of such foreign currency fluctuations, it could be more difficult to detect underlying trends in our business and results of operations. In addition, to the extent that fluctuations in currency exchange rates cause our results of operations to differ from our expectations or the expectations of our investors, the market price of our common shares could be adversely affected.

From time to time, we may engage in exchange rate hedging activities in an effort to mitigate the impact of exchange rate fluctuations. For example, we aim to maintain a natural currency hedge against fluctuations in the U.S./Canadian foreign exchange rate by matching the amount of U.S. dollar and Canadian dollar investments to the expected amount of future U.S. dollar and Canadian dollar obligations, respectively. Any hedging technique we implement may fail to be effective. If our hedging activities are not effective, changes in currency exchange rates may have a more significant impact on the market price of our common shares.

Risks Related to Our Business

We, or our collaborators, may fail to successfully develop our product candidates.

Our clinical product candidates, which include TV-45070 and GDC-0310, along with our preclinical compounds, which include XEN1101 and XEN901, are in varying stages of development and will require substantial clinical development, testing and regulatory approval prior to commercialization. It may be several more years before these product candidates or any of our other product candidates receive marketing approval, if ever. If any of our product candidates fail to become approved products, our business, growth prospects, operating results and financial condition may be adversely affected and a decline in the market price of our common shares could result. For example, in June 2017, we, along with Teva Pharmaceutical Industries Ltd., or Teva, announced topline results from a Phase 2b study designed to evaluate the efficacy and safety of TV-45070 for the treatment of post-herpetic neuralgia, or PHN. Results from this trial showed that TV-45070 did not meet the primary endpoint of a statistically significant change in pain from baseline to week four as assessed by the numeric rating scale. Secondary endpoints were also not met. We and Teva plan to further analyze the data from this study to determine the next steps for TV-45070.

We and our collaborators face substantial competition in the markets for our product candidates, which may result in others discovering, developing or commercializing products before us or doing so more successfully than we or our collaborators do.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face potential competition in target discovery and product development from many different approaches and sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that we or our collaborators successfully develop and commercialize will compete with existing products and any new products that may become available in the future.

The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience and price; the effectiveness and safety of alternative products; the level of generic competition; and the availability of coverage and adequate reimbursement from government and other third-party payers.

With respect to target discovery activities, competitors and other third parties, including academic and clinical researchers, may access rare families and identify novel targets for drug development before we do.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we, or our collaborators, do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaboration arrangements with large and established companies.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products or therapies that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA, EMA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected by decisions made by insurers or other third party payers.

To the extent that we are unable to compete effectively against one or more of our competitors in these areas, our business will not grow and our financial condition, results of operations and the market price of our common shares may suffer.

Drug discovery and development for various pain applications is intensely competitive. There are a large number of approved products for neuropathic pain, inflammatory pain and other pain indications. These approved products include capsaicin, celecoxib, lidocaine, narcotic analgesics, gabapentin, and pregabalin. We are also aware of development programs at several pharmaceutical and biotechnology companies that are developing Nav1.7 inhibitors or other sodium channel inhibitors for the treatment of pain, including Amgen Inc., AstraZeneca PLC, Biogen Inc., Dainippon Sumitomo Co., Ltd., Eli Lilly and Company, Merck & Co., Inc., or Merck, NeuroQuest Inc., Vertex Pharmaceuticals Inc., Voyager Therapeutics, Inc. and Chromocell Corporation in collaboration with its partner Astellas Pharma Inc. Moreover, we are aware of various other product candidates in development that target other mechanisms of action to treat various pain indications, including calcium channel inhibitors, nerve growth factor inhibitors, and Nav1.8 inhibitors.

If XEN901 or XEN1101 were approved for the treatment of epilepsy, we anticipate that they could compete with other anti-epileptic drugs, or AEDs, which typically can be categorized into four classes by AED mechanism: modulation of voltage-gated ion channels, enhancement of GABA-mediated inhibitory neurotransmission, reduction of glutamate-mediated excitatory neurotransmission, and SV2A modulation. Commonly used AEDs to treat focal seizures include carbamazepine, lamotrigine, valproate, oxcarbazepine, gabapentin and topiramate. There are currently no FDA-approved treatments indicated for the early infantile epileptic encephalopathies EIEE7 or EIEE13. We are not aware of other companies that are developing selective Nav1.6 inhibitors for the treatment of epilepsy. There may be other potassium channel modulators in development that could potentially compete with XEN1101, including products in development from SciFluor Lifesciences, Inc., Knopp Biosciences LLC, and Upsher-Smith Laboratories, Inc.

We have no marketed proprietary products and have not yet advanced a product candidate beyond Phase 2 clinical trials, which makes it difficult to assess our ability to develop our future product candidates and commercialize any resulting products independently.

We have no experience in Phase 3 and later stage clinical development, and related regulatory requirements or the commercialization of products. Teva is responsible for the clinical development of TV-45070; Genentech, a member of the Roche Group, is responsible for the clinical development of GDC-0310; and uniQure controls and has been responsible for the development and commercialization of Glybera. Accordingly, we have not yet demonstrated our ability to independently and repeatedly conduct clinical development after Phase 2, obtain regulatory approval, and commercialize therapeutic products. We will need to develop such abilities if we are to execute on our business strategy to selectively develop and independently commercialize product candidates for orphan and niche indications. To execute on our business plan for the development of independent programs, we will need to successfully:

- execute our clinical development plans for later-stage product candidates;
- obtain required regulatory approvals in each jurisdiction in which we will seek to commercialize products;
- build and maintain appropriate sales, distribution and marketing capabilities;
- gain market acceptance for our future products, if any; and
- manage our spending as costs and expenses increase due to clinical trials, regulatory approvals and commercialization activities.

If we are unsuccessful in accomplishing these objectives, we would not be able to develop and commercialize any future orphan and niche disease product candidates independently, and could fail to realize the potential advantages of doing so.

If we are not successful in discovering, acquiring or in-licensing product candidates in addition to TV-45070, GDC-0310, XEN1101 and XEN901, our ability to expand our business and achieve our strategic objectives may be impaired.

We use our discovery platform to identify validated drug targets and develop new product candidates. To date, our discovery platform has yielded one approved product, Glybera, and multiple development candidates, including TV-45070, GDC-0310 and XEN901. Use of our discovery platform requires substantial technical, financial and human resources, regardless of whether we identify any novel drug targets. Our discovery platform may initially show promise in identifying additional potential product candidates, yet fail to yield viable product candidates for clinical development or commercialization. Such failure may occur for many reasons, including the following: any product candidate may, on further study, be shown to have serious or unexpected side effects or other characteristics that indicate it is unlikely to be safe or otherwise does not meet applicable regulatory criteria; and any product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all.

If we are unable to identify additional product candidates suitable for clinical development and commercialization either from our internal research efforts or through acquiring or in-licensing other product candidates or technologies, we may not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely impact the market price of our common shares.

Our approach to drug discovery is unproven, and we do not know whether we will be able to develop any products of commercial value.

Our discovery platform may not reproducibly or cost-effectively result in the discovery of product candidates and development of commercially viable products that safely and effectively treat human disease.

There are various challenges in utilizing our discovery platform to successfully identify novel drug targets, including locating families suffering from rare disorders and severe phenotypes, entering into agreements with foreign collaborators, complying with various domestic and foreign privacy laws, accessing required technologies in a timely manner and transporting DNA across national borders.

To date, only Glybera has been both developed using our discovery platform and approved for commercial sale. If the use of our discovery platform fails to identify novel targets for drug discovery, or such targets prove to be unsuitable for treating human disease, or we are unable to develop product candidates with specificity and selectivity for such targets, we will fail to develop viable products. If we fail to develop and commercialize viable products, we will not achieve commercial success.

If we fail to attract and retain senior management and key personnel, we may be unable to successfully develop our product candidates, perform our obligations under our collaboration agreements, conduct our clinical trials and commercialize our product candidates.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel.

We could experience difficulties attracting and retaining qualified employees as competition for qualified personnel in the biotechnology and pharmaceutical field is intense. We are highly dependent upon our senior management, particularly Dr. Pimstone, our Chief Executive Officer and President, and Mr. Ian Mortimer, our Chief Financial Officer and Chief Operating Officer, as well as other employees. The loss of services of any of these individuals or one or more of our other members of senior management could materially delay or even prevent the successful development of our product candidates.

In addition, we will need to hire additional personnel as we expand our clinical development activities and develop commercial capabilities, including a sales infrastructure to support our independent commercialization efforts. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. The inability to recruit or loss of the services of any executive or key employee may impede the progress of our research, development and commercialization objectives.

Our employees, collaborators and other personnel may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, collaborators, vendors, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA, EMA and other non-U.S. regulators, provide accurate information to the FDA, EMA and other non-U.S. regulators, comply with data privacy and security and healthcare fraud and abuse laws and regulations in the U.S. and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. Additionally, laws regarding data privacy and security, including the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, as well as comparable laws in non-U.S. jurisdictions, may impose obligations with respect to safeguarding the privacy, use, security and transmission of individually identifiable health information such as genetic material or information we obtain through our direct-to-patient web-based recruitment approach for identifying patients with rare or extreme phenotypes.

Various laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Any misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We may encounter difficulties in managing our growth, including headcount, and expanding our operations successfully.

Our business strategy involves continued development and, where development is successful, commercialization of select product candidates for orphan and niche indications independently. In order to execute on this strategy, we will need to build out a regulatory, sales, manufacturing, distribution and marketing infrastructure and expand our development capabilities or contract with third parties to provide these capabilities and infrastructure for us. To achieve this, we will need to identify, hire and integrate personnel who have not worked together as a group previously.

As our operations expand, we expect that we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties.

Drs. Simon Pimstone and Y. Paul Goldberg each devote a small amount of their time to clinical work outside of their duties at our company, conducting, generally, two to three outpatient clinics per month on average. Future growth will impose significant added responsibilities on members of management, and 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.

If we are unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and 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 product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Our business and operations could suffer in the event of system failures.

Computer system, network or telecommunications failures due to events such as damage from malware, unauthorized access, terrorism, war, or natural disasters could interrupt our internal or partner operations. For example, the loss of preclinical trial data or data from completed or ongoing clinical trials for our product candidates could result in delays in our regulatory filings and development efforts and significantly increase our costs. To the extent that any disruption or cybersecurity breach were to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the development of our product candidates could be delayed. While we have implemented security measures and, to date, have not detected a cybersecurity breach nor experienced a material system failure, our internal computer systems and those of our contractors and consultants remain potentially vulnerable to damage from these events.

A variety of risks associated with international operations could materially adversely affect our business.

Our collaborator for TV-45070, Teva, is based in Israel and a significant portion of the research and development activities under our collaboration with Teva are performed outside of North America. Glybera has been approved for commercial sale in the EU by the EMA, subject to uniQure's compliance with certain post-approval reporting and monitoring obligations; however, uniQure announced in April 2017 that it will not pursue the renewal of marketing authorization in Europe when it is scheduled to expire in October 2017. If we continue to engage in significant cross-border activities, we will be subject to risks related to international operations, including:

- different regulatory requirements for maintaining approval of drugs and biologics in foreign countries;
- reduced protection for intellectual property rights in certain countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, political instability or open conflict in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations of doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in North America;
- likelihood of potential or actual violations of domestic and international anti-corruption laws, such as the U.S. Foreign Corrupt Practices Act and the U.K. Bribery Act, or of U.S. and international export control and sanctions regulations, which likelihood may increase with an increase of operations in foreign jurisdictions;
- tighter restrictions on privacy and the collection and use of data, including genetic material, may apply in jurisdictions outside of North America, where we find some of the families with individuals that exhibit the severe phenotypes that we study; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

If any of these issues were to occur, our business could be materially harmed.

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

Generally, for any taxable year in which 75% or more of our gross income is passive income, or at least 50% of the average quarterly value of our assets (which may be determined in part by the market value of our common shares, which is subject to change) are held for the production of, or produce, passive income, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. Based on the composition of our gross income and gross assets and the nature of our business, we do not believe that we were a PFIC for the taxable years ended December 31, 2016, 2015 and 2014, although we could be a PFIC for the calendar year ending December 31, 2017 or in subsequent years. Our status as a PFIC is a fact-intensive determination made on an annual basis and we cannot provide any assurance regarding our PFIC status for the taxable year ending December 31, 2017 or for future taxable years.

If we are a PFIC for any subsequent year, U.S. Holders of our common shares may suffer adverse tax consequences. Gains realized by non-corporate U.S. Holders on the sale of our common shares would be taxed as ordinary income, rather than as capital gain, and the preferential tax rate applicable to dividends received on our common shares would be lost. Interest charges would also be added to taxes on gains and dividends realized by all U.S. Holders.

A U.S. Holder may avoid these adverse tax consequences by timely making a qualified electing fund election. For each year that we would meet the PFIC gross income or asset test, an electing U.S. Holder would be required to include in gross income its pro rata share of our net ordinary income and net capital gains, if any. A U.S. Holder may make a qualified electing fund election only if we commit to provide U.S. Holders with their pro rata share of our net ordinary income and net capital gains. If we are a PFIC in the current or a future tax year, we will provide our U.S. Holders with the information that is necessary in order for them to make a qualified electing fund election and to report their common shares of ordinary earnings and net capital gains for each year for which we are a PFIC.

A U.S. Holder may also mitigate the adverse tax consequences if we are a PFIC by timely making a mark-to-market election. Generally, for each year that we would meet the PFIC gross income or asset test, an electing U.S. Holder would include in gross income the increase in the value of its common shares during each of its taxable years and deduct from gross income the decrease in the value of such shares during each of its taxable years. A mark-to-market election may be made and maintained only if our common shares are regularly traded on a qualified exchange, including The NASDAQ Global Market, or NASDAQ. Whether our common shares are regularly traded on a qualified exchange is an annual determination based on facts that, in part, are beyond our control. Accordingly, a U.S. Holder might not be eligible to make a mark-to-market election to mitigate the adverse tax consequences if we are characterized as a PFIC.

We may become subject to income tax in jurisdictions in which we are organized or operate, which would reduce our future earnings.

There is a risk that we may become subject to income tax in jurisdictions outside of Canada and the United States, if under the laws of any such jurisdiction, we are considered to be carrying on a trade or business there or earn income that is considered to be sourced there and we do not qualify for an exemption. In jurisdictions where we do not believe we are subject to tax, we can provide no certainty that tax authorities in those jurisdictions will not subject one or more tax years to examination. Tax examinations are often complex as tax authorities may disagree with the treatment of items reported by us, the result of which could have a material adverse effect on our operating results and financial condition.

Acquisitions or joint ventures could disrupt our business, cause dilution to our shareholders and otherwise harm our business.

We actively evaluate various strategic transactions on an ongoing basis and may acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures or investments in complementary businesses. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including:

- disruption in our relationships with collaborators or suppliers as a result of such a transaction;
- unanticipated liabilities related to acquired companies;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- retention of key employees;
- diversion of management time and focus from operating our business to management of strategic alliances or joint ventures or acquisition integration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses; and
- possible write-offs or impairment charges relating to acquired businesses.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

Also, the anticipated benefit of any strategic alliance, joint venture or acquisition may not materialize. Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

Risks Related to Development, Clinical Testing and Regulatory Approval of Our Product Candidates

The regulatory approval processes of the FDA, EMA and regulators in other jurisdictions are lengthy, time-consuming and inherently unpredictable. If we, or our collaborators, are unable to obtain timely regulatory approval for our product candidates, our business will be substantially harmed.

The regulatory approval process is expensive and the time required to obtain approval from the FDA, EMA or other regulatory authorities in other jurisdictions to sell any product is uncertain and may take years. Whether regulatory approval will be granted is unpredictable and depends upon numerous factors, including the substantial discretion of the regulatory authorities. Approval policies, regulations, or the type and amount of preclinical and clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. Other than for Glybera in the EU, neither we nor our collaborators have obtained regulatory approval for any of our product candidates. It is possible that none of our existing product candidates or any of our future product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, EMA or other regulatory authorities may disagree with the design or implementation of our or our collaborators' clinical trials;
- we or our collaborators may be unable to demonstrate to the satisfaction of the FDA, EMA or other regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA or other regulatory authorities for approval;
- we, or our collaborators, may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA, EMA or other regulatory authorities may disagree with our or our collaborators' interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a New Drug Application, or NDA, or other submission or to obtain regulatory approval in the U.S. or elsewhere;
- the FDA, EMA or other regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we or our collaborators contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or other regulatory authorities outside of the U.S. may significantly change in a manner rendering our or our collaborators' clinical data insufficient for approval.

Even if we, or our collaborators, obtain approval for a particular product, regulatory authorities may grant approval contingent on the performance of costly post-approval clinical trials, or may approve a product with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product.

Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes. If clinical trials are prolonged or delayed, we, or our collaborators, may be unable to commercialize our product candidates on a timely basis.

Clinical testing of product candidates is expensive and, depending on the stage of development, can take a substantial period of time to complete. Clinical trial outcomes are inherently uncertain, and failure can occur at any time during the clinical development process.

Clinical trials can be halted or delayed for a variety of reasons, including those related to:

- side effects or adverse events in study participants presenting an unacceptable safety risk;
- inability to reach agreement with prospective contract research organizations, or CROs, and clinical trial sites, or the breach of such agreements;
- failure of third-party contractors, such as CROs, or investigators to comply with regulatory requirements;
- delay or failure in obtaining the necessary approvals from regulators or institutional review boards, or IRBs, in order to commence a clinical trial at a prospective trial site, or their suspension or termination of a clinical trial once commenced;

- a requirement to undertake and complete additional preclinical studies to generate data required to support the submission of an NDA;
- inability to enroll sufficient patients to complete a protocol, particularly in orphan diseases;
- difficulty in having patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- problems with drug product or drug substance storage and distribution;
- adding new clinical trial sites;
- our inability to manufacture, or obtain from third parties, adequate supply of drug substance or drug product sufficient to complete our preclinical studies and clinical trials; and
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines.

The results of any Phase 3 or other pivotal clinical trial may not be adequate to support marketing approval. These clinical trials are lengthy and, with respect to non-orphan indications, usually involve many hundreds to thousands of patients. In addition, if the FDA, EMA or another applicable regulator disagrees with our or our collaborator's choice of the key testing criterion, or primary endpoint, or the results for the primary endpoint are not robust or significant relative to the control group of patients not receiving the experimental therapy, such regulator may refuse to approve our product candidate in the region in which it has jurisdiction. The FDA, EMA or other applicable non-U.S. regulators also may require additional clinical trials as a condition for approving any of these product candidates.

We could also encounter delays if a clinical trial is suspended or terminated by us, by our collaborators, by the IRBs of the institutions in which such trial is being conducted, by any Data Safety Monitoring Board for such trial, or by the FDA, EMA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA or other regulatory authorities resulting in the imposition of a clinical hold, product candidate manufacturing problems, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, delays can occur due to safety concerns arising from trials or other clinical data regarding another company's product candidate in the same compound class as one of ours.

If we or our collaborators experience delays in the completion of, or termination of, any clinical trial of one of our product candidates, the commercial prospects of the product candidate will be harmed, could shorten the patent protection period during which we may have the exclusive right to commercialize our products and our or our collaborators' ability to commence product sales and generate product revenue from the product will be delayed. In addition, any delays in completing our clinical trials will increase our costs and slow down our product candidate development and approval process. Any of these occurrences may harm our business, financial condition and prospects significantly. 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.

Our product candidates – including TV-45070 and GDC-0310 for the treatment of pain, as well as XEN1101 and XEN901 for the treatment of epilepsy – target novel molecular mechanisms. Regulatory authorities may require more extensive studies of the long-term effects of such product candidates for regulatory approval, which could delay development of our product candidates or our future product candidates based on novel mechanisms.

Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which could prevent or delay regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of our products, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that the product candidate is both safe and effective for use in each target indication. Clinical trials often fail to demonstrate safety and efficacy of the product candidate studied for the target indication. Most product candidates that commence clinical trials are never approved as products. For example, in June 2017, we, along with Teva, announced topline results from a Phase 2b study designed to evaluate the efficacy and safety of TV-45070 in PHN. Results from this trial showed that TV-45070 did not meet the primary endpoint of a statistically significant change in pain from baseline to week four as assessed by the numeric rating scale. Secondary endpoints were also not met. We and Teva plan to further analyze the data from this study to determine the next steps for TV-45070.

In the case of some of our product candidates, we are seeking to develop treatments for diseases for which there is relatively limited clinical experience, and, in some cases our clinical trials use novel end points and measurement methodologies or subjective patient feedback, which adds a layer of complexity to our clinical trials and may delay regulatory approval. In addition, our focus on orphan and niche markets may cause us to select target indications that are in more challenging therapeutic areas. For example, clinical trials for pain, the indication for which TV-45070 and GDC-0310 are being developed, are inherently difficult to conduct. The primary measure of pain is based on subjective patient feedback, which can be influenced by factors outside of our control, and can vary widely from day to day for a particular patient, and from patient to patient and site to site within a clinical study. The placebo effect also tends to have a more significant impact on pain trials.

If our product candidates are not shown to be both safe and effective in clinical trials, we will not be able to obtain regulatory approval or commercialize these product candidates and products. In such case, we would need to develop other compounds and conduct associated preclinical testing and clinical trials, as well as potentially seek additional financing, all of which would have a material adverse effect on our business, growth prospects, operating results, financial condition and results of operations.

We may find it difficult to enroll patients in our clinical studies, including for orphan or niche indications, which could delay or prevent clinical studies of our product candidates.

We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a study, to complete our clinical studies in a timely manner. Patient enrollment for clinical trials for orphan and niche indications and for more prevalent conditions is affected by factors including:

- severity of the disease under investigation;
- design of the study protocol;
- size of the patient population;
- eligibility criteria for the study in question;
- perceived risks and benefits of the product candidate under study;
- proximity and availability of clinical study sites for prospective patients;
- availability of competing therapies and clinical studies;
- efforts to facilitate timely enrollment in clinical studies; and
- patient referral practices of physicians.

The limited patient populations in orphan and niche indications present significant recruitment challenges for clinical trials. As an example of a rare childhood epilepsy disorder, the prevalence of Dravet Syndrome is estimated to be 7,500-15,000 patients in the U.S. It is estimated that the population of SCN8A epilepsy represents an even smaller subset amongst rare, childhood epilepsies when compared to Dravet Syndrome; however a full understanding of this population size is still unknown. Many of these patients may not be suitable or available for clinical trials. This means that we or our collaborators generally will have to run multi-site and potentially multi-national trials, which can be expensive and require close coordination and supervision. If we experience delays in completing our clinical trials, such delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical studies altogether.

If we fail to obtain or maintain orphan drug designation or other regulatory exclusivity for some of our product candidates, our competitive position would be harmed.

A product candidate that receives orphan drug designation can benefit from a streamlined regulatory process as well as potential commercial benefits following approval. Currently, this designation provides market exclusivity in the U.S. and the EU for seven years and ten years, respectively, if a product is the first such product approved for such orphan indication. This market exclusivity does not, however, pertain to indications other than those for which the drug was specifically designated in the approval, nor does it prevent other types of drugs from receiving orphan designations or approvals in these same indications. Further, even after an orphan drug is approved, the FDA can subsequently approve a drug with similar chemical structure for the same condition if the FDA concludes that the new drug is clinically superior to the orphan product or a market shortage occurs.

In the EU, orphan exclusivity may be reduced to six years if the drug no longer satisfies the original designation criteria or can be lost altogether if the marketing authorization holder consents to a second orphan drug application or cannot supply enough drug, or when a second applicant demonstrates its drug is “clinically superior” to the original orphan drug. TV-45070 has received both fast track and orphan drug designations for the treatment of erythromelalgia, or EM, from the FDA, and flunarizine, a drug we are evaluating internally for the potential treatment of hemiplegic migraine, has received orphan drug designation from the FDA. If we seek orphan drug designations for other indications or in other jurisdictions, such as for TV-45070 in the EU, we may fail to receive such orphan drug designations and, even if we succeed, such orphan drug designations may fail to result in or maintain orphan drug exclusivity upon approval, which would harm our competitive position.

Results of earlier clinical trials may not be predictive of the results of later-stage clinical trials.

The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Interpretation of results from early, usually smaller, studies that suggest a clinically meaningful response in some patients, requires caution. Results from later stages of clinical trials enrolling more patients may fail to show the desired safety and efficacy results or otherwise fail to be consistent with the results of earlier trials of the same product candidates. Later clinical trial results may not replicate earlier clinical trials for a variety of reasons, including differences in trial design, different trial endpoints (or lack of trial endpoints in exploratory studies), patient population, number of patients, patient selection criteria, trial duration, drug dosage and formulation and lack of statistical power in the earlier studies. These uncertainties are enhanced where the diseases under study lack established clinical endpoints and validated measures of efficacy, as is often the case with orphan diseases for which no drugs have been developed previously. For example, our results for two small exploratory clinical trials for primary EM pain, one using a topical formulation and the other an oral formulation of TV-45070, used novel measures of efficacy assessment. While these studies provided promising results, further larger clinical trials would be necessary to confirm and extend these observations.

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

As product candidates are developed through preclinical to late stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates 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 the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and/or jeopardize our or our collaborators’ ability to commence product sales and generate revenue.

Even if we obtain and maintain approval for our product candidates from one jurisdiction, we may never obtain approval for our product candidates in other jurisdictions, which would limit our market opportunities and adversely affect our business.

Sales of our approved products are, and will be, subject to U.S. and foreign regulatory requirements governing clinical trials and marketing approval, and we plan to seek regulatory approval to commercialize our product candidates in North America, the EU and in additional foreign countries. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. For example, approval in the U.S. by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries. Approval procedures vary among jurisdictions and can be lengthy and expensive, and involve requirements and administrative review periods different from, and greater than, those in the U.S., including additional preclinical studies or clinical trials. Even if our product candidates are approved, regulatory approval for any product may be withdrawn by the regulatory authorities in a particular jurisdiction.

Even if a product is approved, the FDA or the EMA, as the case may be, may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. In many countries outside the U.S., a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for a product is also subject to approval.

