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, 2019

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: 001-35935

PORTOLA PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**20-0216859**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
270 E. Grand Avenue **South San Francisco, California**	**94080**
(Address of Principal Executive Offices)	**(Zip Code)**

(650) 246-7000
(Registrant's Telephone Number, Including Area Code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	PTLA	The Nasdaq Global Select Market

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

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

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

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

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

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

As of August 1, 2019, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 68,323,733.

PORTOLA PHARMACEUTICALS, INC.

FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2019

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

PORTOLA PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(Unaudited)

(In thousands, except per share data)

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 185,385	$ 138,951
Short-term investments	88,553	178,013
Restricted cash	2,280	1,062
Trade and other receivables, net	13,955	5,849
Unbilled - collaboration and license revenue	4,795	9,880
Inventories	1,547	7,873
Prepaid and other current assets	9,408	11,699
Total current assets	305,923	353,327
Property and equipment, net	4,769	5,236
Intangible assets	3,844	7,279
Operating lease right-of-use asset	12,316	—
Inventories, noncurrent portion	31,608	9,645
Prepaid and other long-term assets	8,037	10,932
Total assets	$ 366,497	$ 386,419
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 11,832	$ 13,215
Accrued research and development	18,399	19,831
Accrued and other liabilities	33,242	22,310
Deferred revenue, current portion	1,267	1,847
Current portion of notes payable and long-term royalty-based debt	19,567	11,802
Total current liabilities	84,307	69,005
Notes payable, less current portion	44,664	48,298
Long term royalty-based debt, less current portion	157,434	155,256
Long term debt	57,061	—
Long term obligation to collaborator, less current portion	5,833	6,881
Deferred revenue, long-term	4,415	4,488
Long-term portion of lease liability	10,204	—
Other long-term liabilities	1,985	11,924
Total liabilities	365,903	295,852
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value, 150,000 shares authorized at June 30, 2019 and December 31, 2018; 68,235 shares and 66,618 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	70	68
Additional paid-in capital	1,670,627	1,614,320
Accumulated deficit	(1,670,064)	(1,525,704)
Accumulated other comprehensive loss	(39)	(283)
Total Portola stockholders' equity	594	88,401
Noncontrolling interest	-	2,166
Total stockholders' equity	594	90,567
Total liabilities and stockholders' equity	$ 366,497	$ 386,419

See accompanying notes to the unaudited condensed consolidated financial statements.

PORTOLA PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations

(Unaudited)

(In thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues:				
Product revenue, net	$ 27,164	$ 2,265	$ 47,526	$ 2,871
Collaboration and license revenue	1,260	1,746	3,067	7,784
Total revenues	28,424	4,011	50,593	10,655
Operating expenses:				
Cost of sales	4,991	1,052	12,141	1,388
Research and development	33,538	66,440	69,122	126,507
Selling, general and administrative	53,855	40,214	106,889	71,755
Total operating expenses	92,384	107,706	188,152	199,650
Loss from operations	(63,960)	(103,695)	(137,559)	(188,995)
Interest and other income, net	4,021	1,828	6,005	5,199
Interest expense	(8,538)	(4,104)	(15,019)	(6,685)
Net loss	(68,477)	(105,971)	(146,573)	(190,481)
Net (income) loss attributable to noncontrolling interest	2,273	(223)	2,213	109
Net loss attributable to Portola	$ (66,204)	$ (106,194)	$ (144,360)	$ (190,372)
Net loss per share attributable to Portola common stockholders:				
Basic and diluted	$ (0.97)	$ (1.61)	$ (2.14)	$ (2.90)
Shares used to compute net loss per share attributable to Portola common stockholders:				
Basic and diluted	68,128,238	65,884,767	67,602,126	65,698,391

See accompanying notes to the unaudited condensed consolidated financial statements.

PORTOLA PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Comprehensive Loss

(Unaudited)

(In thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Net loss	$ (68,477)	$ (105,971)	$ (146,573)	$ (190,481)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities, net of tax	83	127	244	(265)
Foreign currency translation adjustment	(42)	-	(42)	-
Comprehensive loss	(68,436)	(105,844)	(146,371)	(190,746)
Comprehensive (income) loss attributable to noncontrolling interest	2,273	(223)	2,213	109
Total comprehensive loss attributable to Portola	$ (66,163)	$ (106,067)	$ (144,158)	$ (190,637)

See accompanying notes to the unaudited condensed consolidated financial statements.

PORTOLA PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Stockholders' Equity

(Unaudited)

(In thousands)

	Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Noncontrolling	Total Stockholders'
	Shares	Amount	Capital	Deficit	Income (Loss)	Interest	Equity
Balance at December 31, 2018	66,618	$ 68	$ 1,614,320	$ (1,525,704)	$ (283)	$ 2,166	$ 90,567
Issuance of common stock pursuant to equity award plans	1,359	2	25,660	-	-	-	25,662
Stock-based compensation expense	-	-	12,312	-	-	-	12,312
Other comprehensive income	-	-	-	-	203	-	203
Net income (loss)	-	-	-	(78,156)	-	60	(78,096)
Change in noncontrolling interest	-	-	-	-	-	2	2
Balance at March 31, 2019	67,977	$ 70	$ 1,652,292	$ (1,603,860)	$ (80)	$ 2,228	$ 50,650
Issuance of common stock pursuant to equity award plans	258	–	5,966	–	–	–	5,966
Stock-based compensation expense	–	–	12,369	–	–	–	12,369
Other comprehensive income	–	–	–	–	83	–	83
Net loss	–	–	–	(66,204)	–	(2,273)	(68,477)
Change in noncontrolling interest	–	–	–	–	–	45	45
Foreign currency translation adjustment	–	–	–	–	(42)	–	(42)
Balance at June 30, 2019	68,235	$ 70	$ 1,670,627	$ (1,670,064)	$ (39)	$ —	$ 594

	Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Noncontrolling	Total Stockholders'
	Shares	Amount	Capital	Deficit	Income (Loss)	Interest	Equity
Balance at December 31, 2017	65,297	$ 66	$ 1,551,728	$ (1,204,519)	$ (409)	$ 2,627	$ 349,493
Adjustment to accumulated deficit due to adoption of ASC 606	–	–	–	29,037	–	–	29,037
Issuance of common stock pursuant to equity award plans	514	1	5,678	–	–	–	5,679
Stock-based compensation expense	–	–	10,980	–	–	–	10,980
Other comprehensive loss	–	–	–	–	(392)	–	(392)
Net loss	–	–	–	(84,178)	–	(332)	(84,510)
Change in noncontrolling interest	–	–	–	–	–	(119)	(119)
Balance at March 31, 2018	65,811	$ 67	$ 1,568,386	$ (1,259,660)	$ (801)	$ 2,176	$ 310,168
Issuance of common stock pursuant to equity award plans	143	—	2,543	—	—	—	2,543
Stock-based compensation expense	—	—	13,214	—	—	—	13,214
Other comprehensive income	—	—	—	—	127	—	127
Net loss	—	—	—	(106,194)	—	223	(105,971)
Change in noncontrolling interest	—	—	—		—	(20)	(20)
Balance at June 30, 2018	65,954	$ 67	$ 1,584,143	$ (1,365,854)	$ (674)	$ 2,379	$ 220,061

See accompanying notes to the unaudited condensed consolidated financial statements.

PORTOLA PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(In thousands)

	Six Months Ended June 30,	
	2019	**2018**
Operating activities		
Net loss	$ (146,573)	$ (190,481)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	1,557	1,526
Amortization of right-of-use asset	1,081	—
Accretion of discount on investment securities	(634)	(1,044)
Non-cash interest expense	15,019	6,685
Stock-based compensation expense, net of capitalized labor	30,147	24,194
Remeasurement gain on embedded derivatives liabilities	(2,902)	(1,569)
Provision for excess and obsolete inventories	3,820	—
Loss on impairment of intangibles	3,151	—
Others	67	—
Changes in operating assets and liabilities:		
Inventories	2,864	(5,983)
Trade and other receivables, net	(8,106)	3,035
Unbilled - collaboration and license revenue	5,085	203
Prepaid expenses and other current assets	2,304	(18,932)
Inventories, noncurrent portion	(21,963)	—
Prepaid and other long-term assets	2,897	9,595
Accounts payable	(3,307)	(2,993)
Accrued research and development	(1,432)	(5,958)
Accrued and other liabilities	4,833	(610)
Deferred revenue	(653)	2,499
Notes payable, long term royalty-based debt and long-term obligation to collaborator	(4,955)	—
Other long-term liabilities	—	(476)
Net cash used in operating activities	(117,700)	(180,309)
Investing activities		
Capital expenditures, net	(791)	(1,263)
Purchases of investments	(76,778)	(166,944)
Proceeds from maturities of investments	167,158	236,775
Net cash provided by investing activities	89,589	68,568
Financing activities		
Proceeds from debt issuance, net	59,203	95,000
Proceeds from issuance of common stock pursuant to equity award plans	16,603	8,222
Other	—	(140)
Net cash provided by financing activities	75,806	103,082
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(43)	—
Net (decrease) increase in cash, cash equivalents and restricted cash	47,652	(8,659)
Cash, cash equivalents and restricted cash at beginning of period	140,013	181,741
Cash, cash equivalents and restricted cash at end of period	$ 187,665	$ 173,082

See accompanying notes to the unaudited condensed consolidated financial statements.

1. Organization

Portola Pharmaceuticals, Inc.® (the "Company" or "we" or "our" or "us") is a biopharmaceutical company focused on the development and commercialization of novel therapeutics in the areas of thrombosis, other hematologic diseases and inflammation for patients who currently have limited or no approved treatment options. We were incorporated in September 2003 in Delaware. We have operations in the United States and in select countries in Europe, with headquarters in South San Francisco, California. We operate in one segment.

We refer to our two approved drugs in this report as Andexxa® and Bevyxxa®. If approved outside of the United States, each drug may be marketed under different brand names. For example, andexanet alfa received conditional approval under the brand name Ondexxya® by the European Commission ("EC") on April 26, 2019. In addition, an international nonproprietary name ("INN") has been designated for each drug. Our previous INN for Andexxa was andexanet alfa; however, in the United States this INN has been replaced with "coagulation factor Xa (recombinant), inactivated-zhzo." For the European Union ("EU") and other parts of the world, andexanet alfa could remain the INN for Andexxa. Our use of Andexxa or Bevyxxa in this document in the context of continued development activities for which we have not yet received regulatory approval should not be read to imply that we have received regulatory approval for any indication or in any jurisdiction not reflected in our product labels.