Regulatory authorities in countries outside of the U.S. and the EMA also have their own requirements for approval of product candidates with which we must comply prior to marketing in those countries. Obtaining foreign regulatory approvals and compliance with such foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our current and any future products, in certain countries.

If we fail to receive applicable marketing approvals or comply with the regulatory requirements in international markets, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected.

We work with outside scientists and their institutions in executing our business strategy of developing product candidates using our discovery platform. These scientists may have other commitments or conflicts of interest, which could limit our access to their expertise and harm our ability to leverage our discovery platform.

We work with scientific advisors and collaborators at academic research institutions in connection with our discovery platform. These scientific advisors serve as our link to the various families with extreme phenotypes in that these advisors may:

- identify families as potential candidates for study;
- obtain their consent to participate in our research;
- perform medical examinations and gather medical histories;
- conduct the initial analysis of suitability of the families to participate in our research based on the foregoing; and
- collect data and biological samples from the family members periodically in accordance with our study protocols.

These scientists and collaborators are not our employees, rather they serve as either independent contractors or the primary investigators under research collaboration agreements that we have with their sponsoring academic or research institution. Such scientists and collaborators may have other commitments that would limit their availability to us. Although our scientific advisors generally agree not to do competing work, if an actual or potential conflict of interest between their work for us and their work for another entity arises, we may lose their services. It is also possible that some of our valuable proprietary knowledge may become publicly known through these scientific advisors if they breach their confidentiality agreements with us, which would cause competitive harm to our business.

Risks Related to Commercialization

If, in the future, we are unable to establish our own sales, marketing and distribution capabilities or enter into licensing or collaboration agreements for these purposes, we may not be successful in independently commercializing any future products.

We do not have a sales or marketing infrastructure and, as a company, have no sales, marketing or distribution experience. Our strategy involves, in part, building our own commercial infrastructure to selectively commercialize future products in niche or orphan indications. Where we believe such involvement would advance our business, we seek to retain the right to participate in the future development and commercialization of such products. For example, we have a co-promotion option for TV-45070 with Teva in the U.S.

To develop internal sales, distribution and marketing capabilities, we will have to invest significant amounts of financial and management resources, some of which will need to be committed prior to any confirmation that any of our proprietary product candidates will be approved. For any future products for which we decide to perform sales, marketing and distribution functions ourselves, we could face a number of additional risks, including:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel or develop alternative sales channels;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating and maintaining an independent sales and marketing organization.

Where and when appropriate, we may elect to utilize contract sales forces or distribution partners to assist in the commercialization of our product candidates. If we enter into arrangements with third parties to perform sales, marketing and distribution services for a product, the resulting revenue or the profitability from this revenue to us is likely to be lower than if we had sold, marketed and distributed that product ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market, and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell, market, and distribute our current or any future products effectively.

Even if we receive regulatory approval to commercialize any of the product candidates that we develop independently, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense.

Any regulatory approvals that we receive for our product candidates we commercialize will be subject to limitations on the approved indicated uses for which the product may be marketed or subject to certain conditions of approval, and may contain requirements for potentially costly post-approval trials, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the marketed product.

For any approved product, we will need to ensure continued compliance with extensive regulations and requirements regarding the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product. These requirements include submissions of safety and other post-approval information and reports, as well as continued compliance with current good manufacturing practices, or cGMP, and current good clinical practices, or cGCP, for any clinical trials that we or our collaborators conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on any post-approval clinical trials;
- refusal by the FDA, EMA or another applicable regulatory authority to approve pending applications or supplements to approved applications filed by us or our collaborators, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

Occurrence of any of the foregoing could have a material and adverse effect on our business and results of operations.

If the market opportunities for any product that we or our collaborators develop are smaller than we believe they are, our revenue may be adversely affected and our business may suffer.

We intend to focus our independent product development on treatments for rare diseases. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates. Currently, most reported estimates of the prevalence of these diseases are based on studies of small subsets of the population in specific geographic areas, which are then extrapolated to estimate the prevalence of the diseases in the U.S. or elsewhere. If the prevalence of such diseases is smaller than we have projected, then, even if our products are approved, we may not be able to successfully commercialize them.

Even if we or our collaborators receive approval to commercialize our products, unfavorable pricing regulations and challenging third-party coverage and reimbursement practices could harm our business.

Our or any collaborators' ability to commercialize any products successfully will depend, in part, on the extent to which coverage and reimbursement for these products and related treatments will be available from government healthcare programs, private health insurers, managed care plans, and other organizations. Government authorities and third-party payers, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry is cost containment. Government authorities and third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payers are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we or any collaborator commercialize and, if reimbursement is available, the level of reimbursement. In addition, coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we or a collaborator obtains marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we or our collaborators may not be able to successfully commercialize any product candidate for which marketing approval is obtained.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA, EMA or other regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover our and any collaborator's costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Third-party payers often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our or any collaborator's inability to promptly obtain coverage and profitable payment rates from both government-funded and private payers for any approved products that we or our collaborators develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Our target patient populations in orphan and niche indications, where we intend to selectively develop and commercialize products independently, are relatively small. In order for therapies that are designed to treat smaller patient populations to be commercially viable, the reimbursement for such therapies needs to be higher, on a relative basis, to account for the lack of volume. Accordingly, we will need to implement a coverage and reimbursement strategy for any approved product that accounts for the smaller potential market size. If we are unable to establish or sustain coverage and adequate reimbursement for our current and any future products from third party payers or the government, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those products.

Recently enacted and future legislation may increase the difficulty and cost for us to commercialize any products that we or our collaborators develop and affect the prices we may obtain.

The U.S. and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell any of our products profitably, once such products are approved for sale. Among policy makers and payers in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the PPACA, was enacted in 2010 and includes measures that have significantly changed, or will significantly change, the way healthcare is financed by both governmental and private insurers. Among the provisions of the PPACA of importance to the pharmaceutical industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, that began in 2011;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23% and 13% of the average manufacturer price for branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during 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 covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

- new requirements under the federal Open Payments program, created under Section 6002 of the PPACA and its implementing regulations that 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) report annually to the U.S. Department of Health and Human Services, or HHS, information related to "payments or other transfers of value" made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals and that applicable manufacturers and applicable group purchasing organizations report annually to the HHS ownership and investment interests held by physicians (as defined above) and their immediate family members, with data collection required beginning August 1, 2013 and reporting to the Centers for Medicare & Medicaid Services, or CMS, required by the 90th day of each subsequent calendar year, and disclosure of such information made on a publicly available website starting September 2014;
- a requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- creation of the Independent Payment Advisory Board which, beginning in 2014, has authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and
- establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending, that began, in 2011.

In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize our current or any future products. 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. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. Our future products, if any, might not be considered medically reasonable and necessary for a specific indication or cost-effective by third-party payers. An adequate level of reimbursement might not be available for such products and third-party payers' reimbursement policies might adversely affect our or our collaborators' ability to sell any future products profitably.

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

The Trump administration and Congress are also expected to attempt broad sweeping changes to the current health care laws, including PPACA. The impact of those changes on us and the pharmaceutical industry as a whole is currently unknown. Any changes to the PPACA are likely to have an impact on our results of operations, and may have a material adverse effect on our result of operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Foreign governments tend to impose strict price controls, which may adversely affect our future profitability.

In most foreign countries, particularly those in the EU, prescription drug pricing and/or reimbursement is subject to governmental control. In those countries that impose price controls, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies.

Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we or our collaborators might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue that are generated from the sale of the product in that country. If reimbursement of such products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, or if there is competition from lower priced cross-border sales, our profitability will be negatively affected.

Risks Related to Our Dependence on Third Parties

We depend on our collaborative relationship with Teva to further develop and commercialize TV-45070, and if our relationship is not successful or is terminated, we may not be able to effectively develop and/or commercialize TV-45070, which could have a material adverse effect on our business.

We depend on Teva to collaborate with us to develop and globally commercialize TV-45070. Under the agreement, Teva controls all decision-making with respect to the clinical development and commercialization for TV-45070.

As a result of our dependence on Teva, the eventual success or commercial viability of TV-45070 is largely beyond our control. The financial returns to us, if any, depend in large part on the achievement of development and commercialization milestones, plus a share of any revenue from sales. Therefore, our success, and any associated financial returns to us and our investors, will depend in large part on Teva's performance under the agreement. We are subject to a number of additional specific risks associated with our dependence on our collaborative relationship with Teva, including:

- adverse decisions by Teva or the Joint Development Committee regarding the development and commercialization of TV-45070;
- possible disagreements as to the timing, nature and extent of development plans, including clinical trials or regulatory approval strategy;
- loss of significant rights if we fail to meet our obligations under the agreement;
- our limited control over clinical trials of TV-45070;
- changes in key management personnel at Teva, including in members of the Joint Development Committee; and
- possible disagreements with Teva regarding the agreement, for example, with regard to ownership of intellectual property rights.

If either we or Teva fail to perform our respective obligations, any clinical trial, regulatory approval or development progress could be significantly delayed or halted, could result in costly or time-consuming litigation or arbitration and could have a material adverse effect on our business.

Decisions by Teva to emphasize other drug candidates currently in its portfolio ahead of our product candidates, or to add competitive agents to its portfolio could result in a decision to terminate the agreement, in which event, among other things, we may be responsible for paying any remaining costs of all ongoing or future clinical trials.

In addition, Teva's executive offices and a substantial percentage of their manufacturing capabilities are located in Israel. Teva's Israeli operations are dependent upon materials imported from outside Israel, and Teva also exports significant amounts of products from Israel. Accordingly, our collaboration with Teva could be materially and adversely affected by acts of terrorism or if major hostilities were to occur in the Middle East or trade between Israel and its present trading partners were curtailed, including as a result of acts of terrorism in the U.S. or elsewhere.

Any of the above discussed scenarios could adversely affect the timing and extent of our development and commercialization activities, which could cause significant delays and funding shortfalls for those activities and seriously harm our business.

Our prospects for successful development and commercialization of our partnered products and product candidates are dependent upon the research, development and marketing efforts of our collaborators.

We have no control over the resources, time and effort that our collaborators may devote to our programs and limited access to information regarding or resulting from such programs. We are dependent on Teva, Genentech, and Merck to fund and conduct the research and any clinical development of product candidates under our collaboration with each of them, and for the successful regulatory approval, marketing and commercialization of one or more of such products or product candidates. Such success will be subject to significant uncertainty.

Our ability to recognize revenue from successful collaborations may be impaired by multiple factors including:

- a collaborator may shift its priorities and resources away from our programs due to a change in business strategies, or a merger, acquisition, sale or downsizing of its company or business unit;
- a collaborator may cease development in therapeutic areas which are the subject of our strategic alliances;
- a collaborator may change the success criteria for a particular program or product candidate thereby delaying or ceasing development of such program or candidate;
- a significant delay in initiation of certain development activities by a collaborator will also delay payment of milestones tied to such activities, thereby impacting our ability to fund our own activities;
- a collaborator could develop a product that competes, either directly or indirectly, with our current or future products, if any;
- a collaborator with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution or sale of a product;
- a collaborator with manufacturing responsibilities may encounter regulatory, resource or quality issues and be unable to meet demand requirements;
- a collaborator may exercise its rights under the agreement to terminate our collaboration;
- a dispute may arise between us and a collaborator concerning the research or development of a product candidate, commercialization of a product or payment of royalties or milestone payments, any of which could result in a delay in milestones, royalty payments or termination of a program and possibly resulting in costly litigation or arbitration which may divert management attention and resources;
- a collaborator may not adequately protect the intellectual property rights associated with a product or product candidate; and
- a collaborator may use our proprietary information or intellectual property in such a way as to invite litigation from a third party.

If our collaborators do not perform in the manner we expect or fulfill their responsibilities in a timely manner, or at all, the clinical development, regulatory approval and commercialization efforts could be delayed, terminated or be commercially unsuccessful. Conflicts between us and our collaborators may arise. In the event of termination of one or more of our collaboration agreements, it may become necessary for us to assume the responsibility of any terminated product or product candidates at our own expense or seek new collaborators. In that event, we would likely be required to limit the size and scope of one or more of our independent programs or increase our expenditures and seek additional funding which may not be available on acceptable terms or at all, and our business would be materially and adversely affected.

We may not be successful in establishing new collaborations or maintaining our existing alliances, which could adversely affect our ability to develop future product candidates and commercialize future products.

We may seek to enter into additional product collaborations in the future, including alliances with other biotechnology or pharmaceutical companies, to enhance and accelerate the development of our future product candidates and the commercialization of any resulting products. We face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish other collaborations or other alternative arrangements for any future product candidates because our research and development pipeline may be insufficient, our product candidates may be deemed to be at too early of a stage of development for collaboration effort and/or third parties may view our product candidates as lacking the requisite potential to demonstrate safety and efficacy. Even if we are successful in our efforts to establish collaborations, the terms that we agree upon may not be favorable to us and we may not be able to maintain such collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing.

If any of our existing collaboration agreements is terminated, or if we determine that entering into other product collaborations is in our best interest but we either fail to enter into, delay in entering into or fail to maintain such collaborations:

- the development of certain of our current or future product candidates may be terminated or delayed;
- our cash expenditures related to development of our product candidates would increase significantly and we may need to seek additional financing sooner than expected;
- we may be required to hire additional employees or otherwise develop expertise, such as clinical, regulatory, sales and marketing expertise, which we do not currently have;
- we will bear all of the risk related to the development of any such product candidates; and
- the competitiveness of any product that is commercialized could be reduced.

We intend to rely on third-party manufacturers to produce our clinical product candidate supplies. Any failure by a third-party manufacturer to produce acceptable supplies for us may delay or impair our ability to initiate or complete our clinical trials or commercialize approved products.

We do not currently own or operate any manufacturing facilities nor do we have any in-house manufacturing experience or personnel. We rely on our collaborators to manufacture product candidates licensed to them or work with multiple third party contract manufacturers to produce sufficient quantities of materials required for the manufacture of our product candidates for preclinical testing and clinical trials and intend to do so for the commercial manufacture of our products. If we are unable to arrange for such third-party manufacturing sources, or fail to do so on commercially reasonable terms, we may not be able to successfully produce sufficient supply of product candidate or we may be delayed in doing so. Such failure or substantial delay could materially harm our business.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality control and assurance, volume production, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to synthesize and manufacture our product candidates in accordance with our product specifications) and the possibility of termination or nonrenewal of the agreement by the third party at a time that is costly or damaging to us. In addition, the FDA, EMA and other regulatory authorities require that our product candidates be manufactured according to cGMP and similar foreign standards. Pharmaceutical manufacturers and their subcontractors are required to register their facilities and/or products manufactured at the time of submission of the marketing application and then annually thereafter with the FDA and certain state and foreign agencies. They are also subject to periodic unannounced inspections by the FDA, state and other foreign authorities. Any subsequent discovery of problems with a product, or a manufacturing or laboratory facility used by us or our collaborators, may result in restrictions on the product or on the manufacturing or laboratory facility, including marketed product recall, suspension of manufacturing, product seizure, or a voluntary withdrawal of the drug from the market. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates.

We rely on third parties to monitor, support, conduct and/or oversee clinical trials of the product candidates that we are developing independently and, in some cases, to maintain regulatory files for those product candidates. We may not be able to obtain regulatory approval for our product candidates or commercialize any products that may result from our development efforts, if we are not able to maintain or secure agreements with such third parties on acceptable terms, if these third parties do not perform their services as required, or if these third parties fail to timely transfer any regulatory information held by them to us.

We rely on entities outside of our control, which may include academic institutions, CROs, hospitals, clinics and other third-party collaborators, to monitor, support, conduct and/or oversee preclinical and clinical studies of our current and future product candidates. We also rely on third parties to perform clinical trials on our current and future product candidates when they reach that stage. As a result, we have less control over the timing and cost of these studies and the ability to recruit trial subjects than if we conducted these trials with our own personnel.

If we are unable to maintain or enter into agreements with these third parties on acceptable terms, or if any such engagement is terminated prematurely, we may be unable to enroll patients on a timely basis or otherwise conduct our trials in the manner we anticipate. In addition, there is no guarantee that these third parties will devote adequate time and resources to our studies or perform as required by our contract or in accordance with regulatory requirements, including maintenance of clinical trial information regarding our product candidates. If these third parties fail to meet expected deadlines, fail to transfer to us any regulatory information in a timely manner, fail to adhere to protocols or fail to act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then clinical trials of our future product candidates may be extended or delayed with additional costs incurred, or our data may be rejected by the FDA, EMA or other regulatory agencies.

Ultimately, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with cGCP regulations and guidelines enforced by the FDA, the competent authorities of the member states of the European Economic Area and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these cGCP regulations through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of our CROs fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and our submission of marketing applications may be delayed or the FDA may require us to perform additional clinical trials before approving our marketing applications. Upon inspection, the FDA could determine that any of our clinical trials fail or have failed to comply with applicable cGCP regulations. In addition, our clinical trials must be conducted with product produced under the cGMP regulations enforced by the FDA, and our clinical trials may require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and increase our costs. Moreover, our business may be implicated if any of our CROs violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. Further, if our relationship with any of our CROs is terminated, we may be unable to enter into arrangements with alternative CROs on commercially reasonable terms, or at all.

Switching or adding CROs or other suppliers can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO or supplier commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. If we are required to seek alternative supply arrangements, the resulting delays and potential inability to find a suitable replacement could materially and adversely impact our business.

Risks Related to Intellectual Property

We could be unsuccessful in obtaining or maintaining adequate patent protection for one or more of our products or product candidates.

Our commercial success will depend, in large part, on our ability to obtain and maintain patent and other intellectual property protection with respect to our product candidates. Patents might not be issued or granted with respect to our patent applications that are currently pending, and issued or granted patents might later be found to be invalid or unenforceable, be interpreted in a manner that does not adequately protect our current product or any future products, or fail to otherwise provide us with any competitive advantage. The patent position of biotechnology and pharmaceutical companies is generally uncertain because it involves complex legal and factual considerations. The standards applied by the U.S. Patent and Trademark Office, or USPTO, and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and pharmaceutical patents. Consequently, patents may not issue from our pending patent applications. As such, we do not know the degree of future protection that we will have on our proprietary products and technology, if any, and a failure to obtain adequate intellectual property protection with respect to our product candidates and proprietary technology could have a material adverse impact on our business.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the U.S. in several stages over the lifetime of the patents and/or applications. The USPTO and various non-US governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply with respect to the patents and patent applications that we own, and we rely upon our licensors or our other collaborators to effect compliance with respect to the patents and patent applications that we license. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, 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. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

Our intellectual property rights will not necessarily provide us with competitive advantages.

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 compounds that are similar to our product candidates but that are not covered by the claims of the patents that we or our collaborators own or have exclusively licensed;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we may obtain patents for certain compounds many years before we obtain marketing approval for products containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of our patents may be limited;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may fail to develop additional proprietary technologies that are patentable;
- the laws of certain foreign countries may not protect our intellectual property rights to the same extent as the laws of the U.S., or we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; and
- the patents of others may have an adverse effect on our business, for example by preventing us from marketing one or more of our product candidates for one or more indications.

Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the U.S. These products may compete with our current or future products, if any, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

Our patents covering one or more of our products or product candidates could be found invalid or unenforceable if challenged.

Any of our intellectual property rights could be challenged or invalidated despite measures we take to obtain patent and other intellectual property protection with respect to our product candidates and proprietary technology. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the U.S. and in some other jurisdictions, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the USPTO or the applicable foreign counterpart, or made a misleading statement, during prosecution. A litigant or the USPTO itself could challenge our patents on this basis even if we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith. The outcome following such a challenge is unpredictable.

With respect to challenges to the validity of our patents, for example, there might be invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on a product candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. The cost of defending such a challenge, particularly in a foreign jurisdiction, and any resulting loss of patent protection could have a material adverse impact on one or more of our product candidates and our business.

Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend, particularly in a foreign jurisdiction, and could require us to pay substantial damages, cease the sale of certain products or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms or at all). Any efforts to enforce our intellectual property rights are also likely to be costly and may divert the efforts of our scientific and management personnel.

Patent protection and patent prosecution for some of our product candidates is dependent on, and the ability to assert patents and defend them against claims of invalidity is maintained by, third parties.

There have been and may be times in the future when certain patents that relate to our product candidates or any approved products are controlled by our licensees or licensors. Although we may, under such arrangements, have rights to consult with our collaborators on actions taken as well as back-up rights of prosecution and enforcement, we have in the past and may in the future relinquish rights to prosecute and maintain patents and patent applications within our portfolio as well as the ability to assert such patents against infringers. Currently, some of these rights relating to the patent portfolios for TV-45070, GDC-0310, Glybera and some of our earlier stage product candidates are held by our collaborators.

If any current or future licensee or licensor with rights to prosecute, assert or defend patents related to our product candidates fails to appropriately prosecute and maintain patent protection for patents covering any of our product candidates, or if patents covering any of our product candidates are asserted against infringers or defended against claims of invalidity or unenforceability in a manner which adversely affects such coverage, our ability to develop and commercialize any such product candidate may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

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

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or one of our licensors is not valid or is unenforceable, or may refuse to stop the other party in such infringement proceeding 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, held unenforceable or interpreted narrowly, and could put any of our patent applications at risk of not yielding an issued patent.

Interference proceedings, derivation proceedings, entitlement proceedings, ex parte reexamination, inter partes reexamination, inter partes review, post-grant review, and opposition proceedings provoked by third parties or brought by the USPTO or any foreign patent authority may be used to challenge inventorship, ownership, claim scope, or validity of our patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees.

We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U.S. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common shares.

Claims that our product candidates or the sale or use of our future products infringe the patent or other intellectual property rights of third parties could result in costly litigation or could require substantial time and money to resolve, even if litigation is avoided.

Our commercial success depends upon our ability to develop product candidates and commercialize products that may be approved in the future, using our proprietary technology without infringing the intellectual property rights of others. Our product or product candidates or any uses of them may now and in the future infringe third-party patents or other intellectual property rights. Third parties might allege that we or our collaborators are infringing their patent rights or that we have misappropriated their trade secrets, or that we are otherwise violating their intellectual property rights, whether with respect to the manner in which we have conducted our research or to the composition, use or manufacture of the compounds we have developed or are developing with our collaborators. Such third parties might resort to litigation against us or other parties we have agreed to indemnify, which litigation could be based on either existing intellectual property or intellectual property that arises in the future.

It is possible that relevant patents or patent applications held by third parties will cover our product candidates at the time of launch and we may also fail to identify, relevant patents or patent applications held by third parties that cover our product candidates. For example, applications filed before November 29, 2000, and certain applications filed after that date that will not be filed outside the U.S. remain confidential until patents issue. Other patent applications in the U.S. and several other jurisdictions are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Furthermore, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we or our collaborators were the first to invent, or the first to file patent applications on, our product candidates or for their uses, or that our product candidates will not infringe patents that are currently issued or that are issued in the future. In the event that a third party has also filed a patent application covering one of our product candidates or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the USPTO or its foreign counterpart to determine priority of invention. Additionally, pending patent applications and patents which have been published can, subject to certain limitations, be later amended in a manner that could cover our current or future products, if any, or their use.

Defending against claims of patent infringement, misappropriation of trade secrets or other violations of intellectual property rights could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. Claims that our product candidates or the sale or use of our future products infringe, misappropriate or otherwise violate third-party intellectual property rights could therefore have a material adverse impact on our business.

Most of our competitors are larger than we are and have substantially greater financial resources. They are, therefore, likely to be able to sustain the costs of complex intellectual property litigation longer than we could. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our clinical trials, continue our internal research programs, in-license needed technology, or enter into strategic collaborations that would help us bring our product candidates to market.

In addition, any future intellectual property litigation, interference or other administrative proceedings will result in additional expense and distraction of our personnel. An adverse outcome in such litigation or proceedings may expose us or any future strategic collaborators to loss of our proprietary position, expose us to significant liabilities, or require us to seek licenses that may not be available on commercially acceptable terms, if at all, each of which could have a material adverse effect on our business.

Unfavorable outcomes in intellectual property litigation could limit our research and development activities and/or our ability to commercialize certain products.

If third parties successfully assert their intellectual property rights against us, we might be barred from using certain aspects of our technology, or barred from developing and commercializing certain products. Prohibitions against using certain technologies, or prohibitions against commercializing certain products, could be imposed by a court or by a settlement agreement between us and a plaintiff. In addition, if we are unsuccessful in defending against allegations that we have infringed, misappropriated or otherwise violated patent or other intellectual property rights of others, we may be forced to pay substantial damage awards to the plaintiff. There is inevitable uncertainty in intellectual property litigation and we could lose, even if the case against us is weak or flawed. If litigation leads to an outcome unfavorable to us, we may be required to obtain a license from the intellectual property owner in order to continue our research and development programs or to market any resulting product. It is possible that the necessary license will not be available to us on commercially acceptable terms, or at all. Alternatively, we may be required to modify or redesign our current or future products, if any, in order to avoid infringing or otherwise violating third-party intellectual property rights. This may not be technically or commercially feasible, may render those products less competitive, or may delay or prevent the entry of those products to the market. Any of the foregoing could limit our research and development activities, our ability to commercialize one or more product candidates, or both.

In order to avoid or settle potential claims with respect to any patent or other intellectual property rights of third parties, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both, which could be substantial. These licenses may not be available on acceptable terms, or at all. Even if we or any future collaborators were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced, by court order or otherwise, to cease some or all aspects of our business operations, if, as a result of actual or threatened patent or other intellectual property claims, we are unable to enter into licenses on acceptable terms. Further, we could be found liable for significant monetary damages as a result of claims of intellectual property infringement. For example, we have received, and may in the future receive, offers to license and demands to license from third parties claiming that we are infringing their intellectual property or owe license fees and, even if such claims are without merit, we could fail to successfully avoid or settle such claims.

If Teva, uniQure, Genentech or Merck license or otherwise acquire rights to intellectual property controlled by a third party in various circumstances, for example, where a product could not be legally developed or commercialized in a country without the third-party intellectual property right or, where it is decided that it would be useful to acquire such third-party right to develop or commercialize the product, they are eligible under our collaboration agreements to decrease payments payable to us on a product-by-product basis and, in certain cases, on a country-by-country basis. Any of the foregoing events could harm our business significantly.

If we breach any of the agreements under which we license the use, development and commercialization rights to our product candidates or technology from third parties, we could lose license rights that are important to our business.

Under our existing license agreements, including those associated with our XEN1101 program, we are subject to various obligations, including diligence obligations such as development and commercialization obligations, as well as potential royalty payments and other obligations. If we fail to comply with any of these obligations or otherwise breach our license agreements, our licensing partners may have the right to terminate the applicable license in whole or in part. Generally, the loss of any one of our current licenses, or any other license we may acquire in the future, could materially harm our business, prospects, financial condition and results of operations.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information, which would harm our competitive position.

In addition to patents, we rely on trade secrets, technical know-how and proprietary information concerning our discovery platform, business strategy and product candidates in order to protect our competitive position, which are difficult to protect. In the course of our research and development activities and our business activities, we often rely on confidentiality agreements to protect our proprietary information. Such confidentiality agreements are used, for example, when we talk to vendors of laboratory or clinical development services or potential strategic collaborators. In addition, each of our employees and consultants is required to sign a confidentiality agreement and invention assignment agreement upon joining our company. Our employees, consultants, contractors, business partners or outside scientific collaborators might intentionally or inadvertently disclose our trade secret information in breach of these confidentiality agreements or our trade secrets may otherwise be misappropriated. Our collaborators might also have rights to publish data and we might fail to apply for patent protection prior to such publication. It is possible that a competitor will make use of such information, and that our competitive position will be compromised. In addition, to the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. sometimes are less willing than U.S. courts to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. If we cannot maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information would be jeopardized, which would adversely affect our competitive position.

Patent reform legislation and recent court decisions 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 includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO has developed and implemented regulations and procedures to govern administration of the Leahy-Smith Act, and substantive changes to patent law associated with the Leahy-Smith Act. The full effect of these changes is currently unclear as the courts have yet to address these provisions and the applicability of the Leahy-Smith Act and new regulations on specific patents, including our patents discussed herein, have not been determined and would need to be reviewed. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. As a result, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, all of which could have a material adverse effect on our business and financial condition. On June 13, 2013, the U.S. Supreme Court decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, held that isolated DNA sequences are not patentable. In December 2014, the USPTO issued its Interim Guidance on Patent Subject Matter Eligibility, in which it extended Myriad's "marked difference" standard for patent subject matter eligibility to all potential natural products. This standard applies to patent claims that recite not only nucleic acids (such as DNA in Myriad), but also other subject matter that could be considered a natural product, such as peptides, proteins, extracts, organisms, antibodies, chemicals, and minerals. As a consequence of the Myriad decision and the USPTO's Interim Guidance, if any of our future product candidates utilize isolated DNA, peptides, proteins or the like, we will not be able to obtain patents in the U.S. claiming such novel gene targets that we discover, which could limit our ability to prevent third parties from developing drugs directed against such targets.

If we do not obtain protection under the Hatch-Waxman Act and similar legislation outside of the U.S. by extending the patent terms for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, if any, one or more U.S. patents may be eligible for limited patent term restoration under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during clinical testing of the product and the subsequent FDA regulatory review process. However, 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 obtain patent term extension or restoration or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

We have not registered our corporate name as a trademark in all of our potential markets, and failure to secure those registrations could adversely affect our business.

Our corporate name, Xenon, has not been trademarked in each market where we operate and plan to operate. Our trademark applications for our corporate name or the name of our products may not be allowed for registration, and our registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections, which we may be unable to overcome in our responses. Third parties may also attempt to register trademarks utilizing the Xenon name on their products, and we may not be successful in preventing such usage. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished. Accordingly, the market price of our common shares may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

Risks Related to Our Industry

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our current and any future products.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates, and we will face an even greater risk if we commercialize any product candidates. For example, we may be sued if any of our product candidates, including any that are developed in combination therapies, allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. There is also risk that third parties we have agreed to indemnify could incur liability. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or any resulting products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize our product candidates; and
- a decline in the market price of our common shares.

We currently carry product liability insurance of \$10,000,000 per occurrence and \$10,000,000 aggregate limit. We believe our product liability insurance coverage is appropriate in light of our current clinical programs; however, 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 and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may then be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause the market price of our common shares to decline and, if judgments exceed our insurance coverage, could adversely affect our future results of operations and business.

Patients with certain of the diseases targeted by our product candidates are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening conditions. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market those product candidates, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval process in other countries, or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

Our current and future relationships with customers and third-party payers in the U.S. and elsewhere will be subject, directly or indirectly, to applicable federal and state anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings.

Healthcare providers, physicians and third-party payers in the U.S. and elsewhere play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by the federal government and by the U.S. states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, or other third party payers claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain, or transmit individually identifiable health information for or on their behalf, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Open Payments program; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payers, including private insurers; state and foreign 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 or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the collection, export, privacy, use and security of biological materials and health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

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

Our research and development activities involve the controlled use of potentially harmful biological materials as well as hazardous materials, chemicals, and various radioactive compounds typically employed in molecular and cellular biology. For example, we routinely use cells in culture and we employ small amounts of radioisotopes. We cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling, or disposal of these materials through our maintenance of up-to-date licensing and training programs. In the event of contamination or injury, we could be held liable for damages that result, and any liability could exceed our resources. We currently carry insurance covering certain claims arising from our use of these materials. However, if we are unable to maintain our insurance coverage at a reasonable cost and with adequate coverage, our insurance may not cover any liability that may arise. We are subject to U.S. and Canadian federal, provincial, and local laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. Complying with regulations regarding the use of these materials could be costly, and if we fail to comply with these regulations, it could have a material adverse effect on our operations and profitability.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from serious disaster.

Our headquarters are located in Burnaby, British Columbia, Canada. We are vulnerable to natural disasters such as earthquakes that could disrupt our operations. If a natural disaster, power outage, fire or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. Although we carry insurance for earthquakes and other natural disasters, we may not carry sufficient business interruption insurance to compensate us for all losses that may occur. The disaster recovery and business continuity plans we have in place currently are limited and may not be adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of a natural disaster or earthquake, which could have a material adverse effect on our business. In addition, we may lose samples or other valuable data. The occurrence of any of the foregoing could have a material adverse effect on our business.

Risks Related to Our Common Shares

The market price of our common shares may be volatile, and purchasers of our common shares could incur substantial losses.

The market price of our common shares has fluctuated in the past and is likely to be volatile in the future. As a result of this volatility, investors may experience losses on their investment in our common shares. The market price for our common shares may be influenced by many factors, including the following:

- actions by any of our collaborators regarding our product candidates they are developing, including announcements regarding clinical or regulatory decisions or developments or our collaboration;
- announcements by us or our competitors of new products, product candidates or new uses for existing products, significant contracts, commercial relationships or capital commitments and the timing of these introductions or announcements;
- unanticipated serious safety concerns related to the use of any of our products and product candidates;
- results from or delays of clinical trials of our product candidates;
- failure to obtain or delays in obtaining or maintaining product approvals or clearances from regulatory authorities;
- adverse regulatory or reimbursement announcements;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments;
- the results of our efforts to discover or develop additional product candidates;
- our dependence on third parties, including our collaborators, CROs, clinical trial sponsors and clinical investigators;
- regulatory or legal developments in Canada, the U.S. or other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key scientific or management personnel;
- our ability to successfully commercialize our future product candidates we develop independently, if approved;
- the level of expenses related to any of our product candidates or clinical development programs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- actual or anticipated quarterly variations in our financial results or those of our competitors;
- any change to the composition of the board of directors or key personnel;
- sales of common shares by us or our shareholders in the future, as well as the overall trading volume of our common shares;
- changes in the structure of healthcare payment systems;
- commencement of, or our involvement in, litigation;
- general economic, industry and market conditions in the pharmaceutical and biotechnology sectors and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and
- the other factors described in this “Risk Factors” section.

In addition, the stock market in general, and NASDAQ and the biopharmaceutical industry in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common shares, regardless of our operating performance. In several recent situations where the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our shareholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results.

Future sales of our common shares in the public market could cause the market price of our common shares to fall.

The market price of our common shares could decline as a result of sales of a large number of our common shares or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

In addition, in the future, we may issue additional common shares or other equity or debt securities convertible into common shares in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing shareholders and could cause the market price of our common shares to decline.

Provisions in our corporate charter documents and Canadian law could make an acquisition of us, which may be beneficial to our shareholders, more difficult and may prevent attempts by our shareholders to replace or remove our current management and/or limit the market price of our common shares.

Provisions in our articles and our by-laws, as well as certain provisions under the Canada Business Corporations Act, or CBCA, and applicable Canadian securities laws, may discourage, delay or prevent a merger, acquisition or other change in control of us that shareholders may consider favorable, including transactions in which they might otherwise receive a premium for their common shares. These provisions could also limit the price that investors might be willing to pay in the future for our common shares, thereby depressing the market price of our common shares. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it more difficult for shareholders to replace members of our board of directors. Among other things, these provisions include the following:

- shareholders cannot amend our articles unless such amendment is approved by shareholders holding at least two-thirds of the shares entitled to vote on such approval;
- our board of directors may, without shareholder approval, issue preferred shares having any terms, conditions, rights, preferences and privileges as the board of directors may determine; and
- shareholders must give advance notice to nominate directors or to submit proposals for consideration at shareholders' meetings.

Any provision in our articles, by-laws, under the CBCA or under any applicable Canadian securities law that has the effect of delaying or deterring a change in control could limit the opportunity for our shareholders to receive a premium for their common shares, and could also affect the price that some investors are willing to pay for our common shares.

U.S. civil liabilities may not be enforceable against us, our directors, or our officers.

We are governed by the CBCA and our principal place of business is in Canada. Many of our directors and officers reside outside of the U.S., and all or a substantial portion of their assets as well as all or a substantial portion of our assets are located outside the U.S. As a result, it may be difficult for investors to effect service of process within the U.S. upon us and certain of our directors and officers or to enforce judgments obtained against us or such persons, in U.S. courts, in any action, including actions predicated upon the civil liability provisions of U.S. federal securities laws or any other laws of the U.S. Additionally, rights predicated solely upon civil liability provisions of U.S. federal securities laws or any other laws of the U.S. may not be enforceable in original actions, or actions to enforce judgments obtained in U.S. courts, brought in Canadian courts, including courts in the Province of British Columbia.

We are governed by the corporate laws of Canada which in some cases have a different effect on shareholders than the corporate laws of Delaware, U.S.

We are governed by the CBCA and other relevant laws, which may affect the rights of shareholders differently than those of a company governed by the laws of a U.S. jurisdiction, and may, together with our charter documents, have the effect of delaying, deferring or discouraging another party from acquiring control of our company by means of a tender offer, a proxy contest or otherwise, or may affect the price an acquiring party would be willing to offer in such an instance. The material differences between the CBCA and Delaware General Corporation Law, or DGCL, that may have the greatest such effect include, but are not limited to, the following: (i) for material corporate transactions (such as mergers and amalgamations, other extraordinary corporate transactions or amendments to our articles) the CBCA generally requires a two-thirds majority vote by shareholders, whereas DGCL generally only requires a majority vote; and (ii) under the CBCA a holder of 5% or more of our common shares can requisition a special meeting of shareholders, whereas such right does not exist under the DGCL.

An active trading market for our common shares may not be maintained.

Our common shares are currently traded on NASDAQ, but we can provide no assurance that we will be able to maintain an active trading market on NASDAQ or any other exchange in the future. If an active market for our common shares is not maintained, it may be difficult for our shareholders to sell the common shares they have purchased without depressing the market price for the common shares or at all. Further, an inactive market may also impair our ability to raise capital by selling additional common shares and may impair our ability to enter into strategic collaborations or acquire companies or products by using our common shares as consideration.

Complying with the laws and regulations affecting public companies will increase our costs and the demands on management and could harm our operating results and our ability to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common shares.

As a public company, and particularly after we cease to be an “emerging growth company,” we will incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and the related rules and regulations subsequently implemented by the Securities and Exchange Commission, or SEC, the applicable Canadian securities regulators and NASDAQ impose numerous requirements on public companies, including requiring changes in corporate governance practices. Also, the Securities Exchange Act of 1934, as amended, or the Exchange Act, requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel have and will continue to devote a substantial amount of time to compliance with these laws and regulations. These requirements have increased and will continue to increase our legal, accounting, and financial compliance costs and have made and will continue to make some activities more time-consuming and costly. For example, these rules and regulations make it difficult and expensive for us to maintain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or to incur substantial costs to maintain the same or similar coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or our board committees or as executive officers.

The Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of our internal control over financial reporting annually and the effectiveness of our disclosure controls and procedures quarterly. In particular, Section 404 of the Sarbanes-Oxley Act, or Section 404, requires us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on, and our independent registered public accounting firm potentially to attest to, the effectiveness of our internal control over financial reporting. As an “emerging growth company” we expect to avail ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404. However, we may no longer avail ourselves of this exemption when we cease to be an “emerging growth company.” When our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404 will correspondingly increase. Our compliance with applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our common shares could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Furthermore, investor perceptions of our company may suffer if deficiencies are found, and this could cause a decline in the market price of our common shares. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our stated operating results and harm our reputation. If we are unable to implement these requirements effectively or efficiently, it could hamper our operations, financial reporting, or financial results and could result in an adverse opinion on our internal controls from our independent registered public accounting firm.

We are an “emerging growth company,” and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies could make our common shares less attractive to investors.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an “emerging growth company,” we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies that are not “emerging growth companies,” including, but not limited to, not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We could be an “emerging growth company” for up to five years following the completion of our initial public offering, although, if we have more than \$1.0 billion in annual revenue, if the market value of our common shares held by non-affiliates exceeds \$700 million as of June 30 of any year, or we issue more than \$1.0 billion of non-convertible debt over a three-year period before the end of that five-year period, we would cease to be an “emerging growth company” as of the following December 31. Investors could find our common shares less attractive if we choose to rely on these exemptions. If some investors find our common shares less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common shares and the market price of our common shares may be more volatile.

As an “emerging growth company,” the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. However, we previously decided to “opt out” of such extended transition period, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

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

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

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an “emerging growth company” under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls could detect problems that our management’s assessment might not. In addition, our management did not perform an evaluation of our internal control over financial reporting as of December 31, 2014 or December 31, 2013 and our independent registered public accounting firm did not perform an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act. Had we and our independent registered public accounting firm performed such an evaluation, control deficiencies may have been identified by management or our independent registered public accounting firm, and those control deficiencies could have also represented one or more material weaknesses. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

Future sales and issuances of our common shares or rights to purchase common shares, including pursuant to our equity incentive plans, could cause you to incur dilution and could cause the market price of our common shares to fall.

As of June 30, 2017, options to purchase 2,276,897 of our common shares with a weighted-average exercise price of \$7.66 per common share were outstanding. The exercise of any of these options would result in dilution to current shareholders. Further, because we will need to raise additional capital to fund our clinical development programs, we may in the future sell substantial amounts of common shares or securities convertible into or exchangeable for common shares. Pursuant to our equity incentive plans, our compensation committee (or a subset or delegate thereof) is authorized to grant equity-based incentive awards to our employees, directors and consultants. Future option grants and issuances of common shares under our share-based compensation plans may have an adverse effect on the market price of our common shares.

These future issuances of common shares or common share-related securities, together with the exercise of outstanding options and any additional common shares issued in connection with acquisitions, if any, may result in further dilution to our existing shareholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common shares.

We are at risk of securities class action litigation.

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

NASDAQ may delist our securities from its exchange, which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.

Our common shares are listed on NASDAQ under the trading symbol "XENE." Our securities may fail to meet the continued listing requirements to be listed on NASDAQ. If NASDAQ delists our common shares from trading on its exchange, we could face significant material adverse consequences, including:

- significant impairment of the liquidity for our common shares, which may substantially decrease the market price of our common shares;
- a limited availability of market quotations for our securities;
- a determination that our common shares qualify as a "penny stock" which will require brokers trading in our common shares to adhere to more stringent rules and possibly resulting in a reduced level of trading activity in the secondary trading market for our common shares;
- a limited amount of news and analyst coverage for our company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

If securities or industry analysts do not publish research reports about our business, or if they issue an adverse opinion about our business, the market price of our common shares and the trading volume of our common shares could decline.

The trading market for our common shares is influenced by the research and reports that securities or industry analysts publish about us or our business. If too few securities or industry analysts cover our company, the market price of our common shares would likely be negatively impacted. If securities and industry analysts who cover us downgrade our common shares or publish inaccurate or unfavorable research about our business, the market price of our common shares would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our common shares could decrease, which might cause the market price of our common shares and the trading volume of our common shares to decline.

Our management team has broad discretion as to the use of the net proceeds from our September 2016 public offering of common shares and the investment of these proceeds may not yield a favorable return. We may invest the proceeds in ways with which our shareholders disagree.

We have broad discretion in the application of the net proceeds to us from our September 2016 public offering of common shares. You may not agree with our decisions, and our use of the proceeds and our existing cash and cash equivalents and marketable securities may not improve our results of operation or enhance the value of our common shares. The results and effectiveness of the use of proceeds are uncertain, and we could spend the proceeds in ways that you do not agree with or that do not improve our results of operations or enhance the value of our common shares. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development of our product candidates and cause the market price of our common shares to decline. In addition, until the net proceeds are used, they may be placed in investments that do not produce significant income or that may lose value.

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

We do not currently intend to pay any cash dividends on our common shares in the foreseeable future. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common shares may be investors' sole source of gain for the foreseeable future.

Item 6. Exhibits

(a) Exhibits.

Exhibit Number	Description
10.1†	Letter Agreement, dated May 8, 2017, to Amendment #4, dated May 13, 2015, to the Collaborative Research and License Agreement, dated December 22, 2011, by and among the Company, Genentech, Inc. and F. Hoffman-La Roche Ltd, as amended.
10.2†	Asset Purchase Agreement, dated April 25, 2017, by and between the Company and 1st Order Pharmaceuticals, Inc.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a).
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a).
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350.
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C Section 1350.
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

† Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

* The Certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Xenon Pharmaceuticals Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained 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.

Date: August 3, 2017

XENON PHARMACEUTICALS INC.

By: /s/ Simon Pimstone
Simon Pimstone
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 3, 2017

XENON PHARMACEUTICALS INC.

By: /s/ Ian Mortimer
Ian Mortimer
Chief Financial Officer, Chief Operating Officer and Corporate Secretary
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

Exhibit Number	Description
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May 8, 2017

To:
Xenon Pharmaceuticals Inc.
Attention: Simon Pimstone, President and Chief Executive Officer
3650 Gilmore Way
Burnaby, BC
V5G 4W8

Xenon Pharmaceuticals Inc.
Attention: General Counsel and Corporate Secretary
3650 Gilmore Way
Burnaby, BC
V5G 4W8

Re: Collaborative Research and License Agreement between Xenon Pharmaceuticals Inc. (“**Xenon**”) and Genentech, Inc. (“**GNE**”) together with F. Hoffmann-La-Roche Ltd (“**Roche**”) (GNE and Roche, collectively, “**Genentech**”), made as of December 22, 2011, as amended (the “**Agreement**”)

Dear Simon,

Further to our recent discussions and in accordance with Section 16.14 of the Agreement, and in consideration of the premises and mutual covenants contained herein, Xenon and Genentech agree as follows:

1. This letter agreement (the “**Letter Agreement**”) shall clarify and amend certain provisions of Agreement and specifically makes reference to the Letter Amendment #4 to the Agreement, dated May 13, 2015 (the “**Amendment #4**”).
2. **Definitions.** Except as specifically defined herein, capitalized terms used in this Letter Agreement shall have the same meaning as ascribed to such terms in the Agreement.
3. **Patent Filing and Prosecution regarding NaV1.6 Research Program.** Section 9 of the Amendment #4 shall be replaced in its entirety by the following new Section 9:

“9. **PATENT FILING AND PROSECUTION. NaV1.6 Research Program.**

- a. *Should Xenon wish to file a patent application for NaV1.6 IP (“**NaV1.6 Patent Filing**”) Xenon shall inform in writing to an individual designated in writing by Genentech (e.g., Genentech's outside counsel) of its intention to file such application and in confidence shall specify with particularity the subject matter of the application, including for composition of matter applications directed to new small molecule compounds [†] disclosed in the application. Xenon shall provide Genentech with a complete copy of the specification and claims of the NaV1.6 Patent Filing it intends to file in order to facilitate the review process (“**Final Draft NaV1.6 Patent Filing**”).*
- b. *Genentech shall have [†] ([†]) [†] from the receipt of the Final Draft NaV1.6 Patent Filing by such an individual designated by Genentech to inform Xenon's Alliance Manager in writing as to whether Genentech wishes to coordinate with Xenon on the filing of the NaV1.6 Patent Filing with a filing of a patent application related to Compounds.*

[†] DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

- c. *Upon such notification by Genentech, the Parties shall coordinate and cooperate in good faith to ensure the disclosure and timing of any such NaVI.6 Patent Filing would not adversely affect the validity of claims in (i) any Patent Rights covering Compounds that are being Prosecuted by Genentech and/or (ii) any Patent Rights covering Compounds that Genentech reasonably anticipates Prosecuting following such notification by Genentech (each (i) and (ii) hereinafter referred to as "**Genentech Compound Patents**"), provided that, such process of coordination and cooperation shall, subject to Section 9.d below, not delay the filing of Xenon's NaVI.6 Patent Filing for a timeframe greater than [†] ([†]) [†] following receipt of Genentech's notification that it wishes to coordinate with Xenon on such filing.*
- d. *If Xenon amends the scope of a Final Draft NaVI.6 Patent Filing at any point subsequent to its provision of the Final Draft NaVI.6 Patent Filing to Genentech, Xenon shall promptly provide Genentech with a complete copy of the amended specification and claims of the revised Final Draft NaVI.6 Patent Filing. Xenon shall not file a NaVI.6 Patent Filing until [†]. Genentech will make [†] efforts in good faith to timely review and provide consent to Xenon's NaVI.6 Patent Filing.*
- e. *Thereafter, during the further Prosecution of NaVI.6 Patent Filings, Xenon shall keep Genentech informed as to the Prosecution of all NaVI.6 Patent Filings such that Genentech has [†] to review and comment upon any documents intended for submission to any patent office. Xenon shall not and shall not permit any Third Party on its behalf to cite or characterize (i) Xenon Background Patent Rights, (ii) Genentech Background Patent Rights, (iii) Patent Rights comprised in Collaboration IP, or (iv) Patent Rights covering Compounds developed independently by Genentech, in such Prosecution of NaVI.6 IP Patent Filings without Genentech's prior review, comment, and written permission, provided that such comments by Genentech shall be promptly delivered to Xenon's Alliance Manager, and further provided that such written permission by Genentech will not be withheld or delayed except in circumstances where such citation or characterization would adversely affect the validity of claims of Genentech Compound Patents, in which case the Parties will enter into good faith discussions respecting the NaVI.6 IP Patent Filing(s) at issue, and will devote [†] efforts to finding a [†] compromise that would allow Xenon to continue its Prosecution of such NaVI.6 Patent Filing(s)."*

4. **General.**

- a. Except as specifically provided above in this Letter Agreement, the Agreement remains in full force and effect.
- b. Any rights and obligations of the Parties set out in this Letter Agreement which, from the context hereof, are intended to survive any termination or expiration of the Agreement shall survive any such termination or expiration.

[†] DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

By the signatures below, the Parties have caused this Letter Agreement to be executed by their respective duly authorized officers to be effective as of May 8, 2017.

XENON PHARMACEUTICALS INC.

By: /s/ Dr. Robin Sherrington
Name: Dr. Robin Sherrington
Title: SVP, Business & Corporate Development

GENENTECH, INC.

By: /s/ James Sabry
Name: James Sabry
Title: SVP, Genentech Partnering

F. HOFFMANN-LA ROCHE LTD

By: /s/ Stefan Arnold
Name: Stefan Arnold
Title: Head Legal Pharma

By: /s/ Dr. Urs Schleuniger
Name: Dr. Urs Schleuniger
Title: Head Chugai and Basel Alliance
& Asset Management

[†] DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

ASSET PURCHASE AGREEMENT

by and among

1ST ORDER PHARMACEUTICALS, INC.
(a Delaware corporation),

a n d

XENON PHARMACEUTICALS INC.
(a corporation continued under the federal laws of Canada)

dated as of April 25, 2017

[†] DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

ASSET PURCHASE AGREEMENT

THIS ASSET PURCHASE AGREEMENT (“**Agreement**”) is made as of April 25, 2017 (the “**Effective Date**”), by and among, 1ST Order Pharmaceuticals, Inc., a Delaware Corporation (“**Seller**”) and Xenon Pharmaceuticals Inc., a corporation continued under the federal laws of Canada (“**Acquiror**”).

RECITALS:

A. WHEREAS, the Seller previously entered into an Asset Purchase Agreement between Seller and Valeant Pharmaceuticals Luxembourg S.a.r.l. (“**Valeant**”) dated October 30, 2015 (the “**Valeant APA**”, which is attached hereto as Exhibit A) pursuant to which Seller purchased from Valeant the VRX621698 compound and certain related assets;

B. WHEREAS, the Seller previously entered into an Intellectual Property Assignment Agreement between Seller and Valeant dated February 8, 2017, pursuant to which Valeant assigned to Seller additional intellectual property assets;

C. WHEREAS, Seller and Acquiror entered into a certain Option Agreement effective as of March 13, 2017 (the “**Option Agreement**”), with regard to the 1st Order Technology (as defined in that agreement); and

D. WHEREAS, the Seller desires to sell to Acquiror, and Acquiror desires to purchase from Seller, all of Seller’s right, title and interest in and to all assets purchased by Seller pursuant to the Valeant APA and all Intellectual Property Rights related thereto, including without limitation, all rights with respect to the investigational compound known as 1OP-2198 (previously VRX621698) (the “**Compound**”), and any variant forms thereof, including as salt, freebase or pro-drug, and all other assets of Seller related thereto, including Compound Regulatory Documentation, reports (including all reports of pre-clinical studies), data and API, upon the terms and subject to the conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the respective representations, warranties, covenants and agreements contained herein, and of other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound hereby, agree as follows:

ARTICLE 1 DEFINITIONS

For all purposes of and under this Agreement the capitalized terms shall have the meanings set forth below.