2. Summary of Significant Accounting Policies

Consolidation and Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include the amounts of Portola, its wholly-owned subsidiaries and a development partner that is a variable interest entity (a "VIE") for which Portola is deemed, under applicable accounting guidance, to be the primary beneficiary. The unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"), and follow the requirements of the Securities and Exchange Commission ("SEC") for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP has been condensed or omitted. These condensed consolidated financial statements have been prepared on the same basis as our annual consolidated financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments that are necessary for a fair statement of our financial information. The accompanying unaudited condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2018 included in our Annual Report on Form 10-K filed on March 1, 2019 with the SEC.

The results of operations for the three and six months ended June 30, 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2019 or for any other interim period or for any other future year. The condensed consolidated balance sheet as of December 31, 2018 has been derived from the audited consolidated financial statements at that date but does not include all of the information required by U.S. GAAP for complete financial statements.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent liabilities and the reported amounts of revenues and expenses in these condensed consolidated financial statements and the accompanying notes. On an ongoing basis, we evaluate our significant accounting policies and estimates. Management bases its estimates on historical experience and on various other market-specific and relevant assumptions that management believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates.

Cash as Reported in Condensed Consolidated Statements of Cash Flows

Cash as reported in these condensed consolidated statements of cash flows includes the aggregate amounts of cash and cash equivalents and restricted cash. As of June 30, 2019, restricted cash represents cash restricted for royalty payments to HealthCare Royalty Partners and its Affiliates ("HCR"). Cash as reported in these condensed consolidated statements of cash flows consists of the following (in thousands):

	June 30, 2019	December 31, 2018	June 30, 2018	December 31, 2017
Cash and cash equivalents	$ 185,385	$ 138,951	$ 173,052	$ 181,568
Restricted cash (SRX Cardio)	—	30	30	173
Restricted cash for royalty payments to HealthCare Royalty Partners and its affiliates ("HCR")	2,280	1,032	—	—
Total cash balance in condensed consolidated statements of cash flows	$ 187,665	$ 140,013	$ 173,082	$ 181,741

Customer Concentration

During the three and six months ended June 30, 2019, we had four Andexxa specialty distributor customers who each accounted for 10% or more of total net revenues. During the three and six months ended June 30, 2019, we had no collaboration revenue customers who accounted for more than 10% of total net revenues.

During the three and six months ended June 30, 2018, we had no Andexxa specialty distributor customers who accounted for 10% or more of total net revenues. During the three and six months ended June 30, 2018, we had one and two collaboration revenue customers, respectively, who accounted for more than 10% of total revenues.

Recent Accounting Pronouncements Adopted

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases* (Topic 842), which amends the existing accounting standards for leases. The new standard requires lessees to record a right-of-use ("ROU") asset and a corresponding lease liability on the balance sheet (with the exception of short-term leases). This new standard is effective for annual reporting periods beginning after December 15, 2018, and interim reporting periods within those annual reporting periods, with early adoption permitted. We adopted this new standard effective January 1, 2019 using the optional transition method, which allows us to recognize a cumulative-effect adjustment to the opening balance of accumulated deficit at the date of adoption and apply the new disclosure requirements beginning in the period of adoption. Our adoption of the standard added approximately $2.1 million in ROU assets and $3.3 million in lease liabilities to our condensed consolidated balance sheet upon adoption and did not significantly impact financial results. In addition, our adoption of the standard had no cumulative impact on the accumulated deficit to our condensed consolidated balance sheet as of the adoption date.

The new standard provides a number of optional practical expedients and we elected the following:

- Transition Elections. We elected the package of practical expedients that permits us to not reassess under the new standard our prior conclusions about lease identification, lease classification, and initial direct costs. We also elected the practical expedient to not separate lease and non-lease components for facility lease classes of underlying assets to new or modified leases beginning on or after the adoption date. That is, we will account for each separate lease component of a contract and its associated non-lease components as a single lease component.

- Ongoing Accounting Policy Elections. We elected the short-term lease recognition exemption whereby ROU assets and lease liabilities will not be recognized for leasing arrangements with terms less than one year.

In June 2018, the FASB issued ASU No. 2018-07, *Stock-based Compensation: Improvements to Nonemployee Share-based Payment Accounting*, which amends the existing accounting standards for share-based payments to nonemployees. This ASU aligns much of the guidance on measuring and classifying nonemployee awards with that of awards to employees. Under the new guidance, the measurement of nonemployee equity awards is fixed on the grant date. We adopted this new standard effective January 1, 2019.

Adoption of this standard did not result in an adjustment to our beginning accumulated deficit upon the adoption, and did not significantly impact our financial results.

Recent Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326)*. This ASU implements an impairment model, known as the current expected credit loss model that is based on expected losses rather than incurred losses. For trade receivables, entities will be required to estimate lifetime expected credit losses. This could result in the earlier recognition of credit losses. For available-for-sale debt securities, entities will be required to recognize an allowance for credit losses rather than an other-than-temporary impairment that reduces the cost basis of the investment. Further, an entity will recognize any improvements in estimated credit losses immediately in earnings. Under the current guidance, a recovery of an impairment loss on an available-for-sale debt security is recognized prospectively as interest income. This ASU is effective for all interim and annual reporting periods beginning after December 15, 2019. Early adoption is permitted. We are in the process of assessing the impact of ASU 2016-13 on our condensed consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. This ASU aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. Accordingly, this ASU requires a customer in a hosting arrangement that is a service contract to follow the guidance in Subtopic 350-40 to determine which implementation costs to capitalize as an asset related to the service contract and which costs to expense. This ASU is effective for us for all interim and annual reporting periods beginning after December 15, 2019. Early adoption is permitted. We are in the process of assessing the impact of ASU 2018-15 on our condensed consolidated financial statements.

3. Revenue Recognition

Revenues are recognized when control of the promised goods or services is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services.

The following tables present our revenues, disaggregated by timing of transfer of goods or services for the three and six months ended June 30, 2019 and 2018 (in thousands):

	Three Months Ended June 30, 2019			Six Months Ended June 30, 2019		
	Product Revenue, net	Collaboration and License Revenue	Total	Product Revenue, net	Collaboration and License Revenue	Total
Timing of revenue recognition:						
Transferred at a point in time	$ 27,164	$ —	$ 27,164	$ 47,526	$ —	$ 47,526
Transferred over time	—	1,260	1,260	—	3,067	3,067
Total	$ 27,164	$ 1,260	$ 28,424	$ 47,526	$ 3,067	$ 50,593

	Three Months Ended June 30, 2018			Six Months Ended June 30, 2018		
	Product Revenue, net	Collaboration and License Revenue	Total	Product Revenue, net	Collaboration and License Revenue	Total
Timing of revenue recognition:						
Transferred at a point in time	$ 2,265	$ —	$ 2,265	$ 2,871	$ —	$ 2,871
Transferred over time	—	1,746	1,746	—	7,784	7,784
Total	$ 2,265	$ 1,746	$ 4,011	$ 2,871	$ 7,784	$ 10,655

The following table presents changes in our contract assets and liabilities for the six months ended June 30, 2019 (in thousands):

	Balance at Beginning of Period	Addition	Deduction	Balance at End of Period
Contract assets:				
Unbilled - collaboration and license revenue	$ 9,880	$ 2,452	$ (7,537)	$ 4,795
Total contract assets	$ 9,880	$ 2,452	$ (7,537)	$ 4,795
Contract liabilities:				
Deferred revenue	$ 6,335	$ 1,112	$ (1,765)	$ 5,682
Total contract liabilities	$ 6,335	$ 1,112	$ (1,765)	$ 5,682

Significant changes in the contract liabilities balances during the period are as follows (in thousands):

	Three Months Ended as of June 30, 2019	Six Months Ended as of June 30, 2019
Revenue recognized according to the current period performance that was included in the contract liability at the beginning of the period	$ 442	$ 615

The following table includes estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied or partially unsatisfied as of June 30, 2019 (in thousands):

Collaborator	Transaction Price Allocated to the Remaining Performance Obligation as of June 30, 2019	Expected Year By Which Revenue Recognition Will Be Completed	Percentage of Revenue Recognized
BMS and Pfizer - 2016 agreement	$ 856	2021	93%
Daiichi Sankyo - 2014 agreement	942	2020	97%
Daiichi Sankyo - 2016 agreement	3,120	2023	80%
Bayer - 2016 agreement	2,487	2023	84%
Total	$ 7,405		

Milestone payments or refundable advance payments that are not considered probable of being achieved are excluded from the transaction price until they are probable.

Sales-based royalties, including milestone payments based on the level of sales, related to license arrangements are excluded from variable consideration and will be recognized at the later of (a) when the related sales occur, or (b) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any royalty revenue resulting from any of our licensing arrangements.

Product Revenue, Net

To date, our source of product revenue has been from the U.S. sales of Andexxa and Bevyxxa, which we began shipping to customers in May 2018 and January 2018, respectively. No costs to obtain or fulfill the contracts have been capitalized. For the three and six

months ended June 30, 2019, we recorded a total of $3.7 million and $6.1 million, respectively, as a reduction to revenue consisting primarily of distribution fees and reserves for chargebacks and product returns.

Collaboration and License Revenue

BMS and Pfizer

Agreement Terms

In January 2014, we entered into an agreement with BMS and Pfizer to further study Andexxa as a reversal agent for their jointly-owned, U.S. Food and Drug Administration ("FDA")-approved oral Factor Xa inhibitor, apixaban, through Phase 3 studies (the "2014 BMS and Pfizer Agreement"). We are responsible for the cost of conducting this clinical study.

In February 2016, we entered into a collaboration and license agreement with BMS and Pfizer whereby BMS and Pfizer obtained exclusive rights to develop and commercialize Andexxa in Japan (the "2016 BMS and Pfizer Agreement"). BMS and Pfizer are responsible for all development, regulatory and commercial activities in Japan and we will reimburse BMS and Pfizer for expenses they incur for research and development activities specific to Factor Xa inhibitors other than apixaban. Pursuant to this agreement, we are obligated to provide certain research and development activities outside of Japan, provide clinical drug supply and related manufacturing services and to participate on various committees in exchange for a non-refundable upfront fee of $15.0 million. We are also eligible to receive, contingent payments totaling up to $20.0 million which may be earned upon achievement of certain regulatory events and up to $70.0 million which may be earned upon achievement of specified annual net sales volumes in Japan. We are also entitled to receive royalties ranging from 5% to 15% on net sales of Andexxa in Japan.