1.1 “**Action**” means any action, suit or proceeding, claim, arbitration, litigation or investigation.

1.2 “[†] **Knowledge**” means [†].

1.3 “**Affiliate(s)**” means, with respect to a particular party, a Person that controls, is controlled by or is under common control with such party. For the purposes of this definition, the word “control” (including, with correlative meaning, the terms “controlled by” or “under the common control with”) means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of fifty percent (50%) or more of the voting stock of such entity, or by contract or otherwise.

1.4 “**ANDA Filing**” means that a Third Party files an ANDA with the FDA with regard to a Product in the [†] period after the expiration of the last to expire of U.S. Patents Nos. [†] and [†] (including any patent term extension thereof).

[†] DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

- 1.5 “**API**” means all quantities of the Compound owned or controlled by Seller.
- 1.6 “**Assumed Liabilities**” is defined in Section 2.1(b).
- 1.7 “**Authorization**” means any authorization, approval, consent, certificate, license, notification, registration, permit, franchise, waiver, order, right, or notification of any Governmental Entity.
- 1.8 “**Base Purchase Price**” is defined in Section 2.3.
- 1.9 “**Business Day**” means a day other than a Saturday, Sunday, or other day on which banks located in British Columbia, Canada or North Carolina, USA are authorized or required by Law to close.
- 1.10 “**Closing**” is defined in Section 3.1.
- 1.11 “**Closing Date**” is defined in Section 3.1.
- 1.12 “**Compound Material Adverse Effect**” means [†].
- 1.13 “**Compound Regulatory Documentation**” means any and all Authorizations relating to the Compound, including, without limitation, applications, registrations, licenses, authorizations, approvals, non-clinical and clinical study authorization applications or notifications (including all supporting files, writings, data, studies and reports), correspondence to or with any Medical Product Regulatory Authority with respect to the Compound, and all data contained in any of the foregoing, including all adverse event files and manufacturing records.
- 1.14 “**Confidential Information**” is defined in Section 6.5.
- 1.15 “**Confidentiality Agreement**” means that certain Confidentiality Agreement entered by and between Seller and Acquiror effective as of April 5, 2016.
- 1.16 “**Damages**” is defined in Section 9.1(a).
- 1.17 “**EMA**” means the European Medicines Agency.
- 1.18 “**Encumbrance**” means any lien, mortgage, pledge, hypothecation, charge, preference, security interest, attachment, claim, restriction, including transfer restrictions, put, call, right of first refusal, easement, servitude, right-of-way, option, warrant, conditional sale or installment contract or encumbrance of any kind and any financing lease involving substantially the same effect.
- 1.19 “**FDA**” means the United States Food and Drug Administration.
- 1.20 “**FFDCA**” means the U.S. Federal Food, Drug, and Cosmetic Act.
- 1.21 “**Governmental Entity**” means any entity or body exercising executive, legislative, judicial, regulatory or administrative functions of or pertaining to United States federal, state, local, or municipal government, or foreign, international, multinational or other government, including any department, commission, board, agency, bureau, subdivision, instrumentality, or other regulatory, administrative or judicial authority thereof.
- 1.22 “**Inbound Licenses**” is defined in Section 4.7(j).

1.23 “**IND**” means (i) an investigational new drug application filed with the FDA for authorization to commence clinical studies and its equivalent in the United States or Canada and (ii) all supplements and amendments that may be filed with respect to the foregoing.

1.24 “**Indemnified Acquiror Party**” is defined in Section 9.1.

1.25 “**Indication**” means a separate and distinct disease, disorder or medical condition in humans that a Product is intended to treat, prevent, diagnose, monitor or ameliorate, as set forth in the IND or label for such Product, as approved by the applicable Medical Product Regulatory Authority. For clarity, the use of a Product to treat an expanded set or subset of patients for a disease, disorder or medical condition, when such Product has already received regulatory approval with respect to such disease, disorder or medical condition, shall not constitute a separate Indication with respect to such Product.

1.26 “**Intellectual Property Rights**” means any and all of the rights in or associated with the following throughout, or anywhere in, the world: (i) all letters patent, patent applications, provisional patents, design patents, PCT filings, invention disclosures and other rights to inventions or designs (“**Patents**”), (ii) all registered and unregistered copyrights in both published and unpublished works, mask works, moral rights, and other literary property or authors rights (“**Copyrights**”), (iii) all trademarks and service marks (whether or not registered), trade names, logos, trade dress, Domain Names, and other proprietary indicia and all goodwill associated therewith (“**Marks**”), (iv) Know-How, trade secret rights, and other rights in confidential or proprietary information (“**Trade Secrets**”), (v) all applications, registrations, issuances, divisions, continuations, renewals, reissuances and extensions of the foregoing; and (vi) any equivalent intellectual property or proprietary rights to the foregoing.

1.27 “**Know-How**” means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, clinical, safety, manufacturing and quality control data), results and other material, including high-throughput screening, gene expression, genomics, proteomics and other drug discovery and development technology, assays and any other biological methodology, pre-clinical and clinical trial results, manufacturing procedures, test procedures and purification and isolation techniques, (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form.

1.28 “**Law**” means any statute, law (including common law), constitution, treaty, ordinance, code, order, decree, judgment, rule, regulation and any other binding requirement or determination of any Governmental Entity.

1.29 “**Loan Agreements**” means (a) [†], (b) [†], (c) [†], and (d) all other agreements pursuant to which Seller was granted or received any funding with respect to the operation of its business or exploitation of the Purchased Assets.

1.30 “**Loan Payoff Amounts**” means the aggregate Pay-Off Amount (as defined in the Payoff Letters) set forth under the Payoff Letters.

1.31 “**Major Market**” means each of the United States of America, the European Union, and Japan.

1.32 “**Medical Product Regulatory Authority**” means any Governmental Entity that is concerned with the safety, efficacy, reliability, manufacture, investigation, sale or marketing of pharmaceuticals, medical products, biologics or biopharmaceuticals, including, without limitation, FDA, the EMA, and state and local government authorities.

1.33 “**NDA**” means (a) a New Drug Application, as defined in the FDCA, which is required to be approved by FDA before the marketing of a product for its FDA-approved intended use, and its equivalent in other countries or regulatory jurisdictions or any successor application or procedure, and (b) all supplements and amendments that may be filed with respect to the foregoing.

1.34 “**NDA Approval**” means approval of an NDA by a Medical Product Regulatory Authority in a Major Market, which approval is evidenced in a written communication from the appropriate Medical Product Regulatory Authority.

1.35 “**Order**” means any award, injunction, judgment, decree, order, ruling, subpoena or verdict or other decision entered, issued or rendered by any Governmental Entity.

1.36 “**Outbound Licenses**” is defined in Section 4.7(k).

1.37 “**Payoff Letters**” is defined in Section 7.5.

1.38 “**Permitted Encumbrance**” means Encumbrances arising by operation of law for taxes not yet due and payable.

1.39 “**Person**” means an individual, a corporation, a partnership, a limited liability company, a trust, an unincorporated association, a Governmental Entity or any agency, instrumentality or political subdivision of a Governmental Entity, or any other entity or body.

1.40 “**Phase III Trial**” means, with respect to the Compound, a pivotal clinical study sponsored by Acquiror or its Affiliates or licensees conducted in a sufficient number of patients and whose primary objective is to obtain additional information about the therapeutic efficacy and safety of the Compound in patients for the particular indication in question that is needed to evaluate the overall risk-benefit relationship of the Compound and to provide adequate basis for obtaining requisite regulatory approval(s) and product labeling, as more fully defined in 21 C.F.R. § 312.21(c).

1.41 “[†]” means [†].

1.42 “**Product**” means a pharmaceutical preparation containing the Compound, as an active ingredient, in any formulation, dosage and form thereof, or as a pro-drug, salt, solution, or hydrate, either alone or in combination with other active ingredients, for all human and non-human therapeutic uses.

1.43 “**Purchased Assets**” is defined in Section 2.1.

1.44 “[†] **Knowledge**” means [†].

1.45 “**Representatives**” is defined in Section 6.1.

1.46 “[†]” means [†].

1.47 “**Seller Certificate**” is defined in Section 8.2(d).

1.48 “**Seller Registered IPR**” is defined in Section 4.7(a).

1.49 “**sNDA Approval**” means approval of a supplemental new drug application by a Medical Product Regulatory Authority in a Major Market, which approval is evidenced in a written communication from the appropriate Medical Product Regulatory Authority.

1.50 “[†]” means [†].

1.51 “[†]” means [†].

1.52 “**Technology**” means tangible embodiments of any of the following: (i) inventions (whether or not patentable), trade secrets, technical data, databases, customer lists, designs, tools, methods, processes, technology, ideas, Know-How, product road maps and other proprietary information and materials; (ii) trademarks and service marks (whether or not registered), trade names, logos, trade dress and other proprietary indicia; (iii) documentation, advertising copy, marketing materials, web-sites, specifications, mask works, drawings, graphics, databases, recordings and other works of authorship, whether or not protected by Copyright; (iv) computer programs, including any and all software implementations of algorithms, models and methodologies, whether in source code or object code, firmware, development tools, files, records and data, design documents, flow-charts, user manuals, documentation, and training materials relating thereto and any translations thereof and all media on which any of the foregoing is recorded (collectively, “**Software**”); and (v) domain names, uniform resource locators and other names and locators associated with the Internet (“**Domain Names**”).

1.53 “**Third Party**” shall mean any Person or entity other than Seller, Acquiror and their respective Affiliates.

1.54 “[†]” means [†].

1.55 “**Transaction Documents**” means this Agreement and any other, instrument, agreement or document required to be delivered by the parties to this Agreement pursuant to the terms hereof.

1.56 “**Transactions**” means the purchase and sale of the Purchased Assets hereunder and the other transactions contemplated by the Transaction Documents.

1.57 “**Transferred Intellectual Property**” means, collectively, the Transferred IPR and Transferred Technology.

1.58 “**Transferred IPR**” means all Intellectual Property Rights of Seller, including all Seller Registered IPR, Patent rights, Know-How and other Intellectual Property Rights of Seller relating to the Compound or necessary or useful for the development or commercialization of Products, but excluding the “1st Order” trademark.

1.59 “**Transferred Technology**” means all Technology of Seller relating to or used in connection with the Compound, including (i) the Compound and all reports (including completed development reports), raw data, and APIs related thereto, and (ii) the Technology set forth on Schedule 1.59, but excluding off-the-shelf software programs such as Microsoft 365 and Adobe.

ARTICLE 2 PURCHASE AND SALE

2.1 Purchase and Sale of the Compound.

(a) Purchased Assets. On the terms and subject to the conditions set forth in this Agreement, at the Closing, Acquiror hereby purchases from Seller, and Seller hereby sells to Acquiror, all of Seller's right, title, and interest in and to all assets of Seller relating to or used in connection with the Compound (the "**Purchased Assets**"), free and clear of all Encumbrances, including, without limitation, the following assets:

- (i) The Transferred IPR;
- (ii) The Transferred Technology;
- (iii) All API existing as of the Effective Date;
- (iv) The Compound Regulatory Documentation; and
- (v) All other assets of Seller set forth in Schedule 2.1(a)(v).

(b) Assumed Liabilities. From and after the Closing, Acquiror hereby agrees as follows (collectively, the "**Assumed Liabilities**"):

(i) Acquiror will pay to Valeant any relevant milestone or royalty payments due to Valeant from Seller with regard to the development or commercialization of Products arising under Sections 2.4 and 2.5 of the Valeant APA, and

(ii) Acquiror will perform the obligations of Seller set forth in Sections 2.6, 2.8, and 2.9 of the Valeant APA.

(iii) Acquiror will pay any amounts required to be paid by Seller, or perform any obligation of Seller, pursuant to Section 10.2(a)(ii) or Section 10.2(b) of the Valeant APA in respect of claims by any Indemnified Seller Party (as such term is defined in the Valeant APA, which for clarity refers to Valeant and its specified affiliates) arising out of acts of Acquiror (or Acquiror's failure to act) with respect to (i) and (ii) above, that occur after the Closing.

(c) Retained Assets. Seller shall retain, and Acquiror will not acquire Seller's right, title or interest in or to, and the Purchased Assets will not include the following (collectively, the "**Retained Assets**"):

(i) Seller's rights under this Agreement;

(ii) All cash and cash equivalents and all bank accounts of Seller;

(iii) all Contracts of insurance and policies of insurance held by Seller, including casualty, liability or group life, health or accident insurance;

(iv) Seller's organizational documents, qualification to conduct business, arrangements with registered agents, taxpayer and other identification numbers, corporate seal, minute books, stock transfer books, blank stock certificates, books and records relating to federal, state, local or foreign income, net or gross receipts, franchise, estimated, alternative minimum, or add-on taxes, tax returns, and any other documents relating to the organization, maintenance or existence of Seller as a limited liability company;

- (v) all equity interests in Seller; and
- (vi) the Valeant APA (which Agreement, Acquiror and Seller agree, is not being assigned to

Acquiror).

(d) **Excluded Liabilities.** Acquiror shall not assume pursuant to this Agreement or the Transactions, and shall have no liability for, any liabilities of Seller of any kind, character or description whatsoever other than the Assumed Liabilities, and Seller shall retain responsibility for all such liabilities and obligations.

2.2 **Purchase Price.** The purchase price for the Purchased Assets shall be equal to the Base Purchase Price plus, to the extent the underlying milestone events are achieved, the Milestone Payments in accordance with Section 2.3.

2.3 **Payment of Closing Consideration.** The “**Base Purchase Price**” shall be three hundred and fifty thousand U.S. dollars (\$350,000); provided, pursuant to the terms of the Option Agreement, the [†] U.S. dollars (\$[†]) paid by Acquiror to Seller pursuant to the Option Agreement is fully creditable against the Base Purchase Price. Within [†] ([†]) [†] following the Closing, Acquiror shall (i) deliver to Seller the amount equal to [†] U.S. dollars (\$[†]) (as the remainder of the Base Purchase Price) minus the Loan Payoff Amounts, and (ii) deliver to the applicable creditors the Loan Payoff Amounts. The funds payable by Acquiror pursuant to the immediately preceding sentence shall be made by wire transfer in immediately available funds to accounts designated by Seller or as designated in the Payoff Letters, as applicable.

2.4 **Milestone Payments.**

(a) Subject to the terms and conditions of this Agreement, the Seller shall be entitled to certain milestone payments (each payment as it relates to a particular event, a “**Milestone Payment**”), each of which, if achieved, will be due and payable within [†] ([†]) [†] following achievement of the applicable event set forth below for the first Product to achieve such event (each, a “**Milestone Event**”); provided, however, that no Milestone Payments will be earned or payable to Seller if an applicable event set forth below is achieved on or after the [†] anniversary of the Closing Date:

Milestone Event Number	Patent Milestone Event	Milestone Payment
1.	[†]	[†]
	Regulatory Milestone Event	
2.	[†]	[†]
3.	[†]	[†]
4.	[†]	[†]
5.	[†]	[†]
6.	[†]	[†]
7.	[†]	[†]
8.	[†]	[†]

For purposes of clarity, (a) Milestone Event Number 2 is in addition to, and not a replacement for, Milestone Event Number 3 (i.e., if a Milestone Payment is triggered pursuant to clause (2) of Milestone Event Number 2, then Seller will be entitled Milestone Payments in respect of Milestone Event Number 2 and Milestone Event Number 3), and (b) if Milestone Event 1 is achieved, no payment can be due with respect to Milestone 8.

(b) Seller and Acquiror understand and agree that each of the Milestone Payments referenced in this Section 2.4(a), shall be payable only once, upon the first occurrence of the applicable Milestone Event for the first Product to achieve the applicable Milestone Event.

(c) If an applicable Patent Milestone Event or Regulatory Milestone Event set forth in the table above is not achieved, no Milestone Payment shall be due for such Patent Milestone Event or Regulatory Milestone Event, as applicable.

2.5 Taxes. Notwithstanding anything in this Agreement to the contrary, each of Acquiror and Seller is responsible for payment of any tax for which it is required to pay to the applicable Governmental Entity in connection with the purchase of the transactions contemplated by the Agreement. In the event any tax or similar amount is paid or required to be withheld by Acquiror or any Affiliate thereof on account of any payments payable to Seller under this Agreement, the corresponding amounts payable to Seller shall be reduced by the amount of taxes or similar amounts deducted and withheld, and Acquiror shall pay the amounts of such taxes or similar amounts to the proper Governmental Entities in a timely manner and promptly transmit to Seller an official tax certificate or other evidence of such tax or other obligations together with proof of payment from the relevant Governmental Entity of all amounts deducted and withheld sufficient to enable Seller to claim such payment of taxes or similar amounts. Any such withholding taxes or similar amounts required under applicable Law to be paid or withheld shall be an expense of, and borne solely by, Seller. Acquiror will provide Seller with, at Seller's expense, reasonable assistance to enable Seller to recover such taxes or amounts otherwise withheld as permitted by Law. Without limiting the foregoing, Seller shall be solely responsible for any and all taxes that may be incurred arising from or relating to Seller's corporate conversion to an S-Corporation, and shall indemnify Acquiror for any claims, damages, expenses, or losses with respect thereto.

ARTICLE 3 CLOSING; TERMINATION AND TERM

3.1 Location; Date. The consummation of the Transactions (the "**Closing**") shall be held at the offices of Wyrick Robbins Yates & Ponton, LLP, at 4101 Lake Boone Trail, Suite 300, Raleigh, NC 27607 on a date which shall be no later than [†] ([†]) [†] after satisfaction or waiver of the conditions set forth in 7.5 or at such other date and place as may be mutually agreed upon by Acquiror and Seller (the "**Closing Date**"). The Closing shall be effective for all purposes as of 11:59 p.m. (Eastern Time) on the Closing Date.

3.2 Deliveries. At the Closing and as a condition to Closing, Seller shall deliver or cause to be delivered each of the following to Acquiror, unless Acquiror waives the delivery thereof:

(i) Evidence reasonably satisfactory to Acquiror that the API will be shipped to the address provided by the Acquiror using a carrier selected by Seller and delivered to Acquiror within [†] ([†]) [†] of the Closing Date. Seller and Acquiror will each be responsible for [†];

(ii) Evidence reasonably satisfactory to Acquiror that any and all physical and/or electronic files, reports, data and other documentation constituting Know-How or otherwise related to Compound will be shipped to the address provided by the Acquiror and delivered to Acquiror within [†] ([†]) [†] of the Closing Date. Seller and Acquiror will each be responsible for [†];

(iii) Evidence reasonably satisfactory to Acquiror that each consent, approval, order or authorization of, or registration, declaration or filing with any Person required in connection with the execution, delivery or performance of this Agreement as set forth in Schedules 4.3 and 4.7(c) has been obtained or made and is in full force and effect;

(iv) Transfer documents in form and substance reasonably satisfactory to Acquiror required to transfer the Seller Registered IPR to Acquiror as of the Closing Date, duly executed by an authorized officer of Seller;

(v) Such other and further certificates, assurances and documents as Acquiror may reasonably request in order to evidence the accuracy of Seller's representations and warranties, the performance of covenants to be performed by Seller at or prior to the Closing and the fulfillment of the conditions to Seller's obligations hereunder.

3.3 Termination.

(a) This Agreement may be terminated on or prior to the Closing Date only as follows:

(i) by mutual written consent of Acquiror and Seller;

(ii) by either Acquiror or Seller if a court of competent jurisdiction shall have issued an order, decree or ruling permanently restraining, enjoining or otherwise prohibiting the Transactions, and such order, decree or ruling shall have become final and nonappealable; *provided, however*, that the right to terminate this Agreement under this Section 3.3(a)(ii) shall not be available to a party if such order, decree or ruling was primarily due to the failure of such party to perform any of its obligations under this Agreement;

(iii) by the Seller if Seller is not in material breach of its obligations under this Agreement and there has been a material breach of any representation, warranty, covenant, or agreement of Acquiror contained in this Agreement such that the conditions set forth in Section 8.3 would not be satisfied and such breach has not been cured within [†] ([†]) [†] after written notice thereof to Acquiror; provided that no cure period shall be required for a breach which by its nature cannot be cured; or

(iv) by Acquiror if Acquiror is not in material breach of its obligations under this Agreement and there has been a material breach of any representation, warranty, covenant, or agreement of the Seller contained in this Agreement such that the conditions set forth in Section 8.2 would not be satisfied and such breach has not been cured within [†] ([†]) [†] after written notice thereof to the Seller in accordance with Section 10.1; provided that no cure period shall be required for a breach which by its nature cannot be cured.

(b) The termination of this Agreement by Acquiror shall be effectuated by the delivery by Acquiror to the Seller of a written notice of such termination, in accordance with Section 10.1. The termination of this Agreement by the Seller shall be effectuated by the delivery by the Seller to Acquiror of a written notice of such termination, in accordance with Section 10.1.

(c) In the event of the termination of this Agreement pursuant to this Section 3.3, this Agreement shall forthwith become void, and there shall be no liability on the part of any party hereto (except that Section 3.3(c), ARTICLE 10, and the Confidentiality Agreement shall survive). Notwithstanding the foregoing, in the event that this Agreement is terminated due to a material breach or material failure to fulfill of any of the representations, warranties, covenants or agreements set forth in this Agreement, nothing in this Section 3.3(c) shall be deemed to release any party from any liability for any willful and intentional breach of any of the representations, warranties, covenants or agreements set forth in this Agreement following such termination. This Section 3.3(c) shall not impair the right of any party to compel specific performance by any other party of its obligations under this Agreement.

ARTICLE 4 REPRESENTATIONS AND WARRANTIES OF THE SELLER

Except as set forth on the Seller Disclosure Schedule attached to this Agreement as Schedule 4 (the “**Seller Disclosure Schedule**”), Seller represents and warrants to Acquiror as of the date hereof and as of the Closing Date as to the following:

4.1 Organization and Good Standing. Seller is a corporation duly organized, validly existing and in good standing under the Laws of the jurisdiction of its incorporation, has all requisite power to carry on its business as now being conducted, and is duly qualified or licensed and in good standing to do business in each jurisdiction in which such qualification or licensing is necessary.

4.2 Authority and Enforceability. Seller has the requisite power and authority to enter into each of the Transaction Documents, to perform its obligations under each of the Transaction Documents and to consummate the Transactions. The execution and delivery of the Transaction Documents by Seller and the consummation of the Transactions have been duly authorized by all necessary corporate action on the part of Seller. Each of the Transaction Documents has been duly authorized, executed and delivered by Seller and, assuming due authorization, execution and delivery by the Acquiror, constitute the valid and binding obligations of Seller, enforceable against each of them in accordance with its terms, except as such enforceability may be limited by (a) bankruptcy, insolvency, reorganization, moratorium or other similar Laws affecting or relating to creditors’ rights generally, and (b) the availability of injunctive relief and other equitable remedies.

4.3 No Conflict; Authorizations.

4.3.1 No Authorization or Order of, or notice to, any domestic or foreign Governmental Entity, is required to be made or obtained by Seller at or prior to the Closing in connection with the execution and delivery of this Agreement or the consummation by the Seller of the Transactions or compliance by the Seller with the provisions hereof and thereof other than such customary filings regarding any change of beneficial ownership or similar filings in foreign jurisdictions that would not reasonably be expected to preclude or impede the Seller’s ability to consummate the transactions contemplated by this Agreement.

4.3.2 Neither the execution and delivery of this Agreement nor the performance hereof by Seller will result in the breach of or give rise to any right of termination, rescission, renegotiation or acceleration under, or trigger any other rights under, any agreement or contract to which Seller is a party or to which it may be subject that relates to any of the Purchased Assets.

4.3.3 Neither the execution and delivery of this Agreement nor the performance hereof by Seller will conflict with or violate any provision of the certificate of incorporation or bylaws of Seller.

4.4 Notice to Valeant.

4.4.1 Pursuant to Section 5.1 of the Valeant APA, Seller has notified Valeant that Acquiror has made an offer to Seller to purchase the Purchased Assets and, prior to the Closing Date, Seller has fulfilled its notice and designation obligations to Valeant, and Valeant has expressly waived or failed to timely exercise its rights under Section 5.1 of the Valeant APA such that Seller may enter into this Agreement on the Closing Date with Acquiror without further discussions with, or obligations (in respect of entering into this Agreement) to, Valeant.

4.4.2 The sale contemplated by this Agreement qualifies as [†].

4.5 Compliance with Laws.

4.5.1 Seller is, and since [†] has been, in compliance in all material respects with each Law that is applicable to its business, any of the Purchased Assets or the Assumed Liabilities. No event has occurred, and no condition or circumstance exists, that will (with or without notice or lapse of time) constitute or result in a violation by Seller of, or a failure on the part of Seller to comply with, any Law that is applicable to its business, any of the Purchased Assets or the Assumed Liabilities, except where the failure to so comply does not have a Compound Material Adverse Effect. Seller has not received any written notice (or, to the [†] Knowledge of Seller, other communication) from any Person regarding any actual or possible violation of, or failure to comply with, any Law that is applicable to its business, any of the Purchased Assets or the Assumed Liabilities.

4.5.2 To the [†] Knowledge of the Seller, there is no Action, demand, grievance, citation, summons, subpoena, or inquiry of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or threatened against Seller, any of its Affiliates or any Third Party, in each case in connection with the Purchased Assets, the Compound or relating to the transactions contemplated by this Agreement.

4.6 Regulatory. Seller has made available, or has caused to be made available, to Acquiror all [†]. To Seller's [†] Knowledge, there is not any Compound Regulatory Documentation other than the Compound Regulatory Documentation in Seller's possession or control. Except as set forth in Schedule 4.6, all API was manufactured in compliance with Good Manufacturing Practices ("GMPs") as in effect at the applicable time.

4.7 Intellectual Property.

(a) Schedule 4.7(a) contains a complete and accurate list (by title, registrant, application or registration number, application or registration date, and jurisdiction) of all Intellectual Property Rights that are owned by, exclusively licensed to, or filed in the name of Seller and registered with any Governmental Entity ("Seller Registered IPR"). All registration, maintenance and renewal fees related to the Seller Registered IPR that are due as of the Closing Date have been paid and all documents and certificates related to such Seller Registered IPR have been filed with the relevant Governmental Entity or other authorities in the United States or foreign jurisdictions, as the case may be, for the purposes of maintaining such Seller Registered IPR and perfecting Seller's ownership interests therein. [†].

(b) Schedule 4.7(b) lists the status of any Actions (other than ordinary course office actions in connection with the prosecution of applications relating to the Seller Registered IPR) currently pending before the United States Patent and Trademark Office or any other Governmental Entity anywhere in the world related to any of the Seller Registered IPR, and identifies the due date for any outstanding response by Seller in such Actions. [†].

(c) To its [†] Knowledge, Seller has complied with all Applicable Laws, including any disclosure requirements, in connection with the filing, prosecution and maintenance of Seller Registered IPR.

(d) The conception, development and reduction to practice of the Transferred Intellectual Property have not constituted or involved the misappropriation of trade secrets, Patents or other intellectual property rights of any Third Party, since [†], and, to the [†] Knowledge of Seller, prior to [†].

(e) (i) Seller is the sole legal and beneficial owner of all the Transferred Intellectual Property, free of all Encumbrances other than Permitted Encumbrances, and (ii) no person, firm, corporation or other entity (including any Affiliate of Seller) has any right, interest or claim in or to any Purchased Assets, and (iii) neither Seller nor any of its Affiliates has entered into any agreement granting any right, interest or claim in or to, any Purchased Assets to any Third Party (including any academic organization or agency).

(f) Seller has not received any written or oral claim of ownership or inventorship of any Transferred Intellectual Property from any Third Party (including without limitation by current or former officers, directors, employees, consultants or personnel of Seller or Valeant Pharmaceuticals Luxembourg).

(g) Except as set forth on Schedule 4.7(g), all assignments of Seller Registered IPR to Seller have been properly executed and recorded. To the [†] Knowledge of Seller, each of the patents and patent applications included within the Seller Registered IPR properly identifies each and every inventor of the claims thereof as determined in accordance with the laws of the jurisdiction in which such patent is issued or such patent application is pending.

(h) Seller has heretofore (i) made available to Acquiror for review all material scientific and technical information in its possession or control with respect to the Compound, and (ii) made available to Acquiror for review all data in its possession or control [†].

(i) No item of Transferred Intellectual Property is subject to any Action or outstanding Order or settlement agreement or stipulation in litigation that restricts in any manner the use, provision, transfer, assignment or licensing thereof by Seller or may affect the validity, use, ownership, registrability or enforceability of such Transferred Intellectual Property.

(j) Except as specifically identified and described on Schedule 4.7(j), there are no licenses, sublicenses and other contracts pursuant to which Seller is authorized to use, practice any rights under, or grant sublicenses with respect to, any Intellectual Property Rights owned by a Third Party, including any such Intellectual Property Rights which are embodied by any Transferred Intellectual Property or any Technology incorporated into any Transferred Intellectual Property (“**Inbound Licenses**”) and, with respect to each Inbound License, whether the Inbound License is exclusive or non-exclusive.

(k) Except as specifically identified and described on Schedule 4.7(k), there are no currently in-force licenses, sublicenses and other contracts pursuant to which Seller authorizes a third party to use, practice any rights under, or grant sublicenses with respect to, any Transferred Intellectual Property (“**Outbound Licenses**”) and, with respect to each Outbound License, whether the Outbound License is exclusive or non-exclusive.

(l) Except as specifically identified and described in Schedule 4.7(l), neither this Agreement nor the consummation of the Transactions will result in (i) the Acquiror being bound by, or subject to, any non-compete or other material restriction on the Compound or Acquiror’s business, or (ii) the Acquiror being obligated to pay any [†] to any Third Party in excess of those that the Seller would have been required to pay had the Transactions not occurred.

(m) Neither the operation of Seller's business, nor the use, sale, import, export, and manufacture of the Compound or the Transferred Technology (A) have infringed, misappropriated or otherwise violated or constituted the unauthorized use of, and as currently conducted do not infringe, misappropriate or otherwise violate or constitute the unauthorized use of, any Intellectual Property Rights owned by any Person, and, to the [†] Knowledge of Seller, such conduct will not constitute misappropriation or other violation of the Intellectual Property Rights of any Person when conducted by Acquiror in substantially the same manner, and (B) does not constitute and has not constituted unfair competition or trade practices under the Laws of any jurisdiction. Seller has not received written notice from any Person (1) claiming the operation of Seller's business, or the Compound or any Transferred Technology infringes, misappropriates or otherwise violates or constitutes the unauthorized use of any Intellectual Property Rights of any Person or constitutes unfair competition or trade practices under the Laws of any jurisdiction (nor does Seller have [†] Knowledge of any basis therefor) or (2) demanding or offering to license to Seller any Intellectual Property Rights in connection with the business.

(n) To the [†] Knowledge of Seller, no Person is infringing, misappropriating, or otherwise violating or engaged in the unauthorized use of any item of Transferred Intellectual Property. No Actions have been brought or threatened against any Person by Seller, or, to Seller's [†] Knowledge, by any Third Party, alleging that any Person is infringing, misappropriating or otherwise violating or is engaged in the unauthorized use of, any Transferred Intellectual Property.

(o) Seller has used [†] to maintain, protect and preserve the confidentiality of all Know-How, trade secrets, and other confidential information relating to Compound, Transferred Intellectual Property, and operation of Seller's business with respect thereto (collectively, the "**Compound Confidential Information**"). To the [†] Knowledge of Seller, there has been no unauthorized disclosure by any Person of any such Compound Confidential Information. Without limiting the foregoing, each current and former employee and consultant of Seller who has made any contributions to the development of the Compound or any other Transferred Intellectual Property has executed a proprietary information and inventions agreement or consulting agreement containing proprietary information, confidentiality and assignment provisions that provide for (i) the non-disclosure by such Person of any of confidential information and (ii) the assignment by such Person to Seller of all Intellectual Property Rights arising out of such Person's employment or engagement by, or contract with, Seller, which forms have been provided to Acquiror.

(p) Since [†], and to Seller's [†] Knowledge, prior to [†] no government funding, facilities or resources of a Governmental Entity, university, college, or other educational institution or research center was used in the development of any Transferred Intellectual Property and no Governmental Entity, university, college, or other educational institution or research center has any claim or right in or to any Transferred Intellectual Property. No Person (including any current or former employee of Seller), who was involved in, or who contributed to, the creation or development of any Transferred Intellectual Property, has performed services for any Governmental Entity, university, college, or other educational institution or research center during a period of time during which such Person was also performing services for Seller.

(q) To Sellers' [†] Knowledge, Seller is in compliance with all applicable Laws, regulations, and contractual requirements pertaining to privacy, data security, personally identifiable information, and protected health information. To Seller's [†] Knowledge, Seller has not suffered any security breach with respect to any personally identifiable information.

4.8 Contracts.

(a) Schedule 4.8(a) contains a complete and accurate list of all contracts to which Seller is a party, other than the Inbound Licenses and Outbound Licenses (such contracts, together with the Inbound Licenses and Outbound Licenses, the “**Seller Contracts**”).

(b) Seller has not violated or breached in any material respect, and has not committed any material default under, any Seller Contract, which remains uncured, and, to the [†] Knowledge of Seller, no other Person has violated or breached in any material respect, or committed any material default under, any Seller Contract which remains uncured. To the [†] Knowledge of Seller no event has occurred, and no circumstance or condition exists, that (with or without notice or lapse of time) will, or could reasonably be expected to: (i) result in a material violation or material breach of any of the provisions of any Seller Contract; (ii) give any Person the right to declare a default or exercise any remedy under any Seller Contract; or (iii) give any Person the right to accelerate the maturity or performance of any Seller Contract.

(c) The execution and delivery by Seller of the Transaction Documents, the performance by Seller of its obligations hereunder and thereunder, and the consummation by Seller of the Transactions do not and will not conflict with, result in a breach of, constitute (with or without due notice or lapse of time or both) a default under, result in the acceleration of any obligations under, create in any party the right to accelerate, terminate, modify or cancel, give rise to any obligation under, result in the creation of any Encumbrance upon any of the Purchased Assets pursuant to, require any notice, consent or waiver under, or result in the loss of any benefit under any Seller Contract.

(d) All loan agreements entered into by Seller with any third party that could result in an Encumbrance on any of the Purchased Assets, including the Loan Agreements, have been fully repaid prior to or in connection with the Closing (assuming Acquiror makes the payments as specified in Section 2.3).

4.9 Litigation.

(a) There is no Action pending or, to the [†] Knowledge of the Seller, threatened (i) against the Seller, (ii) relating to the Compound, or (iii) that challenges or seeks to prevent, enjoin or otherwise delay the Transactions. To the [†] Knowledge of the Seller, [†].

(b) There is no unsatisfied judgment, penalty, award, decree, injunction, rule or order of any Governmental Entity, court or arbitrator, outstanding or pending against the Seller or with respect to the Compound.

4.10 Brokerage Fees. Seller has not incurred any liabilities for any brokerage, finder, investment banking or other similar fees, commissions or expenses in connection with the Transactions, except for such fees, commissions and expenses of which will be paid by Seller.

4.11 Complete Copies of Materials. Seller has delivered to Acquiror true, correct and complete copies (or with respect to oral agreements, written summaries of the same) of each contract and other document that has been requested by Acquiror or its agents in connection with this Agreement or any of the other Transaction Documents or that is referred to in the Schedules attached hereto.

4.12 Disclosures. To the [†] Knowledge of Seller, [†].

ARTICLE 5 REPRESENTATIONS AND WARRANTIES OF ACQUIROR

Acquiror hereby represents and warrants to Seller as follows:

5.1 Organization and Good Standing. Acquiror has been duly continued and is validly existing as a corporation in good standing under the Canada Business Corporations Act and is up-to-date in all material corporate filings.

5.2 Authority and Enforceability. Acquiror has the requisite power and authority to enter into each of the Transaction Documents, to perform its obligations under each of the Transaction Documents and to consummate the Transactions. The execution and delivery of the Transaction Documents by Acquiror and the consummation of the Transactions have been duly authorized by all necessary corporate action on the part of Acquiror. Each of the Transaction Documents has been duly authorized, executed and delivered by Acquiror and, assuming due authorization, execution and delivery by the Seller, constitute the valid and binding obligations of Acquiror, enforceable against each of them in accordance with its terms, except as such enforceability may be limited by (a) bankruptcy, insolvency, reorganization, moratorium or other similar Laws affecting or relating to creditors' rights generally, and (b) the availability of injunctive relief and other equitable remedies.

5.3 Financial Capability. Acquiror has, and at the Closing will have, sufficient internal funds (without giving effect to any unfunded financing regardless of whether any such financing is committed) available to pay the Base Purchase Price and any expenses incurred by Acquiror in connection with the Transactions.

5.4 Litigation. There is no Action pending or, to the knowledge of Acquiror, threatened against Acquiror, that challenges or seeks to prevent, enjoin or otherwise delay the Transactions. To the knowledge of Acquiror, no event has occurred or circumstances exist that may give rise or serve as a basis for any such Action.

ARTICLE 6 COVENANTS OF THE SELLER

6.1 Access to Information. Prior to the Closing and subject to the terms of the Confidentiality Agreement, Seller shall afford to Acquiror's officers, directors, employees, accountants, counsel, consultants, advisors and agents ("**Representatives**") reasonable access, during normal business hours and upon reasonable advance notice, to all of the assets and records, reports, contracts and other documents related to the Purchased Assets as the Acquiror and its Representatives may reasonably request, and shall permit them to consult with Seller's officers, employees, accountants, counsel and agents for the purpose of making such investigation of the acquired Purchased Assets as Acquiror shall desire to make.

6.2 Notification of Certain Matters. Prior to the Closing, Seller shall give prompt notice to Acquiror of any fact, event or circumstance known to it that (a) individually or taken together with all other facts, events and circumstances known to it, has had or would reasonably be expected to have, individually or in the aggregate, a Compound Material Adverse Effect, or (b) would cause or constitute a failure of any condition precedent to Acquiror's obligations set forth in this agreement. Seller shall give prompt notice to Acquiror of: (i) any notice or other communication from any Third Party alleging that the consent of such Third Party is or may be required in connection with the Transactions, or (ii) any written notice or other written communication received by the Seller from any Governmental Entity in connection with the Transactions. The delivery of any notice pursuant to this Section 6.2 shall not be considered an admission that any representation or warranty is untrue or that any covenant has been breached and shall not limit or otherwise affect any remedies available to Acquiror or prevent or cure any misrepresentations, breach of warranty or breach of covenant, and disclosure by the Seller shall not be deemed to amend or supplement the schedules hereto or constitute an exception to any representation or warranty.

6.3 Actions Prior to Closing.

6.3.1 Status Quo. Prior to Closing, Seller shall cause all registration, maintenance and renewal fees and any certifications, filings or registrations related to Seller Registered IPR and due prior to Closing to be paid, prepared and/or filed, as the case may be, with the relevant Governmental Entity or other authorities in the United States or foreign jurisdictions, as the case may be, for the purposes of maintaining the Seller Registered IPR and perfecting Seller's ownership interests therein. Prior to Closing, Seller shall take or cause to be taken at its expense all other [†] actions necessary to maintain the Purchased Assets, and shall continue to conduct its business in the ordinary course, consistent with past practice. Without limiting the generality of the foregoing, prior to Closing, Seller shall not take any of the following actions in connection with the Purchased Assets: (1) sell, lease, license or otherwise dispose of any Purchased Asset; (2) enter into, cancel or modify any Inbound License or Outbound License; (3) grant or permit to exist any Encumbrance on any of the Purchased Assets; or (4) agree to any of the foregoing actions.

6.3.2 Exclusivity. [†].

6.4 Efforts and Actions to Cause Closing to Occur. Prior to the Closing, upon the terms and subject to the conditions of this Agreement, Acquiror and Seller shall use [†] to take, or cause to be taken, all actions, and to do, or cause to be done, and cooperate with each other in order to do, all things necessary, proper or advisable (subject to applicable Law) to consummate the Transactions as promptly as practicable, including the matters described in 7.5 hereof and the preparation and filing of all forms, registrations and notices required to be filed and the taking of such actions as are necessary to obtain any requisite consents of any Governmental Entity or other Person. In addition, no party hereto shall take any action that could reasonably be expected to materially delay the obtaining of, or result in not obtaining, any consent from any Governmental Entity or other Person required to be obtained prior to the Closing.

6.5 Confidentiality. Following the Closing, each party hereto shall, and shall cause its Affiliates and Representatives to, hold in strict confidence and not utilize in its respective business any information and documents concerning any other party hereto or any of its respective Affiliates or its or their businesses or confidential or proprietary information (“**Confidential Information**”). Notwithstanding anything herein or in the Confidentiality Agreement to the contrary, Acquiror’s Confidential Information includes all confidential or proprietary documents or information regarding the Purchased Assets in the possession of Seller and its Affiliates, even though such documents and information were first developed by, made known to, or obtained from, Seller and its Affiliates. In the event a party is required to disclose Confidential Information to comply with any applicable Law, the party proposing to disclose such information shall give the original disclosing party with respect to whom such information is Confidential Information reasonable advance notice of such disclosure (to the extent not prohibited by applicable Law) and to cooperate with such disclosing party in seeking a protective order or other appropriate means for limiting the scope of the disclosure. Notwithstanding the foregoing, the following will not constitute “Confidential Information” for purposes of this Agreement: (a) other than confidential or proprietary documents and information regarding the Purchased Assets, (i) information that is independently developed by the receiving party or any Affiliate thereof without the use of the Confidential Information, as demonstrated by the receiving party’s contemporaneous written records, and (ii) information that the receiving party can demonstrate is obtained or was previously obtained by the receiving party or its Affiliates from a third party who is not known by the receiving party after due inquiry to be subject to obligations of confidentiality with respect thereto, and (b) information that the receiving party can demonstrate is or becomes generally available to the public other than as the result of a disclosure by the receiving party or any Affiliate thereof or their respective agents or employees. Following the Closing, the foregoing restrictions in this Section 6.5 shall not apply to the use by Acquiror or its Affiliates and its or their successors, assigns and Representatives, and shall apply to the use by Seller and its Affiliates and its or their successors, assigns and Representatives, of any documents or information concerning the Compound or the Purchased Assets furnished or transferred by Seller or its Affiliates hereunder.

ARTICLE 7 OTHER COVENANTS

7.1 Public Announcements. Seller shall not issue any press release or make any public statement regarding the Transactions without the prior written consent of Acquiror. Acquiror and Seller shall not be restricted from making any disclosure it reasonably determines is required by Law, including, without limitation, disclosure required pursuant to the securities laws of the United States and Canada. Either party may make any disclosure, including public statements, consistent with disclosures previously made pursuant to this Section. Nothing in this Section 7.1 shall restrict or otherwise limit the Acquiror’s ability or right to issue any press release or make any public statement after Closing regarding its operations or the Purchased Assets, including, among other things, the development and commercialization of the Compound; provided that Acquiror shall provide Seller an opportunity to review and comment on Acquiror’s initial press release announcing the Transaction.

7.2 [†]. Acquiror will [†].

7.3 Further Assurances. Upon the terms and subject to the conditions hereof each of the parties hereto shall execute such documents and other instruments and take such further actions as may be reasonably required to carry out the provisions hereof and consummate the Transactions (prior to, at or after the Closing). Each of the parties hereto shall use [†] to consummate the Transactions as soon as practicable following the date hereof.

7.4 License by Seller to Valeant. Acquiror acknowledges that, pursuant to the Valeant APA, Valeant has and will continue to have a [†] license under the Patents listed on Part 1 of Schedule 4.3(a) thereto (the “**Grant-Back Intellectual Property**”), which [†].

7.5 Payoff Letters. Seller shall deliver to Acquiror executed payoff letters, in the form attached hereto as Exhibit B, no later than [†] ([†]) [†] prior to the Closing Date.

7.6 Notice and Inquiry. Until the [†] anniversary of the Effective Date, Acquiror will notify Seller annually not later than [†] of any payments made to Valeant in the prior Calendar Year pursuant to the Valeant APA. In addition, Seller may, with notice, request that Acquiror confirm that appropriate payments have been made to Valeant pursuant to the Valeant APA. Xenon shall respond to such inquiry within [†], but shall not be obligated to disclose the amount of any payment. Any information disclosed by Acquiror to Seller shall be treated as Confidential Information of Acquiror.

ARTICLE 8 CONDITIONS TO CLOSING

8.1 Conditions to Each Party's Obligation. The obligations of Acquiror and the Seller to consummate the Transactions are subject to the satisfaction on or prior to the Closing Date of the following conditions:

(a) All Authorizations and Orders of, declarations and filings with, and notices to any Governmental Entity required to permit the consummation of the Transactions shall have been obtained or made and shall be in full force and effect.

(b) No temporary restraining order, preliminary or permanent injunction or other order preventing the consummation of the Transactions shall be issued by any Governmental Entity of competent jurisdiction and shall be in effect. No Law shall have been enacted which makes the consummation of the Transactions illegal.

8.2 Conditions to Obligations of Acquiror. The obligations of Acquiror to effect the Transactions are subject to the satisfaction (or waiver by Acquiror in its sole discretion) of the following further conditions:

(a) The representations and warranties of the Seller set forth in this Agreement shall have been true and correct at and as of the date hereof and shall be true and correct at and as of the Closing Date as if made at and as of the Closing Date.

(b) There shall not have occurred since the date of this Agreement any event, occurrence or change that has had or would reasonably be expected to have, individually or in the aggregate, a Compound Material Adverse Effect.

(c) No action, proceeding or litigation brought by any Governmental Entity of competent jurisdiction shall be pending or threatened before any court or other Governmental Entity seeking to (i) prevent consummation of the Transactions, (ii) affect adversely the right of Acquiror to control the Compound; or (iii) restrain or prohibit Acquiror's ownership of the Purchased Assets. No such Order shall be in effect.

(d) Seller shall have delivered to Acquiror a certificate executed by an authorized officer of Seller (the "**Seller Certificate**") to the effect that each of the conditions specified in clauses (a)-(c) of this Section 8.2 with respect to Seller are satisfied in all respects.

(e) Seller shall have delivered to Acquiror written consents signed by each member of Seller's Board of Directors and each of Seller's stockholders approving the transactions contemplated by this Agreement under Seller's constitutive and other documents, in each case to the effect that each such director and such stockholders have approved the transactions contemplated by this Agreement.

(f) Seller shall have delivered to Acquiror duly executed Transaction Documents.

(g) Seller shall have delivered to Acquiror documents reasonably satisfactory to Acquiror evidencing repayment and release in full with respect to the Loan Agreements, including delivery of the executed Payoff Letters pursuant to Section 7.5.

(h) Seller shall have delivered the items required by it pursuant to Section 3.2 hereof.

8.3 Conditions to Obligation of the Seller. The obligation of the Seller to effect the Transactions is subject to the satisfaction (or waiver by Seller in its sole discretion) of the following further conditions:

(a) The representations and warranties of Acquiror set forth in this Agreement that are [†] shall have been true and correct at and as of the date hereof and shall be true and correct at and as of the Closing Date as if made at and as of the Closing Date, and the representations and warranties that are [†] shall have been true and correct in all [†] respects at and as of the date hereof and shall be true and correct in all [†] respects at and as of the Closing Date as if made at and as of the Closing Date, except to the extent that such representations and warranties refer specifically to an earlier date, in which case such representations and warranties shall have been true and correct as of such earlier date.

(b) Acquiror shall have performed in all [†] respects all obligations required to be performed by it under this Agreement at or prior to the Closing Date.

8.4 Frustration of Closing Conditions. None of the parties hereto may rely on the failure of any condition set forth in this 7.5 to be satisfied if such failure was caused by such party's failure to act in good faith or to use its [†] to cause the Closing to occur.

ARTICLE 9 INDEMNIFICATION

9.1 By Seller. From and after the Closing Date, Seller, shall indemnify Acquiror, its successors and assigns, and its officers, directors, employees, stockholders and agents (each, an "**Indemnified Acquiror Party**") and hold each Indemnified Acquiror Party harmless from and against:

(a) any liabilities, claims, demands, judgments, losses, costs, settlements, damages or expenses whatsoever (including reasonable attorneys', consultants' and other professional fees and disbursements of every kind, nature and description) ("**Damages**") that such Indemnified Acquiror Party, directly or indirectly, sustains, suffers or incurs and that result from or arise out of:

(i) any breach or inaccuracy of any representation or warranty of Seller in the Transaction Documents; and

(ii) any breach or nonfulfillment of any covenant or agreement of Seller set forth in any Transaction Document;

(b) any Damages arising out of or resulting from any liabilities that are not the Assumed Liabilities; and

(c) any and all actions, suits, claims, proceedings, investigations, allegations, demands, assessments, audits, fines, judgments, costs and other expenses (including reasonable attorneys' fees and expenses) incident to any of the foregoing or to the enforcement of this Section 9.1, but only in connection with a claim for which any Indemnified Acquiror Party is entitled to indemnification.

9.2 By Acquiror. From and after the Closing Date, Acquiror shall indemnify the Seller, its successors and assigns, and its officers, directors, employees, stockholders and agents (each, an “**Indemnified Seller Party**”) and hold each Indemnified Seller Party harmless from and against:

(a) any Damages that such Indemnified Seller Party, directly or indirectly, sustains, suffers or incurs and that result from or arise out of:

(i) any breach or inaccuracy of any representation or warranty of Acquiror in the Transaction Document; and

(ii) any breach or nonfulfillment of any covenant or agreement of Acquiror set forth in any Transaction Document; and

(b) any Damages arising out of or resulting from any of the Assumed Liabilities, and pay any settlement costs or final judgment amounts with respect thereto incident to any of the foregoing or to the enforcement of this Section 9.2, but only in connection with a claim for which any Indemnified Seller Party is entitled to indemnification; provided, in each case, that Acquiror shall have no liability with respect to any such claims arising out of or resulting from the gross negligence, willful misconduct, intentional misrepresentation, or fraudulent conduct of Seller.

9.3 Limitation of Liability. EXCEPT IN CASE OF THE FRAUD OR WILFUL MISCONDUCT OF A PARTY, NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR ANY LOST PROFITS, LOST BUSINESS OR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, PUNITIVE, EXEMPLARY OR OTHER SPECIAL DAMAGES SUFFERED BY THE OTHER PARTY OR ITS AFFILIATES ARISING OUT OF OR RELATED TO THIS AGREEMENT FOR ALL CAUSES OF ACTION OF ANY KIND (INCLUDING TORT, CONTRACT, NEGLIGENCE, STRICT LIABILITY, INDEMNITY AND BREACH OF WARRANTY) EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, UNLESS SUCH DAMAGES ARE PAYABLE TO A THIRD PARTY IN CONNECTION WITH A CLAIM BY SUCH THIRD PARTY THAT IS INDEMNIFIABLE HEREUNDER.