Revenue Recognition

We assessed the 2014 BMS and Pfizer Agreement and the 2016 BMS and Pfizer Agreement in accordance with ASC 606 and concluded that BMS and Pfizer are customers.

For the 2014 BMS and Pfizer Agreement, we determined that the duration of the contract began on the effective date in January 2014 and ends upon Andexxa approval in the United States and Europe, which was achieved in 2019. All the performance obligations under this agreement were delivered and we recognized all related revenues by the first quarter of 2019. For the six months ended June 30, 2019, we recognized less than $0.1 million as license and collaboration revenue under the 2014 BMS and Pfizer Agreement.

For the 2016 BMS and Pfizer Agreement, we determined that the duration of the contract begins on the effective date in February 2016 and ends upon estimated completion of the Andexxa Phase 4 expansion clinical trial in Japan.

We determined that the transaction price of the 2016 BMS and Pfizer Agreement was $12.5 million as of June 30, 2019 which includes routine updates for estimated costs that BMS and Pfizer will incur in developing Andexxa in Japan. In determining the transaction price, we evaluated all the payments to be received during the duration of the contract. As of June 30, 2019, the transaction price included a $15.0 million upfront payment, $5.0 million for acceptance of the Japan New Drug Application ("JNDA") in Japan, as management expects it to be probable of achievement, $4.4 million of estimated variable consideration for cost-sharing payments from BMS and Pfizer for agreed upon research and development services for clinical trials outside of Japan, and $0.6 million for the estimated costs of Andexxa clinical supplies to BMS and Pfizer for Andexxa Phase 4 expansion clinical trial in Japan. Our transaction price is reduced by $12.5 million for estimated payments to be made to BMS and Pfizer for costs they will incur in developing Andexxa in Japan. Regulatory approval milestones were fully constrained and therefore are not included in the transaction price, as the receipts of such milestones are outside of our control. In determining whether to constrain other milestones, we considered numerous factors, including whether receipt of the milestones is within our control, contingent upon success in future clinical trials and/or the licensee's efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to BMS and Pfizer and therefore have also been excluded from the transaction price. We will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

For the three and six months ended June 30, 2019, we recognized $0.2 million and $0.4 million, respectively, as license and collaboration revenue under the 2016 BMS and Pfizer Agreement and recorded $4.7 million as deferred revenue under contract liabilities as of June 30, 2019 on the condensed consolidated balance sheets.

Daiichi Sankyo, Inc. ("Daiichi Sankyo")

Agreement Terms

In July 2014, we entered into an agreement with Daiichi Sankyo to study the safety and efficacy of Andexxa as a reversal agent to edoxaban, in our Phase 3 and Phase 4 studies (the "2014 Daiichi Sankyo Agreement"). We are responsible for the cost of conducting these clinical studies. Pursuant to our agreement with Daiichi Sankyo we are obligated to provide research, development and regulatory services and to manufacture and supply Andexxa in exchange for an upfront nonrefundable fee of $15.0 million, up to two contingent payments totaling $5.0 million which are payable upon the initiation of our Phase 3 study and achievement of certain events associated with scaling up our manufacturing process to support a commercial launch, and up to four payments totaling $20.0 million which are payable upon acceptance of filing and regulatory approval of Andexxa as a reversal agent to edoxaban by the FDA and the European Medicines Agency ("EMA").

In October 2016, we amended this agreement to expedite the expansion of our Phase 4 trial in exchange for an upfront fee of $15.0 million, $8.0 million of which is payable back to Daiichi Sanko based solely on quarterly royalty payments of 1% of world-wide net sales of Andexxa. We are also eligible to receive up to three contingent payments totaling $10.0 million payable upon achieving specified clinical site activation and patient enrollment targets. Additionally, the $2.5 million contingent payment associated with scaling up our manufacturing process from the original agreement has been removed by this amendment.

In March 2016, we entered into an agreement with Daiichi Sankyo to perform an ESS-Study of Japanese ethnicity, perform any further studies requested by the Japanese regulatory authorities and to deliver services in connection with our collaboration agreement to commercialize Andexxa in Japan with BMS and Pfizer (the "2016 Daiichi Sankyo Agreement"). Daiichi Sankyo will reimburse us for 33% of our costs and expenses incurred to conduct the ESS-Study and between 33% and 100% of costs and expenses we incur for other studies that involve edoxaban under the terms of the arrangement.

Revenue Recognition

We assessed the 2014 Daiichi Sankyo Agreement as amended in October 2016 and the 2016 Daiichi Sankyo Agreement in accordance with ASC 606 and concluded that Daiichi Sankyo is a customer.

For the 2014 Daiichi Sankyo Agreement, we determined that the duration of the contract begins on the effective date in July 2014 and ends upon Andexxa approval as a reversal agent to edoxaban in the United States and Europe, which we expect to be achieved in 2020. The contract duration is defined as the period in which parties to the contract have present enforceable rights and obligations. We analyzed the impact of Daiichi Sankyo's terminating the agreement prior to Andexxa approval and determined that there were substantive non-monetary penalties to Daiichi Sankyo for doing so. We considered quantitative and qualitative factors to reach this conclusion.

We determined that the transaction price of the 2014 Daiichi Sankyo Agreement and October 2016 amendment of this agreement was $34.0 million as of June 30, 2019. In order to determine the transaction price, we evaluated all the payments to be received during the duration of the contract. As of June 30, 2019, the transaction price included $22.0 million of upfront payments and $12.0 million in milestones already received upon achievement of specified events. As of June 30, 2019, we had $5.5 million of further milestone payments eligible to be included in the transaction price but have determined they are not probable of achievement and therefore constrained. As part of our evaluation of the constraint, we considered numerous factors, including whether receipt of the milestones is outside of our control and/or contingent upon success in a future clinical trial. We will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

For the three and six months ended June 30, 2019, we recognized $0.2 million and $0.7 million, respectively, as license and collaboration revenue under the combined 2014 Daiichi Sankyo Agreement and October 2016 amendment and recorded $0.9 million as deferred revenue under contract liabilities as of June 30, 2019 on the condensed consolidated balance sheets. There were no costs incurred to obtain or fulfill the contract.

For the 2016 Daiichi Sankyo Agreement, we determined that the transaction price of the 2016 Daiichi Sankyo Agreement was $15.6 million as of June 30, 2019 which includes routine updates for estimated reimbursable costs to be incurred in future periods. In order to determine the transaction price, we evaluated all the payments to be received during the duration of the contract. As of June 30, 2019, the transaction price included $5.0 million of upfront payment and $4.4 million of estimated variable consideration for cost-sharing payments from Daiichi Sankyo for agreed upon research and development services incurred and to be incurred outside of Japan including the ESS-study, and $6.2 million of estimated variable consideration for cost-sharing payments from Daiichi Sankyo associated with the development of Andexxa in Japan. As of June 30, 2019, we had $10.0 million of further regulatory milestone payments eligible for achievement, however, regulatory milestones have been fully constrained and thus are not included in the transaction price. In determining whether to constrain these milestones, we considered numerous factors, including whether receipt of the milestones is within our control and/or contingent upon success in future clinical trials. We will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

For the three and six months ended June 30, 2019, we recognized $0.2 million and $0.8 million, respectively, as license and collaboration revenue under the 2016 Daiichi Sankyo Agreement and recorded $2.1 million as Unbilled - collaboration and license revenue as of June 30, 2019 on the condensed consolidated balance sheets. None of the costs to obtain or fulfill the contract were capitalized.

Bayer Pharma, AG ("Bayer") and Janssen Pharmaceuticals, Inc. ("Janssen")

Agreement Terms

In January 2014, we entered into an agreement with Bayer and Janssen to study Andexxa as a reversal agent to rivaroxaban in our Phase 3 studies and to seek regulatory approval in the United States and Europe (the "2014 Bayer and Janssen Agreement"). We are responsible for the costs associated with this agreement.

Revenue Recognition

We assessed the 2014 Bayer and Janssen Agreement in accordance with ASC 606 and concluded that Bayer and Janssen are customers.

For the 2014 Bayer and Janssen Agreement, we determined that the duration of the contract begins on the effective date of the 2014 Bayer and Janssen Agreement and ends upon Andexxa approval in the United States and Europe for rivaroxaban, which was achieved in 2019. All the performance obligations under this agreement were delivered and we recognized all related revenues by the first quarter of 2019. For the six months ended June 30, 2019, we recognized less than $0.1 million as license and collaboration revenue under the 2014 Bayer and Janssen Agreement. None of the costs to obtain or fulfill the contract were capitalized.

Bayer Pharma, AG ("Bayer")

Agreement Terms

In February 2016, we entered into an agreement with Bayer to perform an ESS-Study of Japanese ethnicity, perform any further studies requested by the Japanese regulatory authorities and to deliver services, in connection with our collaboration agreement to commercialize Andexxa in Japan with BMS and Pfizer (the "2016 Bayer Agreement"). Bayer will reimburse us 33% of our costs and expenses incurred to conduct the ESS-Study and between 33% and 100% of costs and expenses we incur for other studies that involve rivaroxaban under the terms of the arrangement.

We are obligated to provide research and development services, to provide clinical drug supply and related manufacturing services and to provide regulatory approval services in exchange for an upfront nonrefundable fee of $5.0 million. We are also eligible to receive, one payment of $10.0 million which is payable upon the initial regulatory approval for Andexxa for rivaroxaban in Japan. The $10.0 million payment will be reduced to $7.0 million if Japanese regulatory approval is attained based only upon the ESS Study results.

Revenue Recognition

We assessed the 2016 Bayer Agreement in accordance with ASC 606 and concluded that Bayer is a customer.

We determined that the transaction price of the 2016 Bayer Agreement was $15.6 million as of June 30, 2019 which includes routine updates for estimated reimbursable costs to be incurred in future periods. In order to determine the transaction price, we evaluated all the payments to be received during the duration of the contract. As of June 30, 2019, the transaction price included a $5.0 million upfront payment, $4.4 million of estimated variable consideration for cost-sharing payments from Bayer for agreed upon research and development services incurred and to be incurred outside of Japan including the ESS-study and $6.2 million of estimated variable consideration for cost-sharing payments from Bayer associated with the development of Andexxa in Japan. As of June 30, 2019, we had $10.0 million of further regulatory milestone payments eligible for achievement, however, regulatory milestones have been fully constrained and thus are not included in the transaction price. In determining whether to constrain these milestones, we considered numerous factors, including whether receipt of the milestones is within our control and/or contingent upon success in future clinical trials. We will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

For the three months and six months ended June 30, 2019, we recognized $0.6 million and $1.1 million, respectively, as license and collaboration revenue under the 2016 Bayer Agreement and recorded $2.7 million as Unbilled - collaboration and license revenue as of June 30, 2019 on the condensed consolidated balance sheets. There were no costs incurred to obtain or fulfill the contract.