9.4 Procedure for Claims. A party that intends to claim indemnification under this ARTICLE 9 (the “**Indemnitee**”) shall promptly notify the other party (the “**Indemnitor**”) in writing of the assertion or the commencement of any Action by a Third Party (a “**Third Party Claim**”) and will provide the Indemnitor such information with respect thereto that the Indemnitor may reasonably request. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any Action with respect to a Third Party Claim shall not relieve the Indemnitor of its obligations under this ARTICLE 9 unless the delay or failure is materially prejudicial to its ability to defend such action. The Indemnitor shall be entitled to control the defense of any Third Party Claim, at its expense, provided that any such Third Party Claim relates to the ownership of any Purchased Assets, or their use, Acquiror shall be entitled to control the defense of any such Third Party claim, at Seller’s expense. The Indemnitee under this Section 9.1(c) shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any Action with respect to a Third Party Claim covered by this indemnification. The Indemnitor shall conduct the defense of such Action and shall keep the Indemnitee, reasonably informed of the status of such Action. The Indemnitee shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any Action with respect to any Third Party Claim. The Indemnitee shall be entitled to participate in any such defense at its sole cost and expense, subject to the obligation of Seller to pay expenses as described in the third sentence above. The Indemnitor shall seek the prior written consent of the Indemnitee (which consent shall not be unreasonably withheld, conditioned or delayed) in connection with the Indemnitor’s settlement or compromise of any such third party Action.

9.5 Right of Offset. In the event that an Indemnified Acquiror Party is seeking indemnification pursuant to this ARTICLE 9, Acquiror shall be entitled to withhold the amount of any Damages sought from any amounts due from Acquiror to Seller, including any Milestone Payments, to the extent any such amounts are then, or may in the future, become payable.

9.6 Survival. The representations and warranties of Seller contained in this Agreement, and any claims with respect thereto, shall survive the Closing for a period of [†] ([†]) [†]. The representations and warranties of Acquiror contained in this Agreement, and any claims with respect thereto, shall expire at the Closing. The respective covenants of both parties shall survive the Closing in accordance with their terms.

ARTICLE 10 MISCELLANEOUS

10.1 Notices. Any notice, request, demand, waiver, consent, approval or other communication which is required or permitted hereunder shall be in writing and shall be deemed given: (a) on the date established by the sender as the date of actual personal delivery; (b) on the date delivered by a private courier as established by the sender by evidence obtained from the courier; (c) on the date sent by facsimile, with confirmation of transmission, if sent during normal business hours of the recipient, if not, then on the [†]; or (d) on the [†] after the date mailed, by certified or registered mail, return receipt requested, postage prepaid. Such communications, to be valid, must be addressed as follows:

If to Seller, to:

1ST Order Pharmaceuticals
5511 NC Highway 902
Pittsboro, NC 27312
Attn: President and Chief Scientific Officer
Facsimile: (919) 542-5421
Telephone: (919) 812-8119

With a copy to:

Wyrick Robbins Yates & Ponton LLP
4101 Lake Boone Trail, Suite 300
Raleigh, NC 27607
Attn: Thomas A. Allen
Facsimile: (919) 781-4865

If to Acquiror, to:

Xenon Pharmaceuticals, Inc.
3650 Gilmore Way
Burnaby, BC V5G 4W8, Canada
Attn: Legal Department
Facsimile: (604) 484-3450

With a required copy to:

Wilson Sonsini Goodrich & Rosati, PC
650 Page Mill Rd. Palo Alto, CA 94304
Attn: Bryan King
Facsimile: (650) 493-6811

or to such other address or to the attention of such Person or Persons as the recipient party has specified by prior written notice to the sending party. If more than one method for sending notice as set forth above is used, the earliest notice date established as set forth above shall control.

10.2 Amendments and Waivers.

(a) Any provision of this Agreement may be amended or waived if, and only if, such amendment or waiver is in writing and is signed, in the case of an amendment, by Acquiror and the Seller.

(b) No failure or delay by any party in exercising any right or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege.

(c) To the maximum extent permitted by Law, (i) no waiver that may be given by a party shall be applicable except in the specific instance for which it was given and (ii) no notice to or demand on one party shall be deemed to be a waiver of any obligation of such party or the right of the party giving such notice or demand to take further action without notice or demand.

10.3 Expenses. Each of parties hereto shall bear its own costs and expenses in connection with this Agreement and the Transactions, including all legal, accounting, financial advisory, consulting and all other fees and expenses of third parties, whether or not the Transactions are consummated.

10.4 Successors and Assigns. This Agreement may not be assigned by Seller, by operation of law or otherwise, without the prior written consent of Acquiror. Acquiror may freely assign this Agreement and any of its rights obtained hereunder as it deems appropriate. Subject to the foregoing, all of the terms and provisions of this Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective executors, heirs, personal representatives, successors and assigns. Acquiror covenants that to the extent that any person acquires all or substantially all of the assets or operations related to the Purchased Assets, whether by merger, asset acquisition or otherwise, it will ensure that such acquiring person agrees in writing to assume Acquiror's obligations under this Agreement and Acquiror shall provide a copy of such assumption to Seller.

10.5 Governing Law; Venue. This Agreement and the exhibits and schedules hereto shall be governed by and interpreted and enforced in accordance with the Laws of the State of Delaware, without giving effect to any choice of Law or conflict of Laws rules or provisions (whether of the State of Delaware or any other jurisdiction) that would cause the application of the Laws of any jurisdiction other than the State of Delaware. Any legal proceeding relating to this Agreement or the enforcement of any provision of this Agreement may be brought or otherwise commenced only in any state or federal court located in the State of Delaware. Each party to this Agreement: (i) irrevocably and unconditionally consents and submits to the exclusive jurisdiction and venue of the state and federal courts located in State of Delaware; (ii) agrees that each state and federal court located in the State of Delaware shall be deemed to be a convenient forum; and (iii) agrees not to assert (by way of motion, as a defense or otherwise), in any such legal proceeding commenced in any state or federal court located in the State of Delaware, any claim that such party is not subject personally to the jurisdiction of such court, that such legal proceeding has been brought in an inconvenient forum, that the venue of such legal proceeding is improper or that this Agreement or the subject matter of this Agreement may not be enforced in or by such court.

10.6 Counterparts. This Agreement may be executed in any number of counterparts, and any party hereto may execute any such counterpart, each of which when executed and delivered shall be deemed to be an original and all of which counterparts taken together shall constitute but one and the same instrument. This Agreement shall become effective when each party hereto shall have received a counterpart hereof signed by the other parties hereto. The parties agree that the delivery of this Agreement may be effected by means of an exchange of facsimile or other electronic signatures.

10.7 Third Party Beneficiaries. No provision of this Agreement is intended to confer upon any Person other than the parties hereto any rights or remedies hereunder, except that, in the case of ARTICLE 9 hereof, the Indemnitees are intended third party beneficiaries of such sections and shall have the right to enforce such sections in their own names.

10.8 Dispute over Obligations arising under Valeant APA. In the event of any dispute arising as a result of the performance by Acquiror of any Assumed Liabilities or any alleged breach of any such obligations, Seller shall cooperate with Acquiror, at Acquiror's request [†], in collecting any documents or information in respect of the defense of any such action, claim or proceeding, except to the extent such cooperation, upon advice of legal counsel, would jeopardize or undermine any rights or claims of Seller.

10.9 Entire Agreement. This Agreement and the documents, instruments and other agreements specifically referred to herein or delivered pursuant hereto set forth the entire understanding of the parties hereto with respect to the Transactions. All exhibits and schedules referred to herein are intended to be and hereby are specifically made a part of this Agreement. Any and all previous agreements and understandings between or among the parties regarding the subject matter hereof, whether written or oral, are superseded by this Agreement, other than the Confidentiality Agreement which shall continue in full force and effect in accordance with its terms except modified in accordance with Section 6.5 hereof.

10.10 Captions. All captions contained in this Agreement are for convenience of reference only, do not form a part of this Agreement and shall not affect in any way the meaning or interpretation of this Agreement.

10.11 Severability. Any provision of this Agreement which is invalid or unenforceable in any jurisdiction shall be ineffective to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining provisions hereof, and any such invalidity or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction.

10.12 Specific Performance. Acquiror and Seller agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed by them in accordance with the terms hereof and that each party shall be entitled to specific performance of the terms hereof, in addition to any other remedy at Law or equity.

10.13 Dispute Resolution.

10.12.1 In the event of any controversy, dispute, claim or counterclaim arising out of or relating to this Agreement (a “**Dispute**”), the parties shall first attempt to resolve such Dispute through good faith negotiations following notification of such Dispute to the other party in accordance with the procedures set forth in this Section 10.13.

10.12.2 The party claiming that such a Dispute exists shall give notice in writing (a “**Notice of Dispute**”) to the other party of the nature of the dispute.

10.12.3 Within [†] ([†]) [†] of receipt of a Notice of Dispute, the Chief Executive Officer of Acquiror, or his or her designee, and the Chief Executive Officer of Seller, or his or her designee, shall meet in person or by teleconference, as mutually agreed, for the purpose of attempting to resolve such Dispute.

10.12.4 If, within a further period of [†] ([†]) [†], or if in any event within [†] ([†]) [†] of initial receipt of the Notice of Dispute, the Dispute has not been resolved, or if, for any reason, the meeting described in Section 10.12.3 has not been held within [†] ([†]) [†] of initial receipt of the Notice of Dispute, then the parties agree that either party may initiate a proceeding to resolve the Dispute in accordance with Section 10.12.5 or Section 10.5.

10.12.5 Notwithstanding any provision of this Agreement to the contrary, either party may immediately initiate litigation in any court of competent jurisdiction seeking any remedy in equity, including the issuance of a preliminary, temporary or permanent injunction, to preserve or enforce its rights under this Agreement.

10.13 Waiver of Jury Trial. EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM (WHETHER BASED ON CONTRACT, TORT OR OTHERWISE) ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THE ACTIONS OF A PARTY HERETO IN THE NEGOTIATION, ADMINISTRATION, PERFORMANCE AND ENFORCEMENT OF THIS AGREEMENT

10.14 Interpretation.

(a) The meaning assigned to each term defined herein shall be equally applicable to both the singular and the plural forms of such term and vice versa, and words denoting either gender shall include both genders as the context requires. Where a word or phrase is defined herein, each of its other grammatical forms shall have a corresponding meaning.

(b) The terms “hereof”, “herein” and “herewith” and words of similar import shall, unless otherwise stated, be construed to refer to this Agreement as a whole and not to any particular provision of this Agreement.

(c) When a reference is made in this Agreement to an Article, Section, paragraph, Exhibit or Schedule, such reference is to an Article, Section, paragraph, Exhibit or Schedule to this Agreement unless otherwise specified.

(d) References to “dollars” or “\$” are references to United States dollars.

(e) The word “include”, “includes”, and “including” when used in this Agreement shall be deemed to be followed by the words “without limitation”, unless otherwise specified.

(f) A reference to any party to this Agreement or any other agreement or document shall include such party’s predecessors, successors and permitted assigns.

(g) Reference to any Law means such Law as amended, modified, codified, replaced or reenacted, and all rules and regulations promulgated thereunder.

(h) The parties have participated jointly in the negotiation and drafting of this Agreement. Any rule of construction or interpretation otherwise requiring this Agreement to be construed or interpreted against any party by virtue of the authorship of this Agreement shall not apply to the construction and interpretation hereof.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the parties hereto, intending to be legally bound hereby, have caused this Asset Purchase Agreement to be executed by their duly authorized representatives as of the date first written above.

1ST ORDER PHAMACEUTICALS, INC.

By: /s/ Christopher S. Crean

Name: Christopher S. Crean

Title: President and Chief Scientific Officer

XENON PHARMACEUTICALS INC.

By: /s/ Simon Pimstone

Name: Simon Pimstone

Title: Chief Executive Officer

By: /s/ Ian Mortimer

Name: Ian Mortimer

Title: Chief Financial Officer

[†] DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

Exhibit A

Valeant APA

[†] DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

ASSET PURCHASE AGREEMENT

by and among

1st ORDER PHARMACEUTICALS, INC.
(a Delaware corporation),

VALEANT PHARMACEUTICALS LUXEMBOURG,
(a Luxembourg company)

Dated as of October 30, 2015

[†] DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

ASSET PURCHASE AGREEMENT

THIS ASSET PURCHASE AGREEMENT (“**Agreement**”), is made as of October 30, 2015, by and among, 1ST Order Pharmaceuticals, Inc., a Delaware Corporation (“**Acquiror**”) and Valeant Pharmaceuticals Luxembourg S.ar.l. a Luxembourg company (“**Seller**”).

RECITALS:

A. WHEREAS, the Seller desires to sell to Acquiror, and Acquiror desires to purchase from Seller, all of Seller’s right, title and interest in and to the investigational compound known as VRX621698, a potassium channel opener small molecule (the “**Compound**”), and certain completed development reports, raw data, API and intellectual property related thereto, upon the terms and subject to the conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the respective representations, warranties, covenants and agreements contained herein, and of other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound hereby, agree as follows:

ARTICLE 1 DEFINITIONS

For convenience, certain terms used in more than one part of this Agreement are listed in alphabetical order and defined or referred to below.

“**Affiliate(s)**” means, with respect to a particular party, a Person or other entity that controls, is controlled by or is under common control with such party. For the purposes of this definition, the word “control” (including, with correlative meaning, the terms “controlled by” or “under the common control with”) means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of fifty percent (50%) or more of the voting stock of such entity, or by contract or otherwise.

“**Acquiror**” is defined in the Preamble.

“**Agreement**” is defined in the Preamble.

“**Authorization**” means any authorization, approval, consent, certificate, license, notification, registration, permit, franchise, waiver, order, right, notification of any Governmental Entity.

“**Base Purchase Price**” is defined in Section 2.3.

“**Business Day**” means a day other than a Saturday, Sunday or other day on which banks located in New York City are authorized or required by Law to close.

“**Closing**” is defined in Section 3.1.

“**Closing Date**” is defined in Section 3.1.

[†] DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

“**Compound Material Adverse Effect**” means [†].

“**Compound**” is defined in the preamble.

“**Compound Intellectual Property**” means all Patent rights, Know-How and other Intellectual Property relating to the Compound, including, without limitation, the Intellectual Property set forth on Schedule 4.3(a).

“**Compound Registered Items**” is defined in Section 4.3(d).

“**Compound Regulatory Documentation**” means any and all Authorizations relating to the Compound, including, without limitation, applications, registrations, licenses, authorizations, approvals, non-clinical and clinical study authorization applications or notifications (including all supporting files, writings, data, studies and reports), correspondence to or with any Medical Product Regulatory Authority with respect to the Compound, and all data contained in any of the foregoing, including all adverse event files and manufacturing records.

“**Confidentiality Agreement**” is defined in Section 7.1.

“**Confidentiality Information**” is defined in Section 7.6.

“**Damages**” is defined in Section 10.1(a).

“**Drug Product**” means any formulation or presentation of the Compound approved by a Medical Product Regulatory Authority under an NDA for sale.

“**EMA**” means the European Medicines Agency.

“**EU Territory**” is defined in Section 2.5(b).

“**FDA**” means the United States Food and Drug Administration.

“**FFDCA**” means the U.S. Federal Food, Drug, and Cosmetic Act.

“**Generic Equivalent**” means any drug product that is comparable to a Drug Product in dosage form, strength, performance characteristics and intended use.

“**Governmental Entity**” means any entity or body exercising executive, legislative, judicial, regulatory or administrative functions of or pertaining to United States federal, state, local, or municipal government, foreign, international, multinational or other government, including any department, commission, board, agency, bureau, subdivision, instrumentality, official or other regulatory, administrative or judicial authority thereof.

“**Grant-Back Intellectual Property**” is defined in Section 2.8.

“**In-Bound Licenses**” is defined in Section 4.3(b).

“**Indemnified Acquiror Party**” is defined in Section 10.1.

“**Indemnified Party**” is defined in Section 10.2.

“**Indemnified Seller Party**” is defined in Section 10.2.

“**Indemnitor**” is defined in Section 10.3(a).

“[†]” is defined in Section 2.4(b).

“**Intellectual Property**” means: (i) inventions (whether or not patentable), trade secrets, technical data, databases, customer lists, designs, tools, methods, processes, technology, ideas, Know-How, source code, product road maps and other proprietary information and materials (“**Proprietary Information**”); (ii) trademarks and service marks (whether or not registered), trade names, logos, trade dress and other proprietary indicia and all goodwill associated therewith; (iii) documentation, advertising copy, marketing materials, web-sites, specifications, mask works, drawings, graphics, databases, recordings and other works of authorship, whether or not protected by Copyright; (iv) computer programs, including any and all software implementations of algorithms, models and methodologies, whether in source code or object code, firmware, development tools, files, records and data, design documents, flow-charts, user manuals and training materials relating thereto and any translations thereof and all media on which any of the foregoing is recorded (collectively, “**Software**”); (v) domain names, uniform resource locators (“**URLs**”) and other names and locators associated with the Internet (collectively, “**Domain Names**”); and (vi) all forms of legal rights and protections that may be obtained for, or may pertain to, the Intellectual Property set forth in clauses (i) through (v) in any country of the world (“**Intellectual Property Rights**”), including all letters patent, patent applications, provisional patents, design patents, PCT filings, invention disclosures and other rights to inventions or designs (“**Patents**”), all registered and unregistered copyrights in both published and unpublished works (“**Copyrights**”), all trademarks, service marks, trade names and other proprietary indicia (whether or not registered) (“**Marks**”), trade secret rights, mask works, moral rights or other literary property or authors rights, and all applications, registrations, issuances, divisions, continuations, renewals, reissuances and extensions of the foregoing.

“**Know-How**” means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, clinical, safety, manufacturing and quality control data), results and other material, including high-throughput screening, gene expression, genomics, proteomics and other drug discovery and development technology, assays and any other biological methodology, pre-clinical and clinical trial results, manufacturing procedures, test procedures and purification and isolation techniques, (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form.

“**Knowledge**” means [†].

“**Law**” means any statute, law (including common law), constitution, treaty, ordinance, code, order, decree, judgment, rule, regulation and any other binding requirement or determination of any Governmental Entity.

“**Medical Product Regulatory Authority**” means any Governmental Entity that is concerned with the safety, efficacy, reliability, manufacture, investigation, sale or marketing of pharmaceuticals, medical products, biologics or biopharmaceuticals, including, without limitation, FDA, the EMEA, and state and local government authorities.

“**Milestone**” is defined in Section 2.4(a).

“**Milestone Payment**” is defined in Section 2.4(a).

“**Net Sales**” means [†].

“**NDA**” means (a) a New Drug Application, as defined in the FDCA, which is required to be approved by FDA before the marketing of a product for its FDA-approved intended use, and its equivalent in other countries or regulatory jurisdictions or any successor application or procedure, and (b) all supplements and amendments that may be filed with respect to the foregoing.

“**Order**” means any award, injunction, judgment, decree, order, ruling, subpoena or verdict or other decision entered, issued or rendered by any Governmental Entity.

“**Out-Bound License**” is defined in Section 4.3(c).

“**Person**” means an individual, a corporation, a partnership, a limited liability company, a trust, an unincorporated association, a Governmental Entity or any agency, instrumentality or political subdivision of a Governmental Entity, or any other entity or body.

“[†]” is defined in Section 2.4(b).

“**Purchased Assets**” is defined in Section 2.1.

“**Representatives**” is defined in Section 7.1.

“**ROW Territory**” is defined in Section 2.5(c).

“[†]” is defined in Section 2.4(b).

“[†]” is defined in Section 2.4(b).

“**Third Party**” shall mean any Person or entity other than Seller, Acquiror and their respective Affiliates.

“**Third Party Payments**” means all fees, milestones or royalties paid to a Third Party that Acquiror determines are commercially, reasonably necessary to obtain a license to practice such Third Party’s Patent rights in order to sell a Drug Product without infringing such Third Party’s Patents (a “**Third Party Patent**”), provided, however, that Third Party Payments shall exclude fees, milestones or royalties (a) reasonably attributable to a product other than a Drug Product covered by the respective Third Party Patent, and (b) reasonably attributable to Intellectual Property other than a Third Party Patent;

“**Transaction Documents**” means this Agreement and any other, instrument, agreement or document required to be delivered by the parties to this Agreement pursuant to the terms hereof.

“**Transaction**” means the purchase and sale of the Purchased Assets hereunder and the other transactions contemplated by the Transaction Documents.

“**US Territory**” is defined in Section 2.5(a).

ARTICLE 2 PURCHASE AND SALE

2.1 Purchase and Sale of the Compound.

(a) On the terms and subject to the conditions set forth in this Agreement, at the Closing, Acquiror shall purchase from Seller, and Seller shall sell to Acquiror, all of Seller’s rights, titles, and interest in and to the Compound (the “**Purchased Assets**”), including, without limitation, the following assets.

- (i) The Compound Intellectual Property;
- (ii) The tangible drug substance material currently stored with [†]; and
- (iii) The Compound Regulatory Documentation.

(b) Acquiror shall not assume pursuant to this Agreement or the transactions contemplated hereby, and shall have no liability for, any liabilities of Seller of any kind, character or description whatsoever, and Seller shall retain responsibility for all such liabilities and obligations.

2.2 Purchase Price. The purchase price for the Purchased Assets shall be equal to the Base Purchase Price plus, to the extent achieved, the Milestone Payments in accordance with Section 2.4, plus, to the extent payable, the royalty payments in accordance with Section 2.5.

2.3 Payment of Closing Consideration. At the Closing, Acquiror shall deliver to Seller the amount of \$[†] (the “**Base Purchase Price**”).

2.4 Milestone Payments.

(a) Subject to the terms and conditions of this Agreement, the Seller shall be entitled to a milestone payment (each payment as it relates to a particular event for a product, a “**Milestone Payment**”) upon achievement of each of the following events (each, a “**Milestone**”) for the Compound in the particular amounts specified below:

<u>Compound (VRX621698)</u>	
<u>Milestone</u>	<u>Milestone Payment</u>
[†]	[†]
[†]	[†]
[†]	[†]
[†]	[†]
[†]	[†]
[†]	[†]
[†]	[†]
[†]	[†]
[†]	[†]
[†]	[†]
Total possible Milestone Payments:	[†]

(b) **Definitions:** For purposes of determining Milestone Payments:

- (i) “[†]” means [†].
- (ii) “[†]” means [†].
- (iii) “[†]” means [†].
- (iv) “[†]” means [†].
- (v) “[†]” means [†].
- (vi) “[†]” means [†].
- (vii) “[†]” means [†].
- (viii) “[†]” means [†].

(c) **Milestones Payable Only Once.** The Parties understand and agree that, except as otherwise noted in Section 2.4(a) above, each of the Milestone Payments referenced under Section 2.4(a), shall be payable only once, upon the first occurrence of the applicable Milestone, and are subject to the terms and conditions set forth in this Section 2.4.

(d) **Payment of Milestone Payments.** Subject to Acquiror’s right to offset pursuant to Section 10.6, Acquiror shall cause each Milestone Payment, if any, to be distributed to the Seller within [†] ([†]) [†] following the date the applicable Milestone relating thereto is achieved by bank wire transfer of immediately available funds to an account designated by Seller in writing.

2.5 **Royalties.** In addition to (and not in lieu of) the Base Purchase Price and the Milestone Payments, Acquiror shall pay to Seller the following:

[†] DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

(a) Royalties on Products in the United States (US) Territory. As partial consideration of the sale of the Compound to Acquiror hereunder, Acquiror shall pay to Seller amounts equal to the applicable percentage of aggregate Net Sales of Compound as a Drug Product sold in the United States (and its territories) (the “**US Territory**”) as described below, as follows:

- (i) [†] ([†]) of Net Sales of such Drug Product in the US Territory; and
- (ii) [†] ([†]) of Net Sales of such Drug Product in the US Territory.

(b) Royalties on Products in the European Union (EU) Territory. As partial consideration of the sale of the Compound to Acquiror hereunder, Acquiror shall pay to Seller amounts equal to the applicable percentage of aggregate Net Sales of Compound as a Drug Product sold in the European Union (and its territories) (the “**EU Territory**”) as described below, and country-by-country basis as follows:

- (i) [†] ([†]) of Net Sales of such Drug Product in such country; and
- (ii) [†] ([†]) of Net Sales of such Drug Product in such country.

(c) Royalties on Products in the Rest of World (ROW) Territory. As partial consideration of the sale of the Compound to Acquiror hereunder, Acquiror shall pay to Seller amounts equal to the applicable percentage of aggregate Net Sales of Compound as a Drug Product sold outside the US Territory or EU Territory (the “**ROW Territory**”) as described below, and country-by-country basis as follows:

- (i) [†] ([†]) of Net Sales of such Drug Product in such country; and
- (ii) [†] ([†]) of Net Sales of such Drug Product.

(d) Royalty Payments. All royalties due under this Section 2.5 shall be paid within [†] ([†]) [†] of the end of the calendar quarter during which the applicable Net Sales occur. Each royalty payment shall be accompanied by a statement (i) stating (as applicable) the aggregate Net Sales, by country, of each Drug Product sold during the relevant calendar quarter by Acquiror and its Affiliates or its or their licensees, or its or their direct or indirect sub-licensees, and (ii) detailing the calculation of royalties and amounts due for such calendar quarter. All payments due under this Section 2.5 shall be made by bank wire transfer in immediately available funds to an account designated by Seller in writing. All payments hereunder shall be made in the legal currency of the United States. With respect to Net Sales invoiced in a currency other than United States dollars, such Net Sales will be converted into the United States dollar equivalent using the average conversion rate existing in the United States (as reported in The Wall Street Journal, New York edition) during the applicable calendar quarter. If The Wall Street Journal ceases to be published, then the rate of exchange to be used shall be that reported in such other business publication of national circulation in the United States on which the Parties reasonably agree.

2.6 Taxes. Notwithstanding anything in this Agreement to the contrary, each of Acquiror and Seller are responsible for payment of any tax for which it is required to pay to the applicable Governmental Entity in connection with the purchase of the Compound. In the event any tax or similar amount is paid or required to be withheld by Acquiror or any Affiliate thereof for the benefit of Seller on account of any royalties or other payments payable to Seller under this Agreement, the corresponding amounts payable to Seller shall be reduced by the amount of taxes or similar amounts deducted and withheld, and Acquiror shall pay the amounts of such taxes or similar amounts to the proper Governmental Entities in a timely manner and promptly transmit to Seller an official tax certificate or other evidence of such tax or other obligations together with proof of payment from the relevant Governmental Entity of all amounts deducted and withheld sufficient to enable Seller to claim such payment of taxes or similar amounts. Any such withholding taxes or similar amounts required under applicable Law to be paid or withheld shall be an expense of, and borne solely by, Seller. Acquiror will provide Seller with, at Seller's expense, reasonable assistance to enable RNR to recover such taxes or amounts otherwise withheld as permitted by Law.