4. Fair Value Measurements

Financial assets and liabilities are recorded at fair value. The carrying amounts of our receivables from collaborations, prepaid and other current assets, accounts payable, accrued research and development and accrued and other liabilities approximate their fair value due to their short maturities. The accounting guidance for fair value provides a framework for measuring fair value, clarifies the definition of fair value and expands disclosures regarding fair value measurements. Fair value is defined as the price that would be received in the sale of an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value as follows:

Level 1 –Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2 –Inputs (other than quoted market prices included in Level 1) are either directly or indirectly observable for the asset or liability through correlation with market data at the measurement date and for the duration of the instrument's anticipated life.

Level 3 –Inputs reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

In certain cases where there is limited activity or less transparency around inputs to valuation, the related assets or liabilities are classified as Level 3. Our embedded derivative liabilities are measured at fair value using a Monte Carlo simulation model or a discounted cash flow model and are included as a component of other long-term liabilities on the condensed consolidated balance sheets. The embedded derivative liabilities are subject to remeasurement at the end of each reporting period, with changes in fair value recognized as a component of interest and other income, net, in our condensed consolidated statements of operations, and as remeasurement gain or loss on embedded derivatives liabilities in our condensed consolidated statements of cash flows. The assumptions used in the Monte Carlo simulation model or the discounted cash flow model include: (1) our estimates of both the probability and timing of manufacturing regulatory approval of Andexxa and other related events; (2) the probability-weighted net sales of Andexxa; (3) our risk-adjusted discount rate that includes a company specific risk premium; (4) our cost of debt; (5) volatility; and (6) the probability of a change in control occurring during the term of the note.

Our liability-classified Lonza AG ("Lonza") award was measured at fair value using a Black-Scholes model until the settlement date during the first quarter of 2019. Changes in the fair value of the liability-classified Lonza award was recognized as research and development expense in our condensed consolidated statements of operations. The assumptions used in the Black-Scholes model include: (1) expected risk free rate; (2) expected volatility; and (3) expected dividend yield rate. See Note 6, "Contract Manufacturing Agreements", to these condensed consolidated financial statements for further information.

There were no transfers between Level 1, Level 2 and Level 3 during the periods presented. In certain cases where there is limited activity or less transparency around inputs to valuation, securities are classified as Level 3.

The following table sets forth the fair value of our financial assets and liabilities (excluding restricted cash) allocated into Level 1 and Level 2 that were measured on a recurring basis (in thousands):

		June 30, 2019				December 31, 2018			
	Fair Value Hierarchy	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Money market funds	Level 1	$ 36,826	$ —	$ —	$ 36,826	$ 19,500	$ —	$ —	$ 19,500
Corporate notes and commercial paper	Level 2	127,459	3	(25)	127,437	166,363	1	(205)	166,159
U.S. Treasury bills and government agency securities	Level 2	65,168	25	—	65,193	110,270	1	(81)	110,190
		$ 229,453	$ 28	$ (25)	$ 229,456	$ 296,133	$ 2	$ (286)	$ 295,849
Classified as:									
Cash equivalents					$ 140,903				$ 117,836
Short-term investments					88,553				178,013
Total cash equivalents and investments					$ 229,456				$ 295,849

At June 30, 2019, the remaining contractual maturities of available-for-sale securities were less than one year. There have been no significant realized losses on available-for-sale securities for the periods presented. We do not intend to sell the investments with unrealized losses at June 30, 2019, and it is not more likely than not that we will be required to sell those investments with unrealized losses before recovery of their amortized cost bases, which may be maturity. Available-for-sale debt securities that were in a continuous loss position but were not deemed to be other than temporarily impaired were immaterial at both June 30, 2019 and December 31, 2018.

Level 3 liabilities are comprised of embedded derivative liabilities as described in Note 8, “Long Term Obligations”, to these condensed consolidated financial statements and includes a liability-classified Lonza award that was settled in the first quarter of 2019. The estimated fair value of the Notes, long term royalty-based debt and long term debt are discussed in Note 8. The following table sets forth a summary of the changes in the estimated fair value of our embedded derivative liabilities and Lonza award during the six-month period ended June 30, 2019 (in thousands):

	Embedded derivative liabilities	Lonza award	Total
Balance as of December 31, 2018	$ 2,497	$ 9,201	$ 11,698
Net change in the fair value	(2,902)	5,824	2,922
Addition of derivative related to 2019 Secured Term Loan	2,372	—	2,372
Settlement of Lonza award	—	(15,025)	(15,025)
Balance as of June 30, 2019	$ 1,967	$ —	$ 1,967

5. Balance Sheet Components

Inventories

Inventories consisted of the following (in thousands):

	June 30, 2019	December 31, 2018
Raw materials	$ 13,480	$ 279
Work in process	19,282	14,395
Finished goods	393	2,844
Total inventories	$ 33,155	$ 17,518
Balance Sheet Classification		
Inventories	$ 1,547	$ 7,873
Inventories, noncurrent portion	31,608	9,645
Total inventories	$ 33,155	$ 17,518

We began capitalizing inventory for costs associated with Andexxa Gen 1 and Gen 2 supply upon FDA approval on May 3, 2018 and December 31, 2018, respectively. As of June 30, 2019 and December 31, 2018, long-term inventories of $31.6 million and $9.6 million, respectively, are classified as inventories, noncurrent portion, as these inventories are not expected to be sold within the next twelve months, and the amount is deemed recoverable.

As of June 30, 2019 and December 31, 2018, we have made prepayments to manufacturers for the purchase of inventories. These are classified as short and long-term assets based on when the inventories are expected to be utilized in the manufacturing process and/or sold within the next twelve months. As of June 30, 2019 and December 31, 2018, long-term prepaid manufacturing of $7.8 million and $10.9 million, respectively, are classified as prepaid and other long-term assets as these inventories are not expected to be utilized in the manufacturing process and/or sold within the next twelve months.

We recorded an excess and obsolescence inventory charge to cost of sales of $3.8 million during the six months ended June 30, 2019. In developing the estimate for inventory reserve, we used estimates of demand compared to shelf life. If it is determined that inventory utilization will further diminish based on estimates of demand, additional inventory write-downs may be required.

Accrued and Other Liabilities

Accrued and other liabilities consist of the following (in thousands):

	June 30, 2019	December 31, 2018
Manufacturing related	$ 7,280	$ 5,465
Compensation and employee benefits	14,217	10,794
Current portion of lease liability	3,004	—
Others	8,741	6,051
Total accrued and other liabilities	$ 33,242	$ 22,310

6. Contract Manufacturing Agreements

Lonza Manufacturing Services Agreement

In August 2017, we executed a Manufacturing Services Agreement with Lonza to develop our Gen 2 manufacturing process for Andexxa bulk drug substance. The manufacturing commitments included therein were contingent upon marketing approval by either the FDA or the EMA of Andexxa manufactured under the Gen 2 process and will remain in effect for a period of ten years. Additionally, the agreement provides Lonza with two separate rights to purchase shares of our common stock at a purchase price of $1.00 per share, contingent upon certain events. The first purchase right was earned by Lonza in the first quarter of 2019 upon the approval of the Gen 2 process and the commencement of process transfer activities to an additional new facility. The second purchase right will be earned by Lonza upon the approval of the drug substance manufactured at the new facility and the number of shares will be determined based on the achievement of specified performance metrics at the new facility. The number of shares subject to each of the first and the second purchase rights will be capped at the lesser of either: (1) the number of shares with an aggregate market value of $15.0 million based on a 20 day trailing market value average from the date such purchase right is earned by Lonza, or (2) 500,000 shares.

The first purchase right was earned by Lonza during the quarter ended March 31, 2019. The FDA approved Andexxa Gen2 on December 31, 2018 and, in February 2019, Lonza commenced process transfer activities to an additional new facility. During the first quarter of 2019, Lonza exercised their right to purchase 500,000 shares of our common stock at $1.00 per share. We marked to market the liability-classified award up to the settlement date using the valuation assumptions described in Note 4, “Fair Value Measurements”, to these condensed consolidated financial statements and recognized $5.8 million of non-employee stock based compensation expense classified as research and development expense during the six months ended June 30, 2019.

As of June 30, 2019, we have not recognized any expense for the second tranche award because the related performance conditions were not considered probable.

7. Asset Acquisition and License Agreements

SRX Cardio, LLC

In December 2015, we entered into an option agreement with SRX Cardio to explore a novel approach to develop a drug in the field of hypercholesterolemia. This agreement provided us an option to enter into an exclusive license agreement as well as responsibility to lead and fund the development effort during the option period. We made an upfront payment of $0.5 million.

In September 2016, we exercised our right to enter into an exclusive license agreement.

During the second quarter of 2019, we made a decision to discontinue the clinical development of the intellectual property asset that was licensed from SRX Cardio, and a notice was provided to terminate the SRX Cardio relationship. As a result, in the second quarter of 2019, we recorded (1) a full impairment charge of $3.2 million related to the in-process research and development intangible asset, which was recorded in research and development expense, and (2) a gain of $2.3 million for the de-recognition of the contingent milestone payable to SRX Cardio associated with the licensed hypercholesterolemia program, which was recorded in net loss attributable to noncontrolling interest in these condensed consolidated financial statements.

8. Long Term Obligations

BMS and Pfizer Promissory Notes

In December 2016, we entered into a supplemental funding support agreement with BMS and Pfizer whereby we received $50.0 million in exchange for two promissory notes totaling $65.0 million that become due in December 2024 (“Notes”). We may reduce the repayment amount to $62.5 million if such amount is paid by December 31, 2023. The use of funds is restricted to development activities needed for regulatory approval of Andexxa by the FDA and the EMA as provided in the agreement. Pursuant to the terms of the agreement, we are required to pay down the Notes each quarter in an amount equal to 5% of net sales of Andexxa in the United States and the EU.

The upfront cash receipt of $50.0 million is recorded as Notes payable at issuance. We are accruing for interest over the term of the Notes. The carrying values of the Notes payable includes accrued interest of $9.2 million and $7.6 million at June 30, 2019 and December 31, 2018, respectively.

Our payment obligations for BMS and Pfizer Promissory Notes are as follows (in thousands):

	June 30, 2019	December 31, 2018
Total repayment obligations	$ 62,500	$ 62,500
Less: interests to be accreted in future periods	(7,003)	(8,643)
Less: payments made	(2,211)	(497)
Carrying value of notes payable	53,286	53,360
Less: current portion of royalties	(8,622)	(5,062)
Non-current portion of notes payable	$ 44,664	$ 48,298

We evaluated the features of the Notes and determined that certain features require acceleration of payments such as pursuant to a change of control. We determined that these features (embedded derivatives) require bifurcation and fair value recognition. We determined the fair value of each derivative using a Monte Carlo simulation model taking into account the probability of these events occurring and potential repayment amounts and timing of such payments that would result under various scenarios (see Note 4, “Fair Value Measurements”, to these condensed consolidated financial statements). We will remeasure the embedded derivatives to fair value each reporting period until the repayment, termination or maturity of the Notes. For the three and six months ended June 30, 2019, we recognized a gain of $0.7 million and a gain of $1.2 million, respectively, upon remeasurement of the embedded derivatives. For the three and six months ended June 30, 2018, we recognized a loss of $0.2 million and a loss of $0.8 million, respectively, upon remeasurement of the embedded derivatives.

The estimated fair value of the Notes at June 30, 2019 and December 31, 2018 was $52.7 million and $53.2 million, respectively, and the fair value was measured using Level 3 inputs. The estimated fair market value was calculated using a Monte Carlo simulation model with inputs consistent with those used in determining the embedded derivative values as described in Note 4, “Fair Value Measurements”, to these condensed consolidated financial statements.

Royalty-based Financing

In February 2017, we entered into a purchase and sale agreement (the “Royalty Sales Agreement”) with HCR whereby HCR acquired a term royalty interest in future worldwide net sales of Andexxa. We received $50.0 million upon closing and received an additional $100.0 million following the U.S. regulatory approval of Andexxa in May 2018. We are required to pay royalties to HCR based on tiered net worldwide sales of Andexxa in a range of 8.46% to 4.19%. The applicable rate decreases starting at worldwide net annual sales levels above $150.0 million. Total royalty payments are capped at 195% of the funding received less certain transaction expenses, or $290.6 million.

Upon the closing of the Royalty Sales Agreement in February 2017, we incurred a fee to HCR of $2.0 million and paid additional debt issuance costs totaling $0.6 million, which included expenses that we paid on behalf of HCR and expenses incurred directly by us. Upon the subsequent funding of $100.0 million in May 2018, we incurred fees to HCR of $5.0 million. Fees and debt issuance costs have been netted against the debt and are being amortized over the estimated term of the debt using the effective interest method.

The effective interest rate as of June 30, 2019 was 14.2%. We are accruing for interest over the term of the royalty-based debt. The carrying value of the royalty-based debt includes accrued interest of $33.9 million and $22.9 million, net of unamortized debt discount of $6.4 million and $6.8 million, at June 30, 2019 and December 31, 2018, respectively.

Our payment obligations for HCR royalty-based debt are as follows (in thousands):

	June 30, 2019	December 31, 2018
Total repayment obligations	$ 290,550	$ 290,550
Less: interests to be accreted in future periods	(114,812)	(125,851)
Less: payments made	(3,716)	(816)
Carrying value of long term royalty-based debt	172,022	163,883
Less: current portion of royalties	(14,588)	(8,627)
Non-current portion of long term royalty-based debt	$ 157,434	$ 155,256

We determined that certain features, such as the variability in the royalty payments based upon the timing of regulatory approval, were embedded derivatives that required bifurcation from the royalty-based debt instrument. Upon the Andexxa Gen2 FDA approval on December 31, 2018, it was determined that there was no longer a derivative associated with the debt contract. For the three months and six months ended June 30, 2018, we recognized gains of $0.1 million and $2.4 million, respectively, upon remeasurement of the embedded derivative.

The estimated fair value of royalty-based debt at June 30, 2019 and December 31, 2018 was $159.3 million and $154.2 million, respectively, and the fair value was measured using Level 3 inputs. The estimated fair market value was calculated using a Monte Carlo simulation model with inputs as described in Note 4, “Fair Value Measurements”, to these condensed consolidated financial statements.

Secured Term Loan

In February 2019, we entered into a credit agreement (the “Credit Agreement”) with HCR and Athyrium Opportunities III Acquisition LP (“Athyrium”) whereby we received the first tranche of $62.5 million (“Secured Term Loan”) in March 2019 and we have access to the second tranche of $62.5 million at our option if we receive regulatory approval from the EMA for Ondexxya, the brand name of andexanet alfa in the EU, and achieve a U.S. Andexxa net product revenue of $50.0 million for the nine-months period ended September 30, 2019. If we satisfy both conditions, we have until November 15, 2019 to exercise our option to access the second tranche.

All obligations under the Credit Agreement are due on February 28, 2025 with certain scheduled payments of the principal starting from March 31, 2022. The outstanding principal balance of the loan bears interest at 9.75% per annum. The loan is secured by substantially all of our assets. The Credit Agreement contains certain covenants that, among others, require us to deliver financial reports at designated times of the year and limit or restrict our ability to incur additional indebtedness or liens, acquire, own or make any investments, pay cash dividends or enter into certain corporate transactions, including mergers and changes of control, and require us to maintain $31.3 million of cash, such amount to be increased if we draw on the second tranche of funding. Violating covenants would put us in default and that the lenders would then have the option to demand repayment plus certain penalties or allow us to continue to service the loan but at the default interest rate of 12.75%. As of June 30, 2019, we were not in violation of any covenants.

For the three and six months ended June 30, 2019, we accrued interest of $1.7 million and $2.0 million, respectively. Upon the closing of the Credit Agreement, we incurred fees of $2.8 million to HCR and Athyrium and other debt issuance cost of $0.5 million. Loan origination fees and debt issuance costs are netted against the loan balance and are amortized over the contractual term of the loan using the effective interest method. The effective interest rate as of June 30, 2019 was 12.3%.

As of June 30, 2019, the future principal maturities of our Secured Term Loan for each of the next five years are as follows (in thousands):

Year ended December 31,	
2022	$ 9,615
2023	9,615
2024	9,615
Thereafter	33,655
Total	$ 62,500

We evaluated the terms of the loan and determined that one feature could require acceleration of payments and a prepayment penalty (make-whole provision) upon a change of control if it occurs prior to the 30-month anniversary period from the funding date in March 2019. We determined that this feature (embedded derivative) requires bifurcation from the debt instrument and fair value recognition. We determined the fair value of the derivative using a discounted cash flow model taking into account the probability of a change of control occurring and potential repayment amounts and timing of such payments that would result under various scenarios, as further described in Note 4, "Fair Value Measurements", to these condensed consolidated financial statements. We will remeasure the embedded derivative to fair value each reporting period until the feature with make-whole provision lapses after 30 months from the funding date in March 2019. For the three and six months ended June 30, 2019, we recognized a gain of $1.7 million upon remeasurement of the embedded derivatives.

The estimated fair value of long-term debt at June 30, 2019 was $71.0 million, and the fair value was measured using Level 3 inputs. The estimated fair market value was calculated using a discounted cash flow model with inputs consistent with those used in determining the embedded derivative values as described in Note 4, "Fair Value Measurements", to these condensed consolidated financial statements.

9. Stock Based Compensation

Stock Options

The following table summarizes stock option activity under our 2013 Equity Incentive Plan (the "2013 Plan") and an Inducement Plan, and related information during the six months ended June 30, 2019 and 2018:

	Shares Subject to Outstanding Options	Weighted-Average Exercise Price Per Share
Balance at December 31, 2018	7,507,690	$ 33.25
Options granted	1,716,643	27.71
Options exercised	(632,254)	20.79
Options canceled	(678,423)	39.19
Balance at June 30, 2019	7,913,656	$ 32.54

Performance Stock Options ("PSOs")

In March 2019, the Compensation Committee of our Board of Directors approved a program to award up to 490,986 PSOs to the management team based on the achievement of certain net revenue goals. The following table summarizes PSO activities under our 2013 Plan and related information during the six months ended June 30, 2019:

	Shares Subject to Outstanding PSOs	Weighted-Average Exercise Price Per Share
Balance at December 31, 2018	143,335	$ 23.76
Options granted	490,986	33.29
Options exercised	(26,667)	23.76
Options canceled	(11,250)	33.29
Balance at June 30, 2019	596,404	$ 31.43

Restricted Stock Units ("RSUs")

The following table summarizes RSU activity under our 2013 Plan and Inducement Plan, and related information during the six months ended June 30, 2019:

	Shares Subject to Outstanding RSUs	Weighted-Average Grant Date Fair Value Per Share
Balance at December 31, 2018	979,278	$ 34.00
RSUs granted	638,970	27.86
RSUs released	(314,311)	35.29
RSUs canceled	(76,836)	35.77
Balance at June 30, 2019	1,227,101	$ 30.36

Performance Stock Units ("PSUs")

The following table summarizes PSU activity under our 2013 Plan and related information during the six months ended June 30, 2019:

	Subject to Outstanding PSUs	Weighted-Average Grant Date Fair Value Per Share
Balance at December 31, 2018	153,503	$ 29.85
PSUs granted	—	—
PSUs released	(52,670)	28.29
PSUs canceled	(87,708)	30.36
Balance at June 30, 2019	13,125	$ 32.66

The table below sets forth the functional classification of stock-based compensation expense for the periods presented (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Research and development	$ 3,811	$ 5,320	$ 13,706	$ 9,772
Selling, general and administrative	8,442	7,894	16,441	14,422
Stock-based compensation expense included in total expenses	$ 12,253	$ 13,214	$ 30,147	$ 24,194
Capitalized stock-based compensation costs	$ (116)	$ -	$ (358)	$ -

10. Net Loss per Share Attributable to Portola Common Stockholders

Basic net loss per share attributable to Portola Common Stockholders has been computed by dividing the net loss attributable to Portola Common Stockholders by the weighted-average number of shares of Common Stock outstanding during the period. Diluted net loss per share attributable to Portola Common Stockholders is calculated by dividing net loss attributable to Portola Common Stockholders by the weighted average number of shares of Common Stock and potential dilutive securities outstanding during the period. Since we were in a loss position for all periods presented, basic net loss per share attributable to Portola Common Stockholders is the same as diluted net loss per share attributable to Portola Common Stockholders as the inclusion of all potentially dilutive common shares would have been anti-dilutive.