2.7 License by Acquiror to Seller. Effective as of the Closing Date, the Acquiror hereby grants to the Seller [†] license under the Patents listed on Part 1 of Schedule 4.3(a) (the "**Grant-Back Intellectual Property**"), which license may [†].

2.8 Filing, Prosecution and Maintenance of Patents. Except as set forth herein, Acquiror will be solely responsible for the preparation, filing, prosecution and maintenance of the Grant-Back Intellectual Property at its sole expense. Acquiror will keep the Seller advised on the status of the preparation, filing, prosecution and maintenance of all patent applications included within the Grant-Back Intellectual Property and the maintenance of any issued patents included within the Grant-Back Intellectual Property. If Acquiror elects not to file a patent application included in the Grant-Back Intellectual Property in any jurisdiction or elects to cease the prosecution or maintenance of any Grant-Back Intellectual Property in any jurisdiction, Acquiror will provide Seller with written notice immediately, but not less than [†] ([†]) [†] before any action is required, upon the decision to not file or continue the prosecution of such patent application or maintenance of such Patent. In such event, Acquiror will permit Seller, in Seller's sole discretion, to file or continue prosecution or maintenance of any such Grant-Back Intellectual Property in such jurisdiction on Acquiror's behalf at Seller's sole expense. If Seller elects to continue such prosecution or maintenance, Acquiror will execute such documents and perform such acts, at Seller's expense, as may be reasonably necessary to assign to Seller all right, title and interest in and to such Grant-Back Intellectual Property in such jurisdiction.

2.9 Enforcement and Defense of Patent Rights. Except as otherwise provided in this Section 2.9 as between the Parties, Acquiror will have the exclusive right, but not the obligation, to institute litigation or take other steps to remedy any infringement of the Grant-Back Intellectual Property by a Third Party or to defend any declaratory judgment action against any Grant-Bank Intellectual Property (or alternatively that such patent rights are invalid or unenforceable), and any such litigation, steps or defense will be at the Acquiror's expense. Acquiror will not, without the prior written consent of Seller, enter into any compromise or settlement relating to such litigation that (i) admits the invalidity or unenforceability of any Grant-Back Intellectual Property or (ii) requires either party to abandon any Grant-Back Intellectual Property; provided, that Seller's consent shall be deemed given if Seller does not respond to Acquiror within [†] ([†]) [†] after delivery of written notice to Seller of such proposed action. Seller will cooperate with the Acquiror in such litigation, steps or defense at Seller's expense. Seller will have the right to consult with the Acquiror about such litigation and to participate in and be represented by independent counsel in such litigation at Seller's own expense. If Acquiror fails to defend any declaratory judgment action against any Grant-Back Intellectual Property within [†] ([†]) [†] of its receipt of notice thereof, then Seller will have the right, but not the obligation, upon [†] ([†]) [†] prior notice to Acquiror, to defend such litigation at Seller's expense. In such event, at Seller's request and expense, Acquiror will timely commence or join in any such litigation and in any event will cooperate with the Seller in such litigation, steps or defense at the Seller's expense. Acquiror will have the right to consult with Seller about such litigation and to participate in and be represented by independent counsel in such litigation at Acquiror's own expense. Seller will not, without the prior written consent of Acquiror, enter into any compromise or settlement relating to such litigation that (i) admits the invalidity or unenforceability of any Grant-Back Intellectual Property or (ii) requires Acquiror to abandon any Grant-Back Intellectual Property. All recoveries collected by the Parties in such litigation, steps or defense will first be allocated between the Parties on a pro rata basis to reimburse the Parties for their costs incurred in connection with such litigation, steps or defense, and any remaining recoveries will be retained by the party controlling such litigation, steps or defense.

ARTICLE 3 CLOSING; TERMINATION AND TERM

3.1 Location; Date. The consummation of the Transaction (the "**Closing**") shall be held at the offices of Wyrick Robbins Yates & Ponton, LLP, at 4101 Lake Boone Trail, Suite 300, Raleigh, NC 27607 on a date which shall be no later than [†] ([†]) [†] after satisfaction or waiver of the conditions set forth in ARTICLE 9 or at such other date and place as may be mutually agreed upon by Acquiror and Seller (the "**Closing Date**"). The Closing shall be effective for all purposes as of 11:59 p.m. (Eastern Time) on the Closing Date.

3.2 Deliveries. At the Closing and as a condition to Closing, Seller shall deliver or cause to be delivered each of the following to Acquiror, unless Acquiror waives the delivery thereof:

(i) Evidence reasonably satisfactory to Acquiror that the tangible drug substance material currently stored with [†] will be shipped to the address provided by the Acquiror to the Seller [†];

(ii) Evidence reasonably satisfactory to Acquiror that any and all physical files, reports, data and other documentation related to Compound will be shipped to the address provided by the Acquiror to the Seller [†];

(iii) Evidence reasonably satisfactory to Acquiror that each consent, approval, order or authorization of, or registration, declaration or filing with any Person required in connection with the execution, delivery or performance of this Agreement has been obtained or made and is in full force and effect;

(iv) Transfer documents in form and substance reasonably satisfactory to Acquiror required to transfer the Compound Intellectual Property that is registered Compound Intellectual Property to Acquiror as of the Closing Date, duly executed by an authorized officer of Seller;

(v) Termination or other modification of the Confidentiality Agreement reasonably necessary for Acquiror to commercialize and develop the Compound after Closing; and

(vi) Such other and further certificates, assurances and documents as Seller may reasonably request in order to evidence the accuracy of Seller's representations and warranties, the performance of covenants to be performed by Seller at or prior to the Closing and the fulfillment of the conditions to Acquiror's obligations hereunder.

3.3 Termination.

(a) This Agreement may be terminated on or prior to the Closing Date only as follows:

(i) by mutual written consent of Acquiror and Seller;

(ii) by either Acquiror or Seller if a court of competent jurisdiction shall have issued an order, decree or ruling permanently restraining, enjoining or otherwise prohibiting the Transaction, and such order, decree or ruling shall have become final and nonappealable; *provided, however*, that the right to terminate this Agreement under this Section 3.3(a)(ii) shall not be available to a party if such order, decree or ruling was primarily due to the failure of such party to perform any of its obligations under this Agreement;

(iii) by Acquiror if Acquiror is not in material breach of its obligations under this Agreement and there has been a material breach of any representation, warranty, covenant, or agreement of the Seller contained in this Agreement such that the conditions set forth in Section 9.2 would not be satisfied and such breach has not been cured within [†] ([†]) [†] after written notice thereof to the Seller; provided that no cure period shall be required for a breach which by its nature cannot be cured; or

(iv) by the Seller if Seller is not in material breach of its obligations under this Agreement and there has been a material breach of any representation, warranty, covenant, or agreement of Acquiror contained in this Agreement such that the conditions set forth in Section 9.3 would not be satisfied and such breach has not been cured within [†] ([†]) [†] after written notice thereof to Acquiror; provided that no cure period shall be required for a breach which by its nature cannot be cured.

(b) The termination of this Agreement by Acquiror shall be effectuated by the delivery by Acquiror to the Seller of a written notice of such termination. The termination of this Agreement by the Seller shall be effectuated by the delivery by the Seller to Acquiror of a written notice of such termination.

(c) In the event of the termination of this Agreement pursuant to this Section 3.3, this Agreement shall forthwith become void, and there shall be no Liability on the part of any party hereto (except for Sections 3.3, 8.2 and 11 and the Confidentiality Agreement). Notwithstanding the foregoing, in the event that this Agreement is terminated due to a material breach or material failure to fulfill of any of the representations, warranties, covenants or agreements set forth in this Agreement, nothing in this Section 3.3(c) shall be deemed to release any party from any liability for any willful and intentional breach of any of the representations, warranties, covenants or agreements set forth in this Agreement following such termination. This Section 3.3(c) shall not impair the right of any party to compel specific performance by any other party of its obligations under this Agreement.

ARTICLE 4 REPRESENTATIONS AND WARRANTIES OF THE SELLER

4.1 No Conflict; Authorizations. No Authorization or Order of, or notice to, any domestic or foreign Governmental Entity, is required to be made or obtained by Seller at or prior to the Closing in connection with the execution and delivery of this Agreement or the consummation by the Seller of the transactions contemplated by this Agreement or compliance by the Seller with the provisions hereof and thereof other than such customary filings regarding any change of beneficial ownership or similar filings in foreign jurisdictions that would not reasonably be expected to preclude or materially impede the Seller's ability to consummate the transactions contemplated by this Agreement.

4.2 Regulatory. Seller has made available, or has caused to be made available, to Acquiror [†].

4.3 Intellectual Property.

(a) Schedule 4.3(a) contains a complete and accurate list of (by name, contact information and, where applicable, registration number and jurisdiction of registration, application, certification or filing) all Intellectual Property that is owned by Seller relating to or filed in the name of the Compound ("**Compound Intellectual Property**"); provided that Seller is not required to list items of Intellectual Property which are not registered or the subject of an application for registration. Except as specifically identified and described in the Schedule 4.3(a), the Seller solely and exclusively owns the entire right, title and interest to all Compound Intellectual Property free and clear of all liens or encumbrances.

(b) Schedule 4.3(b) contains a complete and accurate list of all licenses, sublicenses and other Contracts pursuant to which Seller is authorized to use, practice any rights under, or grant sublicenses with respect to, any Intellectual Property owned by a Third Party which is incorporated into any Compound Intellectual Property ("**In-Bound Licenses**") and, with respect to each In-Bound License, whether the In-Bound License is exclusive or non-exclusive.

(c) Schedule 4.3(c) contains a complete and accurate list of all currently in-force licenses, sublicenses and other contracts pursuant to which Seller authorizes a third party to use, practice any rights under, or grant sublicenses with respect to, Compound Intellectual Property or pursuant to which Seller grants rights to use or practice any rights under any Intellectual Property owned by a Third Party with respect to any Compound Intellectual Property and (“**Out-Bound Licenses**”), with respect to each Out-Bound License, whether the Out-Bound License is exclusive or non-exclusive.

(d) All registration, maintenance and renewal fees related to Compound Intellectual Property and any other certifications, filings or registrations related to registered Compound Intellectual Property that are owned by Seller (“**Compound Registered Items**”) that are currently due, or due within [†] ([†]) [†] of the Closing Date, have been paid and all documents and certificates related to such Compound Registered Items have been filed with the relevant Governmental Entity or other authorities in the United States or foreign jurisdictions, as the case may be, for the purposes of maintaining such Compound Registered Items and perfecting Seller’s ownership interests therein. [†].

(e) To the Knowledge of the Seller, [†]. Schedule 4.3(e) lists the status of any Actions (for the avoidance of doubt, excluding office actions in connection with the prosecution of applications relating to the Compound Registered Items) currently pending before the United States Patent and Trademark Office or any other Governmental Entity anywhere in the world related to any of the Compound Registered Items, including the due date for any outstanding response by Seller in such Actions. [†].

(f) Except as specifically identified and described in Schedule 4.3(f), neither this Agreement nor the transactions contemplated by this Agreement, including the assignment to Acquiror by operation of Law or otherwise (if any) of any contracts or agreements to which Seller is a party, will result in (i) either the Acquiror’s being bound by, or subject to, any non-compete or other material restriction on the Compound contained in an Out-Bound License or an In-Bound License, or (ii) either the Acquiror’s being obligated, under an Out-Bound License or an In-Bound License, to pay any [†] to any Third Party in excess of those that the Seller would have been required to pay had the transactions contemplated by this Agreement not occurred.

4.4 Litigation.

(a) There is no action, suit or proceeding, claim, arbitration, litigation or investigation (each, an “**Action**”) pending or, to the Knowledge of the Seller, threatened (i) against the Seller relating to the Compound, or (ii) that challenges or seeks to prevent, enjoin or otherwise delay the transactions contemplated by this Agreement. To the Knowledge of the Seller, [†].

(b) There is no unsatisfied judgment, penalty, award, decree, injunction, rule or order of any Governmental Entity, court or arbitrator, outstanding or pending against the Seller with respect to the Compound.

ARTICLE 5 RIGHT OF FIRST REFUSAL AND FIRST OFFER

5.1 Third Party Offer. As soon as practicable, and in any event within [†] ([†]) [†] after Acquiror receives an offer to purchase the Compound for continued development or an offer to commercialize the Compound (a “**Third Party Offer**”) from any Third Party (each such Third Party, an “**Offeror**”), Acquiror shall (a) provide Seller with written notice setting forth the material terms of the Third Party Offer (a “**ROFR Notice**”), (b) not enter into a confidentiality or non-disclosure agreement that would prevent Acquiror from making such disclosures to Seller, and (c) not agree to an [†] agreement without first complying with this Article 5.

5.2 ROFR Procedure.

(a) Following receipt of any ROFR Notice, Seller shall have [†] ([†]) [†] from the date of receipt of such ROFR Notice to notify Acquiror in writing that it would like to enter into negotiations with Acquiror to commercialize the Compound (each, a “**ROFR Negotiation Notice**”). If Seller fails to provide a ROFR Negotiation Notice within such [†] ([†]) [†] time period, Acquiror shall be free to accept any Third Party Offer (including, without limitation, the Third Party Offer subject to the ROFR Notice) and close such a transaction within [†] ([†]) [†] of the end of such [†] ([†]) [†] time period, and Acquiror shall not be required to comply with Section 5.1 with respect to any other Third Party Offer during such [†] ([†]) [†] period.

(b) If Seller provides a ROFR Negotiation Notice to Acquiror, Acquiror shall engage in good faith discussions with Seller for a period of at least [†] ([†]) [†] or such other period as Seller and Acquiror may agree upon (the “**ROFR Negotiation Period**”). During the ROFR Negotiation Period, Acquiror and Seller agree to undertake good-faith discussions regarding Seller’s interest in purchasing the Compound for further development and/or commercializing the Compound on terms at least as favorable to Acquiror as those contained in the ROFR Notice, and the Parties shall negotiate in good faith to finalize an agreement or letter of intent that is mutually agreeable with respect to the terms of such transaction. If Acquiror and Seller do not enter into a written agreement or letter of intent regarding the purchase or commercialization of the Compound during the ROFR Negotiation Period, Acquiror shall be free to accept any Third Party Offer (including, without limitation, the Third Party Offer subject to the ROFR Notice) and close such a transaction within ([†]) [†] of the end the ROFR Negotiation Period on terms that are, for the Acquiror, equal or superior to the terms set forth in the ROFR Notice, and Acquiror shall not be required to comply with Section 5.1 with respect to any other Third Party Offer during such [†] ([†]) [†] period.

(c) If Acquiror does not enter into an agreement with a Third Party within the [†] ([†]) [†] period set forth in Sections 5.2(a) or (b), then Acquiror shall again comply with the provisions of this Article 5 with respect to any Third Party Offer received after the end of such [†] ([†]) [†] period.

5.3 Right of First Offer. If Acquiror desires to, on its own behalf or in conjunction with any Third Party, directly or indirectly, in any capacity whatsoever commercialize the Compound including any sale of the commercial rights to the Compound, Acquiror shall first provide Seller the opportunity to commercialize the Compound by providing Seller with written notice of such desire (the “**ROFO Notice**”) and agrees that it will not agree to [†] agreement with any Third Party without first complying with this Article 5.

5.4 ROFO Procedure.

(a) Following receipt of any ROFO Notice, Seller shall have [†] ([†]) [†] from the date of receipt of such ROFO Notice to notify Acquiror in writing that it would like to enter into negotiations with Acquiror to commercialize the Compound (each, a “**ROFO Negotiation Notice**”). If Seller fails to provide a ROFO Negotiation Notice within such [†] ([†]) [†] time period, Acquiror shall be free to commercialize the Compound independently and shall also be free to enter into a definitive agreement with any Third Party to sell or otherwise grant rights to such Third Party with respect to the commercialization of the Compound, .

(b) If Seller provides a ROFO Negotiation Notice to Acquiror, Acquiror shall engage in good faith discussions with Seller for a period of at least [†] ([†]) [†] or such other period as Seller and Acquiror may agree upon (the “**ROFO Negotiation Period**”). During the ROFO Negotiation Period, Acquiror and Seller agree to undertake good-faith discussions regarding Seller’s interest in commercializing the Compound, and the Parties shall negotiate in good faith to finalize an agreement or letter of intent that is mutually agreeable with respect to the terms of such transaction. If Acquiror and Seller do not enter into a written agreement or letter of intent regarding the commercialization of the Compound during the ROFO Negotiation Period or agree to extend the ROFO Negotiation Period, the negotiation period automatically shall be extended for [†] ([†]) [†] in which time period Seller may, if it wishes to do so, provide Acquiror with a written offer with respect to the commercialization of the Compound (the “**Seller Offer**”). Thereafter, Acquiror shall be free to commercialize the Compound independently and shall also be free to enter into a definitive agreement with any Third Party to sell or otherwise grant rights to such Third Party with respect to the Compound, but only on terms with a Third Party as a whole that are superior to those of the Seller Offer. If Acquiror does not take any substantive actions towards the commercialization of the Compound independently or enter into an agreement with a Third Party to sell or otherwise grant rights to such Third Party with respect to the Compound in any manner, within [†] ([†]) [†] after the end of the ROFO Negotiation Period, then Acquiror shall again comply with the provisions of this Article 5 before taking such an action thereafter.

5.5 Exclusions and Termination. For the avoidance of doubt, nothing in this Article 5 shall restrict or limit the Acquiror’s ability to sell or issue equity or debt securities or otherwise incur indebtedness or encumber its assets, in each case for bona fide financing purposes, and the Seller’s rights hereunder shall not apply to any such transaction. This Article 5 shall terminate upon the occurrence of (1) the closing of any transaction or series of related transactions (including without limitation, any reorganization, merger or consolidation) which will result in the Acquiror’s stockholders immediately prior to such transaction(s) not holding (by virtue of such shares or securities issued solely with respect thereto) at least a majority of the voting power of the surviving, resulting or continuing entity, or (2) the closing of the sale, license, lease or other disposition of all or substantially all of the assets of the Acquiror.

ARTICLE 6 REPRESENTATIONS AND WARRANTIES OF ACQUIROR

Acquiror represents and warrants to Seller as follows:

6.1 **Organization and Good Standing.** Acquiror is a corporation duly organized, validly existing and in good standing under the Laws of the jurisdiction of its incorporation, has all requisite power to carry on its business as now being conducted, and is duly qualified to do business and is in good standing in which it conducts any business.

6.2 **Authority and Enforceability.** Acquiror has the requisite power and authority to enter into each of the Transaction Documents, to perform its obligations under each of the Transaction Documents and to consummate the Transaction. The execution and delivery of the Transaction Documents by Acquiror and the consummation of the transactions contemplated thereby have been duly authorized by all necessary corporate action on the part of Acquiror. Each of the Transaction Documents has been duly executed and delivered by Acquiror and, assuming due authorization, execution and delivery by the Seller Party, constitute the valid and binding obligations of Acquiror, enforceable against each of them in accordance with its terms, except as such enforceability may be limited by (a) bankruptcy, insolvency, reorganization, moratorium or other similar Laws affecting or relating to creditors' rights generally, and (b) the availability of injunctive relief and other equitable remedies.

6.3 **Financial Capability.** Acquiror has, and at the Closing will have, sufficient internal funds (without giving effect to any unfunded financing regardless of whether any such financing is committed) available to pay the Base Purchase Price and any expenses incurred by Acquiror in connection with the transactions contemplated by this Agreement.

6.4 **Litigation.** There is no Action pending or, to the knowledge of Acquiror, threatened against Acquiror, that challenges or seeks to prevent, enjoin or otherwise delay the Transaction. To the knowledge of Acquiror, no event has occurred or circumstances exist that may give rise or serve as a basis for any such Action.

ARTICLE 7 COVENANTS OF THE SELLER

7.1 **Access to Information.** Subject to the terms of the Confidentiality Agreement by and between Acquiror and the Seller dated [†] (the "**Confidentiality, Agreement**"), and except as prohibited by applicable Law, Seller shall, and shall cause its Subsidiaries to, afford to Acquiror's officers, directors, employees, accountants, counsel, consultants, advisors and agents ("**Representatives**") reasonable access, during normal business hours and upon reasonable advance notice, to all of the assets and records, reports, contracts and other documents related to the Compound as the Acquiror and its Representatives may reasonably request, and shall permit them to consult with Seller's officers, employees, accountants, counsel and agents for the purpose of making such investigation of the acquired Compound as Acquiror shall desire to make.

7.2 Notification of Certain Matters. Prior to the Closing, Seller shall give prompt notice to Acquiror of any fact, event or circumstance known to it that (a) individually or taken together with all other facts, events and circumstances known to it, has had or would reasonably be expected to have, individually or in the aggregate, a Compound Material Adverse Effect, or (b) would cause or constitute a failure of any condition precedent to Acquiror's obligations set forth in this agreement. Seller shall give prompt notice to Acquiror of: (i) any notice or other communication from any Third Party alleging that the consent of such Third Party is or may be required in connection with the Transaction, or (ii) any written notice or other written communication received by the Seller from any Governmental Entity in connection with the Transaction. The delivery of any notice pursuant to this Section 7.2 shall not be considered an admission that any representation or warranty is untrue or that any covenant has been breached and shall not limit or otherwise affect any remedies available to Acquiror or prevent or cure any misrepresentations, breach of warranty or breach of covenant and disclosure by the Seller shall not be deemed to amend or supplement the schedules hereto or constitute an exception to any representation or warranty.

7.3 [†]. [†].

7.4 Actions Prior to Closing. Prior to Closing, Seller shall cause all registration, maintenance and renewal fees and any certifications, filings or registrations related to Compound Registered Items to be paid, prepared and/or filed, as the case may be, with the relevant Governmental Entity or other authorities in the United States or foreign jurisdictions, as the case may be, for the purposes of maintaining the Compound Registered Items and perfecting Seller's ownership interests therein. Prior to Closing, Seller shall take or cause to be taken at its expense all other [†] actions necessary to maintain the Purchased Assets. Without limiting the generality of the foregoing, prior to Closing, Seller shall not take any of the following actions in connection with the Purchased Assets: (1) sell, lease, license or otherwise dispose of, or agree to sell, lease, license or otherwise dispose of, any Purchased Asset; (2) enter into, cancel or modify any In-Bound License or Out-Bound License; or (3) grant or permit to exist any lien or encumbrance on any of the Purchased Assets.

7.5 Efforts and Actions to Cause Closing to Occur. Prior to the Closing, upon the terms and subject to the conditions of this Agreement, Acquiror and Seller shall use [†] to take, or cause to be taken, all actions, and to do, or cause to be done, and cooperate with each other in order to do, all things necessary, proper or advisable (subject to applicable Law) to consummate the transactions contemplated hereby as promptly as practicable, including the matters described in Article 9 hereof and the preparation and filing of all forms, registrations and notices required to be filed and the taking of such actions as are necessary to obtain any requisite consents of any Governmental Entity or other Person. In addition, no party hereto shall take any action that could reasonably be expected to materially delay the obtaining of, or result in not obtaining, any consent from any Governmental Entity or other Person required to be obtained prior to the Closing.

7.6 Confidentiality. Following the Closing, each party hereto shall, and shall cause its Affiliates and Representatives to, hold in strict confidence and not utilize in its respective business any information and documents concerning any other party hereto or any of its respective Affiliates (“**Confidential Information**”), including all confidential or proprietary documents or information regarding the Compound in the possession of Seller and its Affiliates even though such documents and information were first developed by, made known to, or obtained from, Seller and its Affiliates, except where disclosure may be necessary for any such party to enforce its rights under this Agreement or any Transaction Document or to comply with applicable Law. In the event a party is required to disclose Confidential Information to comply with any applicable Law, the party proposing to disclose such information shall give the original disclosing party with respect to whom such information is Confidential Information reasonable advance notice of such disclosure (to the extent not prohibited by applicable Law) and to cooperate with such disclosing party in seeking a protective order or other appropriate means for limiting the scope of the disclosure. Notwithstanding the foregoing, the following will not constitute “**Confidential Information**” for purposes of this Agreement: (a) other than confidential or proprietary documents and information regarding the Compound, (i) information that is independently developed by the receiving party or any Affiliate thereof without the use of the Confidential Information, and (ii) information that is obtained or was previously obtained by the receiving party or its Affiliates from a third party who is not known by the receiving party after due inquiry to be subject to obligations of confidentiality with respect thereto, and (b) information that is or becomes generally available to the public other than as the result of a disclosure by the receiving party or any Affiliate thereof or their respective agents or employees. Notwithstanding the foregoing, following the Closing, the foregoing restrictions in this Section 7.6 shall not apply to the use by Acquiror or its Affiliates and its or their successors, assigns and Representatives of any documents or information concerning the Compound or the Purchased Assets furnished or transferred by Seller or its Affiliates hereunder.

ARTICLE 8 OTHER COVENANTS

8.1 Public Announcements. None of the parties hereto shall issue any press release or make any public statement regarding the transactions contemplated hereby without the prior written consent of Acquiror (in the case of a press release or statement by any of the Seller) or the Seller (in the case of a press release or statement by Acquiror). Acquiror and Seller shall not be restricted from making any disclosure it reasonably determines is required by Law. Either party may make any disclosure consistent with disclosures previously made pursuant to this Section. Nothing in this Section 8.1 shall restrict or otherwise limit the Acquiror’s ability or right to issue any press release or make any public statement after Closing regarding its operations or the Purchased Assets, including, among other things, the development and commercialization of the Compound.

8.2 Expenses. Each of parties hereto shall bear its own costs and expenses in connection with this Agreement and the transactions contemplated hereby, including all legal, accounting, financial advisory, consulting and all other fees and expenses of third parties, whether or not the Transaction is consummated.