The following outstanding shares of common stock equivalents were excluded from the computation of diluted net loss per share attributable to Portola Common Stockholders for the periods presented because including them would have been antidilutive:

	Six Months Ended June 30,	
	2019	2018
Stock options to purchase common stock	7,913,656	7,391,411
Performance stock options	596,404	155,669
Common stock warrants	1,500	1,500
Restricted stock units	1,227,101	749,412
Performance stock units	13,125	330,416
Employee stock purchase plan	67,958	47,743

Up to 500,000 shares of our common stock may be contingently issued, if certain regulatory and performance conditions are met under an agreement with a contract manufacturer, as described in Note 6, “Contract Manufacturing Agreements”, to these condensed consolidated financial statements.

11. Leases

We have operating leases for our office facilities. We renewed one operating lease for our office facilities in June 2019. Our leases have remaining lease terms of up to 3.8 years as of June 30, 2019. Upon adoption of ASC 842, we did not elect to apply the hindsight expedient in evaluating our renewal option, and as such, we did not include the renewal period in our lease term because at the inception we were not reasonably certain that we would exercise the renewal option. Our lease agreements do not contain any material residual value guarantees or material restrictive covenants.

Our operating lease right-of-use asset and liability were recognized at the adoption date of ASC 842 based on the present value of lease payments over the remaining lease term at the adoption date. In determining the net present value of lease payments, we used our incremental borrowing rate based on the information available, including remaining lease term, at the adoption date of ASC 842.

Upon the renewal of the operating lease in June 2019, we remeasured the lease liability to reflect the changes to the lease term and the lease payments using a discount rate at the date of remeasurement on the basis of the remaining lease term and the remaining lease payments. We recognized the remeasurement amount of the lease liability as an adjustment to the lease right-of-use asset. This resulted in an $11.1 million increase to the lease liability and the lease right-of-use asset at the remeasurement date.

The components of lease expense are as follows (in thousands):

	Three Months Ended June 30, 2019	Six Months Ended June 30, 2019
Operating lease cost	$ 622	$ 1,081
Short-term lease cost	89	178
Total	$ 711	$ 1,259

Cash flow information related to leases are as follows (in thousands):

	Six Months Ended June 30, 2019
Cash paid for amounts included in the measurement of lease liability:	
Operating cash flows from operating lease	$ 1,372
Supplemental non-cash information:	
Right-of-use asset obtained in exchange for lease obligation due to remeasurement	$ 11,103

Supplemental balance sheet information related to leases are as follows (in thousands):

	Classification	As of June 30, 2019
Operating lease		
Lease right-of-use asset		
Non-current	Operating lease right-of-use asset	$ 12,316
Lease liability		
Current	Accrued and other liabilities	$ 3,004
Non-current	Long-term portion of lease liability	$ 10,204
Weighted Average Remaining Lease Term		
Operating lease		3.8 years
Weighted Average Discount Rate		
Operating lease		6.61%

As of June 30, 2019, the maturity of our lease liability was as follows (in thousands):

Year ending December 31,	Operating Lease
Remainder of 2019	$ 1,392
2020	4,024
2021	4,553
2022	4,713
2023	1,188
Total lease payments	15,870
Less imputed interests	(2,662)
Total lease liability	$ 13,208

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the consolidated financial statements and notes thereto included elsewhere in this report and with the audited consolidated financial statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2018.

Special note regarding forward-looking statements

This report contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed in the forward-looking statements. The statements contained in this report that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements are often identified by the use of words such as, but not limited to, "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "may," "plan," "project," "seek," "should," "strategy," "target," "will," "would" and similar expressions or variations intended to identify forward-looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section titled "Risk Factors" included under Part II, Item 1A below. Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

OVERVIEW

Portola Pharmaceuticals, Inc. (the "Company" or "we" or "our" or "us") is a biopharmaceutical company focused on the development and commercialization of novel therapeutics in the areas of thrombosis, other hematologic diseases and inflammation for patients who currently have limited or no approved treatment options. Our headquarters are located in South San Francisco, California. Our lead product is Andexxa [coagulation factor Xa (recombinant), inactivated-zhzo] which we are marketing under the brand name of Ondexxya in Europe, the first and only antidote approved by the FDA and the EC, respectively, for patients treated with rivaroxaban or apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. Bevyxxa (betrixaban) is the first and only oral, once-daily Factor Xa inhibitor approved by the FDA for the prevention of venous thromboembolism ("VTE") in adult patients hospitalized for an acute medical illness. Bevyxxa is currently being marketed in a limited manner and we are evaluating potential partnership opportunities for this product. We are advancing cerdulatinib, an investigational oral, dual spleen tyrosine kinase ("SYK") and Janus kinase ("JAK") inhibitor in development to treat hematologic cancers. We also have a number of other molecules in earlier stage and pre-clinical development.

Pipeline

	Description	Approved or Investigational Indication	Stage	Commercial rights
Andexxa	Reversal agent for certain Factor Xa (fXa) inhibitors	Patients treated with rivaroxaban or apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding	U.S. Approval EU Approval	Worldwide excluding Japan
Bevyxxa	Oral fXa inhibitor	Extended duration VTE prophylaxis in acute medically ill patients in-hospital and post discharge for 35-42 days	U.S. Approval	Worldwide
Cerdulatinib	Oral, dual SYK and JAK inhibitor	Relapsed/refractory B- and T-cell malignancies	Phase 2a	Worldwide excluding topical formulation in non-oncology indications

Approved Products:

Andexxa

Andexxa is approved by the FDA as a reversal agent for patients treated with rivaroxaban or apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. Andexxa was approved under the FDA's Accelerated Approval pathway based on the change from baseline in anti-Factor Xa activity in healthy volunteers. Continued approval for this indication is contingent upon post-marketing study results to demonstrate an improvement in hemostasis in patients.

On December 31, 2018, the FDA approved our Gen 2 manufacturing process, which provides commercial scale volume that we believe is sufficient to support a global launch that can meet worldwide commercial demand for at least the next several years. In early January 2019, we began shipping Gen 2 product and commenced a full-scale commercial launch in the United States.

Andexanet alfa received conditional approval under the brand name Ondexxya by the EC on April 26, 2019. This conditional approval included several post-authorization requirements, including specific obligations to submit a final clinical study report for the randomized controlled trial of Andexxa (U.S.)/Ondexxya (EU), a final clinical study report for the ANNEXA-4 study, and an obligation to provide some additional pharmacokinetic data. We completed our first sales of Ondexxya in Europe in July 2019 and are executing a phased launch of Ondexxya in Europe, with an initial focus on the United Kingdom, Germany, Austria, Denmark, Finland and the Netherlands.

In May 2019, we announced a new analysis of the ANNEXA-4 study among patients with spontaneous (non-traumatic) intracranial hemorrhage – a bleeding event in the brain not caused by trauma and associated with high rates of mortality and morbidity. The data presented demonstrate that, even among this important and difficult-to-treat subset of patients, the hemostatic efficacy and safety of Andexxa is compelling and consistent. Specifically, the data show:

- A high rate of hemostatic efficacy (79%) consistent with that of the full ANNEXA-4 trial across patients with all types of bleeds (82%)

- Of the patients that achieved excellent or good hemostatic efficacy within one hour post Andexxa, 98% (n=55/56) maintained excellent or good hemostatic control 12 hours following Andexxa administration.

- The majority of thrombotic events occurred in patients who delayed or did not re-start anticoagulation therapy with a Factor Xa inhibitor during the follow-up period.

- Importantly, no thrombotic events were observed among the 18 patients who re-started oral anticoagulation therapy within 30 days.

In August 2019, the U.S. Centers for Medicare and Medicaid Services (CMS) announced its intention to increase the reimbursement amount for the New Technology Add-on Payment (NTAP), granted in October 2018, to Andexxa from up to 50% to 65% of the wholesale acquisition cost of the standard dose, effective October 1, 2019.

Bevyxxa

Bevyxxa is the first and only anticoagulant approved in the U.S. for hospital and extended duration prophylaxis (35 to 42 days) of VTE in adult patients hospitalized for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE. Bevyxxa was approved by the FDA in June 2017 and we commenced the commercial launch in the U.S. in January 2018.

Following the approval of Andexxa in May 2018, due to our limited resources, we greatly scaled back our commercial efforts for Bevyxxa in the second half of 2018 in order to focus on the commercial launch of Andexxa. We are re-evaluating our marketing strategy for Bevyxxa and also exploring potential partnership and other strategic options for Bevyxxa.

Product Candidate:

Cerdulatinib

Cerdulatinib is our investigational SYK and janus kinase ("JAK") inhibitor that uniquely inhibits two key cell signaling pathways implicated in certain hematologic malignancies and autoimmune diseases. There is a rationale for inhibiting both SYK (B-cell receptor pathway) and JAK (cytokine receptors) in B-cell malignancies where both targets have been shown to promote cancer cell growth and survival. In addition, pre-clinical data suggest an important role for SYK and JAK in Peripheral T-Cell Lymphoma ("PTCL") tumor survival.

There is a significant unmet need for the treatment of patients with relapsed/refractory PTCL. Current approved therapies for relapsed/refractory PTCL are all given via IV infusion and have limited activity with overall response rates of approximately 30%. In addition, most of these responses are partial responses. Based on the unmet need and on the activity to date with cerdulatinib, we have prioritized development in PTCL. Following our End of Phase 2 meeting with the FDA in January 2019, the FDA has requested additional data supporting the proposed dose and we have submitted the requested data. Pending the outcome of our discussions, we hope to start a registrational study by the end of the year.

In June 2019, we presented new interim Phase 2a data for cerdulatinib alone and in combination with rituximab in Follicular Lymphoma (FL) patients at the European Hematology Association's (EHA) Annual Congress and at the International Conference on Malignant Lymphoma (ICML). Data among patients in the single-agent cerdulatinib arm demonstrated consistent clinical activity (including a 45% objective response rate) and good tolerability of cerdulatinib with no evidence of cumulative toxicity. The combination of cerdulatinib with rituximab resulted in improved response rates (including a 62% objective response rate) with a similar safety profile when compared to the data from the single-agent cerdulatinib arm. Follow-up analysis of these cohorts is ongoing. In addition to our planned registration study in PTCL, we remain focused on development in cutaneous T-cell lymphoma and are exploring potential paths to approval in these diseases.

Other early stage programs

We continue to progress certain early discovery activities that align with our scientific expertise. During the second quarter of 2019, we decided to curtail efforts associated with our in-license agreement with SRX Cardio LLC and opted out of our cost sharing arrangement with Ora, Inc. for the development of PRT2761.

Critical accounting policies and significant judgments and estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles, ("U.S. GAAP"). The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the condensed consolidated financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no significant or material changes in our critical accounting policies during the six months ended June 30, 2019, as compared to those disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations-Critical Accounting Policies and Significant Judgments and Estimates" in our Annual Report on Form 10-K for the year ended December 31, 2018 filed with the SEC on March 1, 2019.

Recent Accounting Pronouncements

See Note 2 to the Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for information regarding recent accounting pronouncements.

Results of operations

Comparison of the three and six months ended June 30, 2019 and 2018

Revenue

	Three Months Ended June 30,				Six Months Ended June 30,			
	2019	2018	Change	% Change	2019	2018	Change	% Change
	(in thousands, except percentages)							
Andexxa	$ 27,090	$ 2,232	$ 24,858	1114%	$ 47,375	$ 2,232	$ 45,143	2023%
Bevyxxa	74	33	41	124%	151	639	(488)	(76%)
Total product revenue, net	27,164	2,265	24,899	1099%	47,526	2,871	44,655	1555%
Total collaboration and license revenue	1,260	1,746	(486)	(28%)	3,067	7,784	(4,717)	(61%)
Total revenues	$ 28,424	$ 4,011	$ 24,413	609%	$ 50,593	$ 10,655	$ 39,938	375%

The increase in total revenues during the three months ended June 30, 2019 compared to the three months ended June 30, 2018 was primarily attributable to:

- commercial product revenue earned from U.S. net sales of Andexxa, which we began shipping to customers in May 2018 and more broadly in January 2019 following the FDA approval of our Gen 2 manufacturing process; offset by
- a decrease in Phase 3 collaboration revenue from certain collaboration partners as related performance obligations have been mostly fulfilled by the first quarter of 2019.

The increase in total revenues during the six months ended June 30, 2019 compared to the six months ended June 30, 2018 was primarily attributable to:

- commercial product revenue earned from U.S. net sales of Andexxa, which we began shipping to customers in May 2018 and more broadly in January 2019 following the FDA approval of our Gen 2 manufacturing process; offset by a decrease of Bevyxxa product revenue; further offset by
- a decrease in Phase 3 collaboration revenue from certain collaboration partners, as related performance obligations have been mostly fulfilled by the first quarter of 2019.

Cost of Sales

	Three Months Ended June 30,				Six Months Ended June 30,			
	2019	2018	Increase	% Increase	2019	2018	Increase	% Increase
	(in thousands, except percentages)							
Cost of sales	$ 4,991	$ 1,052	$ 3,939	374%	$ 12,141	$ 1,388	$ 10,753	775%

During the three and six months ended June 30, 2019 and 2018, we recognized $4.9 million and $12.1 million, respectively, of cost of sales related to Andexxa and Bevyxxa. The increase is primarily attributable to a full six months of Andexxa Gen 1 product sales in 2019. Prior to the approvals of our approved products, manufacturing and related costs were expensed; accordingly, these costs were not capitalized and, as a result, are not fully reflected in the cost of sales during the current period. Cost of product sales consists of certain finish costs incurred after FDA approvals related to approved products sold, in addition to certain distribution and overhead costs. We expect costs of sales to increase in relation to product revenues as we deplete inventories that we had expensed prior to receiving our FDA approvals.

Research and development expenses

Product candidate	Phase of Development	Three Months Ended June 30, 2019	2018	Change	% Change	Six Months Ended June 30, 2019	2018	Change	% Change
Andexanet alfa	Phase 2/3/4	$ 18,224	$ 51,144	$ (32,920)	(64%)	$ 43,114	$ 97,030	$ (53,916)	(56%)
Betrixaban	Phase 1/3	815	5,147	(4,332)	(84%)	1,381	13,436	(12,055)	(90%)
Cerdulatinib	Phase 1/2a	9,000	6,946	2,054	30%	16,197	11,393	4,804	42%
Other research and development expenses(1) (2)		5,499	3,203	2,296	72%	8,430	4,648	3,782	81%
Total research and development expenses		$ 33,538	$ 66,440	$ (32,902)	(50%)	$ 69,122	$ 126,507	$ (57,385)	(45%)

(1) Amounts in all periods include costs for other potential product candidates.

(2) Includes the $3.2 million impairment charge related to the in-process research and development intangible asset resulting from the abandonment of the SRX Cardio program during the second quarter of 2019. See Note 7, "Asset Acquisition and License Agreements", to the Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for further information.

The program-specific expenses summarized in the table above include costs directly attributable to our product candidates. We allocate research and development salaries, benefits, stock-based compensation and indirect costs to our product candidates on a program-specific basis, and we include these costs in the program-specific expenses.

The decrease in research and development expenses during the three and six months ended June 30, 2019 and 2018 was primarily attributable to:

- decreased program costs related to Andexxa, which was largely the result of capitalizing manufacturing expenses that were recorded as research and development expenses in 2018; and
- decreased program costs related to Bevyxxa, which was the result of overall decreased spending; offset by
- increased program costs related to 1) cerdulatinib, primarily due to increased manufacturing expenses and 2) an impairment charge of $3.2 million due to the abandonment of the SRX Cardio program during the second quarter of 2019.

Selling, general and administrative expenses

	Three Months Ended June 30, 2019	2018	Increase	% Increase	Six Months Ended June 30, 2019	2018	Increase	% Increase
	(in thousands, except percentages)							
Selling, general and administrative expenses	$ 53,855	$ 40,214	$ 13,641	34%	$ 106,889	$ 71,755	$ 35,134	49%

Selling, general and administrative expenses consist primarily of personnel costs, allocated facilities costs and other expenses for outside professional services, including legal, human resources, audit and accounting services and sales and marketing expenses related to commercial launch preparation and execution.

The increase in selling, general and administrative expenses during the three months ended June 30, 2019 compared to the three months ended June 30, 2018 was primarily attributable to:

- increased headcount-related costs of $6.4 million resulting from the hiring of our sales force and supporting commercial functions; and
- increased external costs of $5.7 million associated with commercial and marketing initiatives to support the launch of Andexxa.

The increase in selling, general and administrative expenses during the six months ended June 30, 2019 compared to the six months ended June 30, 2018 was primarily attributable to:

- increased headcount-related costs of $22.9 million resulting from the hiring of our sales force and supporting commercial functions; and

- increased external costs of $10.2 million associated with commercial and marketing initiatives to support the launch of Andexxa.

We expect selling, general and administrative expenses to increase in the future as we incur additional expenses associated with expanding our sales force in the United States and in Europe for our initial launch in select countries, as well as commercial infrastructure initiatives including information technology systems, quality and compliance systems, and personnel support for the organization.

Interest expense

	Three Months Ended June 30,				Six Months Ended June 30,			
	2019	2018	Increase	% Increase	2019	2018	Increase	% Increase
	(in thousands, except percentages)							
Interest expense	$ 8,538	$ 4,104	$ 4,434	108%	$ 15,019	$ 6,685	$ 8,334	125%

The increase in interest expense during the three and six months ended June 30, 2019 compared to the three and six months ended June 30, 2018 was primarily due to:

- An additional $95.0 million of funding received in May 2018 under the Andexxa Royalty Sales Agreement with HCR; and
- An additional $62.5 million of funding received in March 2019 under the Credit Agreement with HCR and Athyrium.

Liquidity and capital resources

Due to our significant research and development and selling, general and administrative expenditures, we have generated significant operating losses since our inception. We have financed our operations primarily through sales of our equity securities, collaborations, including loans from our collaboration partners, a royalty-based financing arrangement, a secured term loan and sales of commercial and development rights to some of our product candidates. Our expenditures are primarily related to the global launch of Andexxa, including manufacturing and clinical trial costs required to satisfy post-marketing commitments required by the FDA and EMA, as well as research and development activities, including clinical trial costs associated with Andexxa label expansion and advancing our other product candidates. At June 30, 2019, we had cash, cash equivalents and investments of $273.9 million which includes the $31.3 million minimum cash holdings required by our secured term loan agreement (See Note 8, “Long Term Obligations”, to these Condensed Consolidated Financial Statements). Our cash, cash equivalents and investments are held in a variety of interest-bearing instruments, including investments backed by U.S. government agencies, corporate debt securities and money market accounts. Cash in excess of immediate requirements is invested with a view toward liquidity and capital preservation, and we seek to minimize the potential effects of concentration and degrees of risk.

We believe that our existing capital resources, together with interest thereon, will be sufficient to meet our projected operating requirements for at least the next 12 months from the date of this filing. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for product development and commercialization sooner than planned. We currently have no credit facility or committed sources of capital other than the second tranche funding from the Credit Agreement with HCR and Athyrium and potential milestones receivable under our current collaboration and license agreements. Our future funding requirements will depend on many factors, including the following:

- the timing, receipt and amount of sales, profit sharing or royalties, if any, from our current and potential products;
- the cost of manufacturing our current products and product candidates, including process improvements in order to manufacture product candidates at commercial scale, and establishing commercial supplies of our product candidates;
- the cost and timing of establishing sales, marketing and distribution capabilities in the United States and abroad;
- the terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- the receipt of any collaboration payments;
- the number and characteristics of product candidates that we pursue;
- the cost, timing and outcomes of regulatory approvals;

- the scope, rate of progress, results and cost of our clinical studies, preclinical testing and other related activities;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions; and
- partnerships and other strategic options for our products and product candidates.

If we need to raise additional capital to fund our operations, funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our clinical studies, research and development programs or commercialization efforts. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. To the extent that we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to additional covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

The following table summarizes our cash flows for the periods indicated:

	Six Months Ended June 30,	
	2019	2018
	(in thousands)	
Cash used in operating activities	$ (117,700)	$ (180,309)
Cash provided by investing activities	89,589	68,568
Cash provided by financing activities	75,806	103,082
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(43)	-
Net (decrease) increase in cash, cash equivalents and restricted cash	$ 47,652	$ (8,659)

Cash used in operating activities

Cash used in operating activities for the six months ended June 30, 2019 includes payments made to our contract manufacturing organizations for the manufacture of Andexxa and Bevyxxa, totaling $26.9 million and $1.1 million, respectively, $84.5 million of disbursements to third-party vendors to support research and development and selling and general and administrative operations, and $47.2 million in payroll and related employee costs. These cash outflows were partially offset by cash receipts of $44.1 million associated with Andexxa commercial sales and $6.8 million from our Andexxa collaboration agreements.