8.3 Further Assurances. Upon the terms and subject to the conditions hereof each of the parties hereto shall execute such documents and other instruments and take such further actions as may be reasonably required to carry out the provisions hereof and consummate the Transaction contemplated hereby (prior to, at or after the Closing). Each of the parties hereto shall use their [†] to consummate the Transaction as soon as practicable following the date hereof.

ARTICLE 9 CONDITIONS TO CLOSING

9.1 Conditions to Each Party's Obligation. The obligations of Acquiror and the Seller to consummate the Transaction are subject to the satisfaction on or prior to the Closing Date of the following conditions:

- (a) All Authorizations and Orders of, declarations and filings with, and notices to any Governmental Entity required to permit the consummation of the Transactions shall have been obtained or made and shall be in full force and effect.
- (b) No temporary restraining order, preliminary or permanent injunction or other order preventing the consummation of the Transaction shall be issued by any Governmental Entity of competent jurisdiction and shall be in effect. No Law shall have been enacted which makes the consummation of the Transaction illegal.

9.2 Conditions to Obligations of Acquiror. The obligations of Acquiror to effect the Transaction are subject to the satisfaction (or waiver by Acquiror in its sole discretion) of the following further conditions:

- (a) The representations and warranties of the Seller set forth in this Agreement shall have been true and correct at and as of the date hereof and shall be true and correct at and as of the Closing Date as if made at and as of the Closing Date.
- (b) There shall not have occurred since the date of this Agreement any event, occurrence or change that has had or would reasonably be expected to have, individually or in the aggregate, a Compound Material Adverse Effect.
- (c) No action, proceeding or litigation brought by any Governmental Entity of competent jurisdiction shall be pending or threatened before any court or other Governmental Entity seeking to (i) prevent consummation of the Transaction, (ii) affect adversely the right of Acquiror to control the Compound; or (iii) restrain or prohibit Acquiror's ownership of the Purchased Assets. No such Order shall be in effect.
- (d) Seller shall have delivered to Acquiror duly executed Transaction Documents.
- (e) Seller shall have delivered the items required by it pursuant to Section 3.2 hereof.

9.3 Conditions to Obligation of the Seller. The obligation of the Seller to effect the Transaction is subject to the satisfaction of the following further conditions (or waiver by the Seller Parties to which the condition relates):

(a) The representations and warranties of Acquiror set forth in this Agreement that are [†] shall have been true and correct at and as of the date hereof and shall be true and correct at and as of the Closing Date as if made at and as of the Closing Date, and the representations and warranties that are [†] shall have been true and correct in all [†] respects at and as of the date hereof and shall be true and correct in all [†] respects at and as of the Closing Date as if made at and as of the Closing Date, except to the extent that such representations and warranties refer specifically to an earlier date, in which case such representations and warranties shall have been true and correct as of such earlier date.

(b) Acquiror shall have performed in all [†] respects all obligations required to be performed by it under this Agreement at or prior to the Closing Date.

9.4 Frustration of Closing Conditions. None of the parties hereto may rely on the failure of any condition set forth in this Article 9 to be satisfied if such failure was caused by such party's failure to act in good faith or to use its [†] to cause the Closing to occur.

ARTICLE 10 INDEMNIFICATION

10.1 By the Seller. To the extent provided in this Article 10, following the Closing, the Seller, shall indemnify Acquiror, its successors and assigns, and its officers, directors, employees, stockholders and agents (each, an "**Indemnified Acquiror Party**") and hold each Indemnified Acquiror Party harmless from and against:

- (a) [†]:
 - (i) [†]
 - (ii) [†]
- (b) [†].

10.2 By Acquiror. From and after the Closing Date, to the extent provided in this Article 10, Acquiror shall indemnify the Seller, its successors and assigns, and its officers, directors, employees, stockholders and agents (each, an "**Indemnified Seller Party**") and hold each Indemnified Seller Party harmless from and against:

- (a) [†]:
 - (i) [†]
 - (ii) [†]
- (b) [†].

10.3 Limitation of Liability. EXCEPT [†], NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR ANY LOST PROFITS, LOST BUSINESS OR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, PUNITIVE, EXEMPLARY OR OTHER SPECIAL DAMAGES SUFFERED BY THE OTHER PARTY OR ITS AFFILIATES ARISING OUT OF OR RELATED TO THIS AGREEMENT FOR ALL CAUSES OF ACTION OF ANY KIND (INCLUDING TORT, CONTRACT, NEGLIGENCE, STRICT LIABILITY, INDEMNITY AND BREACH OF WARRANTY) EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, UNLESS SUCH DAMAGES ARE PAYABLE TO A THIRD PARTY IN CONNECTION WITH A CLAIM BY SUCH THIRD PARTY THAT IS INDEMNIFIABLE HEREUNDER.

10.4 Procedure for Claims. A Party that intends to claim indemnification under this Article 10 (the “**Indemnitee**”) shall promptly notify the other Party (the “**Indemnitor**”) in writing of the assertion or the commencement of any Action by a Third Party (a “**Third Party Claim**”) and will provide the Indemnitor such information with respect thereto that the Indemnitor may reasonably request. The Indemnitor shall be entitled to control and appoint lead counsel for such defense, in each case at its expense. If the Indemnitor shall assume the control of the defense of any Third Party Claim in accordance with the provisions, the Indemnitor shall obtain the prior consent of the Indemnitee (which shall not be unreasonably withheld) before entering into any settlement of such Third Party Claim. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim shall not relieve the Indemnitor of its obligations under this Article 10 unless the delay or failure is materially prejudicial to its ability to defend such action. The Indemnitee under this Section 10.4 shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Third Party Claim covered by this indemnification.

10.5 [†]. [†].

10.6 Survival. The Parties hereto agree that their respective representations, warranties, covenants and agreements contained in this Agreement shall survive the Closing for a period of [†].

ARTICLE 11 MISCELLANEOUS

11.1 Notices. Any notice, request, demand, waiver, consent, approval or other communication which is required or permitted hereunder shall be in writing and shall be deemed given: (a) on the date established by the sender as the date of actual personal delivery; (b) on the date delivered by a private courier as established by the sender by evidence obtained from the courier; (c) on the date sent by facsimile, with confirmation of transmission, if sent during normal business hours of the recipient, if not, then on the [†]; or (d) on the [†] after the date mailed, by certified or registered mail, return receipt requested, postage prepaid. Such communications, to be valid, must be addressed as follows:

If to Acquiror, to:

1st Order Pharmaceuticals
5511 NC Highway 902
Pittsboro, NC 27312
Attn: Chief Executive Officer
Facsimile: (919) 542-5421
Telephone: (919) 812-8119

With a copy to:

Wyrick Robbins Yates & Ponton LLP
4101 Lake Boone Trail, Suite 300
Raleigh, NC 27607
Attn: Thomas A. Allen
Facsimile: (919) 781-4865

If to Seller, to:

[†]

With a required copy to:

[†]

or to such other address or to the attention of such Person or Persons as the recipient party has specified by prior written notice to the sending party. If more than one method for sending notice as set forth above is used, the earliest notice date established as set forth above shall control.

11.2 Amendments and Waivers.

- (a) Any provision of this Agreement may be amended or waived if, and only if, such amendment or waiver is in writing and is signed, in the case of an amendment, by Acquiror and the Seller.
- (b) No failure or delay by any party in exercising any right or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege.
- (c) To the maximum extent permitted by Law, (i) no waiver that may be given by a party shall be applicable except in the specific instance for which it was given and (ii) no notice to or demand on one party shall be deemed to be a waiver of any obligation of such party or the right of the party giving such notice or demand to take further action without notice or demand.

11.3 Successors and Assigns. This Agreement may not be assigned by any party hereto without the prior written consent of the other parties; *provided*, that Acquiror may assign any of its rights and obligations under this Agreement to any Affiliate of Acquiror, so long as Acquiror shall remain liable for its obligations hereunder. Subject to the foregoing, all of the terms and provisions of this Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective executors, heirs, personal representatives, successors and assigns.

11.4 Governing Law; Venue. This Agreement and the exhibits and schedules hereto shall be governed by and interpreted and enforced in accordance with the Laws of [†], without giving effect to any choice of Law or conflict of Laws rules or provisions (whether of [†] or any other jurisdiction) that would cause the application of the Laws of any jurisdiction other than [†]. Any legal proceeding relating to this Agreement or the enforcement of any provision of this Agreement may be brought or otherwise commenced only in any state or federal court located in [†]. Each party to this Agreement: (i) irrevocably and unconditionally consents and submits to the exclusive jurisdiction and venue of the state and federal courts located in [†]; (ii) agrees that each state and federal court located in [†] shall be deemed to be a convenient forum; and (iii) agrees not to assert (by way of motion, as a defense or otherwise), in any such legal proceeding commenced in any state or federal court located in [†], any claim that such party is not subject personally to the jurisdiction of such court, that such legal proceeding has been brought in an inconvenient forum, that the venue of such legal proceeding is improper or that this Agreement or the subject matter of this Agreement may not be enforced in or by such court.

11.5 Counterparts. This Agreement may be executed in any number of counterparts, and any party hereto may execute any such counterpart, each of which when executed and delivered shall be deemed to be an original and all of which counterparts taken together shall constitute but one and the same instrument. This Agreement shall become effective when each party hereto shall have received a counterpart hereof signed by the other parties hereto. The parties agree that the delivery of this Agreement may be effected by means of an exchange of facsimile or other electronic signatures.

11.6 Third Party Beneficiaries. No provision of this Agreement is intended to confer upon any Person other than the parties hereto any rights or remedies hereunder, except that: (a) in the case of Article 10 hereof, the Indemnified Acquiror Parties or the Indemnified Seller Parties are intended third party beneficiaries of such sections and shall have the right to enforce such sections in their own names.

11.7 Entire Agreement. This Agreement and the documents, instruments and other agreements specifically referred to herein or delivered pursuant hereto set forth the entire understanding of the parties hereto with respect to the Transaction. All exhibits and schedules referred to herein are intended to be and hereby are specifically made a part of this Agreement. Any and all previous agreements and understandings between or among the parties regarding the subject matter hereof, whether written or oral, are superseded by this Agreement, other than the Confidentiality Agreement which shall continue in full force and effect in accordance with its terms except as terminated or modified in accordance with Section 3.2 hereof.

11.8 Captions. All captions contained in this Agreement are for convenience of reference only, do not form a part of this Agreement and shall not affect in any way the meaning or interpretation of this Agreement.

11.9 Severability. Any provision of this Agreement which is invalid or unenforceable in any jurisdiction shall be ineffective to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining provisions hereof, and any such invalidity or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction.

11.10 Specific Performance. Acquiror and Seller agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed by them in accordance with the terms hereof and that each party shall be entitled to specific performance of the terms hereof, in addition to any other remedy at Law or equity.

11.11 Waiver of Jury Trial. EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM (WHETHER BASED ON CONTRACT, TORT OR OTHERWISE) ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THE ACTIONS OF A PARTY HERETO IN THE NEGOTIATION, ADMINISTRATION, PERFORMANCE AND ENFORCEMENT OF THIS AGREEMENT.

11.12 Interpretation.

(a) The meaning assigned to each term defined herein shall be equally applicable to both the singular and the plural forms of such term and vice versa, and words denoting either gender shall include both genders as the context requires. Where a word or phrase is defined herein, each of its other grammatical forms shall have a corresponding meaning.

(b) The terms “hereof”, “herein” and “herewith” and words of similar import shall, unless otherwise stated, be construed to refer to this Agreement as a whole and not to any particular provision of this Agreement.

(c) When a reference is made in this Agreement to an Article, Section, paragraph, Exhibit or Schedule, such reference is to an Article, Section, paragraph, Exhibit or Schedule to this Agreement unless otherwise specified.

(d) References to “dollars” or “\$” are references to United States dollars.

(e) The word “include”, “includes”, and “including” when used in this Agreement shall be deemed to be followed by the words “without limitation”, unless otherwise specified.

(f) A reference to any party to this Agreement or any other agreement or document shall include such party’s predecessors, successors and permitted assigns.

(g) Reference to any Law means such Law as amended, modified, codified, replaced or reenacted, and all rules and regulations promulgated thereunder.

(h) The parties have participated jointly in the negotiation and drafting of this Agreement. Any rule of construction or interpretation otherwise requiring this Agreement to be construed or interpreted against any party by virtue of the authorship of this Agreement shall not apply to the construction and interpretation hereof.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

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[†] DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

IN WITNESS WHEREOF, the parties hereto, intending to be legally bound hereby, have caused this Asset Purchase Agreement to be executed by their duly authorized representatives as of the date first written above.

1st ORDER PHAMACEUTICALS, INC.

By: /s/ Christopher S. Crean

Name: Christopher S. Crean

Title: President & CSO

VALEANT PHARMACEUTICALS LUXEMBOURG
S.A.R.L

By: [†]

Name: [†]

Title: [†]

[†] DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

[†]	[†]	[†]	[†]	[†]	[†]
[†]	[†]	[†]	[†]	[†]	[†]
[†]	[†]	[†]		[†]	
[†]	[†]	[†]		[†]	
[†]	[†]	[†]		[†]	

[†] DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

Seller Schedule 4.3(b)

Section 1. In bound Licenses

[†]

[†] DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

Seller Schedule 4.3(c)

Section 1. Out-bound Licenses

[†]

[†] DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

Seller Schedule 4.3(e)

Section 1. Status of Actions with Applications pending in the USPTO and other Governmental Entity

Jones Day Reference	Country	Title	App. Date	App. No.	Pub Date	Pub No.	Status	Outstanding Actions
[†]	[†]	[†]	[†]	[†]	[†]	[†]	[†]	[†]
[†]	[†]	[†]	[†]	[†]	[†]		[†]	[†]
[†]	[†]	[†]	[†]	[†]			[†]	[†]
[†]	[†]	[†]	[†]	[†]	[†]	[†]	[†]	
[†]	[†]	[†]	[†]	[†]			[†]	
[†]	[†]	[†]	[†]	[†]			[†]	[†]
[†]	[†]	[†]	[†]	[†]			[†]	[†]
[†]	[†]	[†]	[†]	[†]			[†]	

[†]

Section 2. Scheduled Actions that are required to be taken by Seller within [†] of Closing Date with respect to Compound Registered Items

[†]

Section 3. Compound Intellectual Property that Seller has abandoned, cancelled, forfeited or relinquished or Seller has not taken any action nor failed to take any action during the [†] ([†]) [†] prior to the date of this Agreement.

Jones Day Reference	Country	Title	Application Date	Application No.	Pub Date	Pub No.	Issued Date	Patent No.	Status
[†]	[†]	[†]	[†]	[†]	[†]	[†]	[†]		
[†]	[†]	[†]	[†]	[†]	[†]	[†]	[†]		[†]
[†]	[†]	[†]	[†]	[†]	[†]	[†]			[†]
[†]	[†]	[†]	[†]	[†]					[†]

[†] DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

Seller Schedule 4.3(f)

Section 1. Material Restrictions; Third Party Payments

[†]

[†] DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

Exhibit B

Form of Payoff Letter

[†] DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

[DATE]

1st Order Pharmaceuticals Inc.

[Address]

[Address]

Attn: []

Re: Pay-Off Letter

Dear []:

Reference is made to the Loan Agreement dated as of [•] ([as the same may from time to time have been amended, restated, or otherwise modified,] the “**Loan Agreement**”), the Promissory Note dated as of as of [•] ([as the same may from time to time have been amended, restated, or otherwise modified,] the “**Note**”), and any related loan documents (together with the Loan Agreement and the Note, the “**Loan Documents**”), in each case by and among 1st Order Pharmaceuticals, Inc., a Delaware corporation (the “**Borrower**”) and [•] (the “**Lender[s]**”), and the loans contemplated thereby (the “**Loans**”). Capitalized terms used and not defined in this letter shall have the respective meanings given them in the Loan Agreement.

Borrower has entered into that certain Asset Purchase Agreement by and among Borrower and Xenon Pharmaceuticals Inc., a corporation continued under the federal laws of Canada (“**Xenon**”), dated [•] (the “**Asset Purchase Agreement**”). Pursuant to the terms of the Asset Purchase Agreement, Borrower has agreed to sell to Xenon, and Xenon has agreed to purchase from Borrower, all of Borrower’s right, title and interest in and to the Purchased Assets (as defined in the Asset Purchase Agreement).

Borrower has advised Lender that, in connection with the Asset Purchase Agreement, Xenon intends to repay all amounts due and owing by Borrower under the Loan Documents and has requested that Lender provide Borrower with appropriate pay-off amounts for the principal, interest, and other amounts owing by Borrower to Lender under the Loan Documents (such amounts, collectively, the “**Obligations**”). The pay-off amounts for Borrower as of April [•], 2017 (the “**Computation Date**”) under the Loan Documents are as follows (collectively, together with any additional interest accruing after the Computation Date that must be repaid by Borrower, the “**Pay-Off Amount**”):

Principal:	\$[]
Interest:	\$[]
Fees:	\$[]
Total Amount Owing:	\$[]

[†] DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

From and after the Computation Date and until 5:00 pm Pacific time on the date of the Lender[‘s] receipt of the Pay-Off Amount, interest shall continue to accrue on the unpaid principal amount at the rate set forth in the Loan Documents. The per diem accrual of interest on the unpaid principal amount is \$[]. Upon request of Borrower, the Lender[s] shall provide Borrower with a revised figure for the amount of interest to be paid as a part of the Pay-Off Amount. The foregoing accrued interest amount assumes no change in the operative interest rates after the date hereof.

The Borrower shall pay or cause to be paid to the Lender[s] the Pay-Off Amount, at the Borrower’s cost and expense, by federal funds wire transfer the Pay-Off Amount (in immediately available funds) as follows (the “**Release Condition**”):

[LENDER’S NAME AND LENDER’S ADDRESS]

ABA No.: [ABA NUMBER]

For credit to: 1ST ORDER PHARMACEUTICALS, INC.

Re: []

Account No.: [ACCOUNT NUMBER]

Upon the occurrence of the Release Condition, (a) the Loans shall be paid in full and all other indebtedness of the Borrower under the Loan Documents shall be satisfied in full, (b) any commitments under the Loan Documents shall be terminated, and the Lender[s] shall have no further obligation to make any Loans or any other obligations, duties or responsibilities in connection with the Loan Documents, (c) all the security interests, mortgages, liens, pledges, charges and other encumbrances in favor of the Lender[s] to secure the Obligations shall be automatically released with no further action on the Borrower’s part, (d) all guaranties supporting the Loan Documents shall be released with no further action on the Borrower’s part, (e) all of the other respective obligations of each of the Borrower, or any of their subsidiaries or affiliates under the Loan Documents shall be released with no further action on the Borrower’s part and (f) the Loan Documents shall be terminated, canceled and of no further force and effect; provided that, the Borrower shall remain liable for any other provisions of the Loan Documents which by their terms survive the payment of the Loans.

In consideration of the payment in full of the Obligations and upon the occurrence of the Release Condition, the Lender[s], hereby agree[s] to promptly deliver to the Borrower, in each case at the expense of the Borrower, the following: (a) [all certificates delivered to the Lender[s] representing stock pledged by the Borrower in favor of the Lender[s] under the Loan Documents together with related stock powers delivered to the Lender[s],] (b) all chattel paper and other instruments or documents delivered to the Lender pursuant to the Loan Documents, (c) Uniform Commercial Code releases and/or terminations and other terminations and intellectual property releases in form acceptable for recording, terminating all of the Lenders’ liens and security interests in the collateral, (d) releases, discharges and satisfactions of all mortgages in favor of the Lender[s] in form and substance satisfactory to the Borrower, (e) all other collateral in the actual physical possession of the Lender[s] and (f) reassignments of all assignments in favor of the Lender[s] in form and substance satisfactory to the Borrower.

The Lender[s] agree[s] that the occurrence of the Release Condition constitutes payment in full of all of the liabilities and obligations of the Borrower and its respective affiliates, directors, managers, officers, members, stockholders, successors and assigns (collectively, the “**Released Parties**”) to the Lender[s], including any and all fees, expenses, reimbursements and other liabilities and obligations on behalf of Borrower or any of its affiliates on or prior to the date hereof. The Lender[s] further waive[s] any notice requirements under the Loan Documents, including Section 5(e) of the Loan Agreement.

Upon the occurrence of the Release Condition the Lender[s] and any affiliates of the Lender[s] knowingly and voluntarily waive[s], remise[s], release[s] and forever discharge[s] each of the Released Parties from any and all liabilities and obligations in respect of the Loans and the Loan Documents, whether known or unknown and whether absolute or contingent.

Upon the occurrence of the Release Condition, the Lender[s] agree[s] to procure, deliver or execute and deliver to the Borrower, from time to time, all further releases, termination statements, certificates, instruments and documents, each in form and substance satisfactory to the Borrower, and take any other actions, as may be reasonably requested by the Borrower or which are required to evidence the consummation of the payoff contemplated hereby, in each case at the expense of the Borrower (including attorneys' fees and expenses).

Upon the occurrence of the Release Condition, the Lender[s] hereby authorize[s] the Borrower, or any other party on behalf of the Borrower, to prepare and file termination statements, intellectual property releases and other instruments and documents evidencing the consummation of the payoff contemplated hereby and the aforementioned termination and release.

This letter may be executed in multiple counterparts and by facsimile signature, each of which shall be deemed an original and all of which together shall constitute one instrument.

[Signature page follows]

Very truly yours,

[LENDER NAME]

By

Name:

Title:

ACKNOWLEDGED AND CONSENTED TO BY:

1ST ORDER PHARMACEUTICALS, INC.

By

Name:

Title:

Signature page to Pay-Off Letter

[†] DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

[+]
[+]
[+]
[+]

ARCHIVED RAW DATA FILES

IOP Box	Study Number	Report Title	Format
IOP-1	[+]	[+]	[+]
IOP-2	[+]	[+]	[+]
IOP-3	[+]	[+]	[+]
IOP-4	[+]	[+]	[+]
IOP-5	[+]	[+]	[+]
IOP-6	[+]	[+]	[+]
IOP-7	[+]	[+]	[+]
IOP-8	[+]	[+]	[+]
IOP-9	[+]	[+]	[+]
IOP-10	[+]	[+]	[+]
IOP-11	[+]	[+]	[+]

[+] DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

Schedule 4 - Seller Disclosure Schedule

This Seller Disclosure Schedule is delivered pursuant to that certain Asset Purchase Agreement (the “**Agreement**”), dated as of April 25, 2017, by and between 1st Order Pharmaceuticals, Inc., a Delaware corporation and Xenon Pharmaceuticals Inc., a corporation continued under the federal laws of Canada. All capitalized terms used and not otherwise defined herein have the meanings ascribed thereto in the Agreement.

Any disclosure hereunder shall not be deemed to be an admission or acknowledgment by the Seller that such information is material to, or outside the ordinary course of business of, the Seller. Nothing herein constitutes an admission of liability. Nothing in this Seller Disclosure Schedule is intended to broaden the scope of any representation or warranty contained in the Agreement or to create any covenant. Any disclosure made in one section of this Disclosure Schedule is deemed to be a disclosure in each other section of this Disclosure Schedule, whether or not specifically mentioned in such other section, to the extent that it is reasonably apparent from the disclosure that such disclosure is applicable to such other section.

The sections of the Seller Disclosure Schedule are numbered to correspond to the applicable section of the Agreement. The Seller Disclosure Schedules set forth, among other things, items the disclosure of which is necessary or appropriate either in response to an express disclosure requirement contained in a provision of the Agreement or as an exception to one or more representations or warranties contained in the corresponding section of the Agreement.

Schedule 4.3 - No Conflict; Authorizations.

None.

4.6 - Non-cGMP API

The following APIs were not manufactured in accordance with GMPs:

Lot/Batch	Quantity	Sent to Ricerca	Last Storage	Details
[†]	[†]	[†]	[†]	[†]
[†]	[†]	[†]	[†]	[†]
[†]	[†]	[†]	[†]	[†]
[†]	[†]	[†]	[†]	[†]
[†]	[†]	[†]	[†]	[†]
[†]	[†]	[†]	[†]	[†]
[†]	[†]	[†]	[†]	[†]
[†]	[†]	[†]	[†]	[†]
[†]	[†]	[†]	[†]	[†]
[†]	[†]	[†]	[†]	[†]
[†]	[†]	[†]	[†]	[†]
[†]	[†]	[†]	[†]	[†]
[†]	[†]	[†]	[†]	[†]
[†]	[†]	[†]	[†]	[†]
[†]	[†]	[†]	[†]	[†]
[†]	[†]	[†]	[†]	[†]

[†] DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

4.7(j) - Inbound Licenses

[†].

4.7(k) - Outbound Licenses

[†]

4.7(l) - Restrictions/Royalties on Acquiror

[†].

4.7(p) - Services to Governmental Entities

[†]

4.8 - Seller Contracts

4.8(a):

[†]

[†] DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

CERTIFICATIONS

I, Simon Pimstone, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Xenon Pharmaceuticals Inc.;
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(s) 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(s) 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 3, 2017

By: _____
/s/ Simon Pimstone
Simon Pimstone
President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATIONS

I, Ian Mortimer, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Xenon Pharmaceuticals Inc.;
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(s) 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(s) 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 3, 2017

By: _____
/s/ Ian Mortimer
Ian Mortimer
Chief Financial Officer and Chief Operating Officer
(Principal Financial and Accounting Officer)

**XENON PHARMACEUTICALS INC.
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 of Xenon Pharmaceuticals Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Simon Pimstone, President and Chief Executive Officer (*Principal Executive Officer*) of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

Date: August 3, 2017

By: _____
/s/ Simon Pimstone
Simon Pimstone
President and Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

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

**XENON PHARMACEUTICALS INC.
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 of Xenon Pharmaceuticals Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ian Mortimer, Chief Financial Officer and Chief Operating Officer (*Principal Financial and Accounting Officer*) of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

Date: August 3, 2017

By: _____
/s/ Ian Mortimer
Ian Mortimer
Chief Financial Officer and Chief Operating Officer
(Principal Financial and Accounting Officer)

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

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