Cash used in operating activities for the six months ended June 30, 2018 includes payments made to our contract manufacturing organizations for the manufacture of Andexxa and Bevyxxa totaling $76.5 million and $7.6 million, respectively, $71.4 million of disbursements to third-party vendors to support planned research and development and selling and general and administrative operations, and $36.5 million in payroll and related employee costs. These cash outflows were partially offset by cash receipts of $16.7 million, which was primarily from $12.8 million in receipts from our Andexxa collaboration agreements and the receipt of $3.8 million associated with a milestone earned pursuant to our out-license of cerdulatinib in topical formulation.

Cash provided by investing activities

Cash provided by investing activities for the six months ended June 30, 2019 was primarily related to proceeds from maturities of investments of $167.2 million, partially offset by investment purchases of $76.8 million and fixed asset purchases of $0.8 million.

Cash provided by investing activities for the six months ended June 30, 2018 was primarily related to proceeds from maturities of investments of $236.8 million, partially offset by investments of $166.9 million and fixed asset purchases of $1.3 million.

Cash provided by financing activities

Cash provided by financing activities for the six months ended June 30, 2019 was primarily related to net proceeds from debt issuance of $59.2 million and $16.6 million in net proceeds from the issuance of common stock pursuant to equity awards.

Cash provided by financing activities was $103.1 million for the six months ended June 30, 2018, was primarily related to net proceeds from debt issuance of $95.0 million and $8.2 million in net proceeds from the issuance of common stock pursuant to equity awards.

Off-balance sheet arrangements and contractual obligations

In March 2019, we received $62.5 million of funding from HCR and Athyrium pursuant to the Credit Agreement. We have access to the second tranche of $62.5 million at our option which will be available until November 15, 2019 if we receive all regulatory approvals from the EMA for Ondexxya and achieve a revenue goal of $50.0 million for the nine-months period ended September 30, 2019. See Note 8, "Long Term Obligations", to the Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for further information regarding this obligation.

In June 2019, we renewed one operating lease for our office facilities. See Note 11, "Leases", to the Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for further information regarding the lease renewal.

There were no material changes during the six months ended June 30, 2019 outside of the ordinary course of business, and other than pursuant to the above-mentioned Credit Agreement with HCR and Athyrium and the lease renewal, in our specified contractual obligations as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on March 1, 2019.

ITEM 3: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of our investment activities is to preserve our capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality. As of June 30, 2019, we had cash, cash equivalents and investments of $273.9 million consisting of cash and liquid investments deposited in highly-rated financial institutions in the United States. A portion of our investments may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our investments are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio. We actively monitor changes in interest rates.

We contract for the conduct of certain clinical development, manufacturing, regulatory and commercialization activities with vendors in Europe. We made payments in the aggregate amount of €18.9 million and €54.7 million to our European vendors during the six months ended June 30, 2019 and 2018, respectively. We are subject to exposure due to fluctuations in foreign exchange rates in connection with these agreements and with our cash balance denominated in Euros and British Pounds, to a lesser extent. For the six months ended June 30, 2019 and 2018, respectively, the effect of the exposure to these fluctuations in foreign exchange rates was not material.

ITEM 4: CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the rules and regulations thereunder, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our President and Chief Executive Officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) under the Exchange Act, our management, under the supervision and with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of June 30, 2019. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of June 30, 2019, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal controls over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended June 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

Item 1A. RISK FACTORS.

Investing in our common stock involves a high degree of risk. You should consider carefully the following risks, together with all the other information in this report, including our financial statements and notes thereto, before you invest in our common stock. If any of the following risks actually materializes, our operating results, future prospects, financial condition and liquidity could be materially adversely affected. As a result, the trading price of our common stock could decline and you could lose part or all of your investment.

In assessing these risks, you should also refer to other information contained in this quarterly report on Form 10-Q, including our Condensed Consolidated Financial Statements and related Notes. We have marked with an asterisk (*) those risks described below that reflect substantive changes from, or additions to, the risks described in our annual report on Form 10-K for the year ended December 31, 2018.

1) RISKS RELATED TO OUR FINANCIAL CONDITION AND NEED FOR ADDITIONAL CAPITAL

We have incurred significant operating losses, and expect to incur substantial losses in the near term as we continue to develop and commercialize our products and product candidates.

We are an early stage commercial biopharmaceutical company. We launched our two commercial products in 2018 and continue to incur significant expenses related to commercialization, our ongoing and planned future clinical studies, research and development activities, and selling, general and administrative activities. As of June 30, 2019, we had an accumulated deficit of approximately $1.7 billion.

To date, we have financed our operations primarily through sales of our equity securities, collaborations, including a loan from one of our collaboration partners, a sale of a royalty stream from future product sales, a term loan, sales of commercial and development rights to some of our product candidates, and to a lesser extent, government grants, equipment leases, venture debt and with the benefit of tax credits made available under a federal stimulus program supporting drug development. We have devoted substantially all of our efforts to product commercialization, research and development, including manufacturing and clinical studies. We anticipate that we will continue to incur substantial expenses as we:

- establish and scale-up manufacturing capabilities and a sales, marketing and distribution infrastructure to commercialize our products in the U.S. and abroad;
- initiate or continue clinical studies, including a post-marketing randomized controlled trial of Andexxa;
- continue the research and development of our product candidates;
- seek to discover or in-license additional product candidates;
- seek regulatory approvals for our product candidates that successfully complete clinical studies; and
- enhance operational, compliance, financial, quality and information management systems.

To be profitable in the future, we must succeed in commercializing our products and developing and commercializing other products with significant market potential. This will require us to be successful in a range of activities, including manufacturing, marketing and selling our products and any other products for which we may obtain regulatory approval, obtaining additional regulatory approvals and successfully completing clinical studies. We are only in the preliminary stages of some of these activities. We may not succeed in these activities and may never generate revenue that is sufficient to be profitable in the future. Even if we are profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to achieve sustained profitability would depress the value of our company and could impair our ability to raise capital, expand our business, diversify our product candidates, market our product candidates, if approved, or continue our operations.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our operating results are difficult to predict and will likely fluctuate from quarter to quarter and year to year. Due to the recent approval by the FDA and/or the EC of our products and the absence of historical sales data, our product sales will be difficult to predict from period to period and as a result, you should not rely on sales results in any period as being indicative of future performance and sales may be below the expectation of securities analysts or investors in the future. We believe that our quarterly and annual results of operations may be affected by a variety of factors, including:

- the level of demand and market acceptance;
- the results of our clinical trials;
- our abilities to obtain desired regulatory approvals in the U.S., EU and other foreign jurisdictions;
- the extent to which coverage and reimbursement is available from government and health administration authorities, private health insurers, managed care programs and other third-party payors;
- rebates, discount, other pricing concessions and fees that we may provide to integrated delivery networks, group purchasing organizations, other purchasers and pharmacy benefits managers and other third-party payors;
- the timing, cost and level of investment in our marketing efforts to support sales;
- the timing, cost and level of investment in our research and development activities involving approved products and product candidates;
- the cost of manufacturing, distribution and the amount of legally mandated discounts to government entities, other discounts and rebates, product returns and other gross-to-net deductions;
- the risk/benefit profile, cost and reimbursement of existing and potential future drugs which compete with approved products;
- the timing and amount of non-cash items such as stock compensation expenses, reserves, cost of goods sold and non-recurring charges such as inventory write-offs; and
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

We will need additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all, which would force us to delay, reduce or suspend our research and development programs and other operations or commercialization efforts. Raising additional capital may subject us to unfavorable terms, cause dilution to our existing stockholders, restrict our operations, reduce future profitability or require us to relinquish rights to our product candidates and technologies.

We will continue to require substantial funds to support commercial operations and pursue further research and development efforts. Our financing requirements will depend on many factors, some of which are beyond our control, including the following:

- product sales of Andexxa and Ondexxya, and if approved for commercial marketing, our product candidates;
- the costs of commercialization activities, including product sales, marketing, manufacturing and distribution and general corporate and commercial infrastructure;
- the costs and timing of international expansion;
- the timing of, and costs involved in, seeking and obtaining approvals from the FDA and other regulatory authorities;
- the possible development of additional product candidates, including through in-licensing and acquisitions;
- the degree and rate of market acceptance of any products launched by us or partners;

- our ability to enter into additional collaboration, licensing, commercialization or other financing arrangements and the terms and timing of such arrangements;
- the rate of progress and cost of our clinical studies; and
- the emergence of competing technologies or other adverse market developments.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other financing, marketing and distribution arrangements. Additional financing may not be available to us when we need it or it may not be available on favorable terms.

If we raise additional capital through financing, marketing and distribution arrangements or other collaborations, strategic alliances, licensing or other financial arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and our repayment obligations may reduce future financial performance. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, or suspend one or more of our clinical studies, research and development programs or commercialization efforts.

Our obligations under our credit facility are secured by substantially all of our assets, so if we default on those obligations, the lenders could foreclose on our assets. As a result of these security interests, such assets would only be available to satisfy claims of our general creditors or to holders of our equity securities if we were to become insolvent at a time when the value of such assets exceeded the amount of our indebtedness and other obligations. Additionally, our credit facility contains restrictions and limitations that could significantly affect our ability to operate our business.

Pursuant to the Credit Agreement by and among us, the guarantor and lenders ("Lenders") party thereto, and HCR Collateral Management, LLC, as Administrative Agent, dated February 28, 2019 (the "Credit Facility"), the Administrative Agent, in its capacity as Collateral Agent for the Lenders, has been granted a security interest in substantially all of our assets. As a result, if we default under our obligations to the Lenders, the Collateral Agent could foreclose on its security interest and liquidate some or all of these assets, which would harm our business, financial condition and results of operations.

In the event of a default in connection with our bankruptcy, insolvency, liquidation, or reorganization, the Collateral Agent would have a prior right to substantially all of our assets to the exclusion of our general unsecured creditors. In that event, our assets would first be used to repay in full all indebtedness and other obligations under the Credit Facility, resulting in all or a portion of our assets being unavailable to satisfy the claims of any unsecured indebtedness. Only after satisfying the claims of the Lenders and any unsecured creditors would any amount be available for our equity holders. Events of default under the Credit Facility include, among other things, our failure to pay any amounts due under the Credit Facility or any of the other loan documents, a breach of covenants under the Credit Facility, our insolvency, a material adverse effect occurring, the occurrence of certain defaults under certain other indebtedness for which we are obligated or certain final judgments against us.

The pledge of these assets and other restrictions imposed in the Credit Facility may limit our flexibility in raising capital for other purposes. Because substantially all of our assets are pledged to secure the Credit Facility obligations, our ability to incur additional secured indebtedness or to sell or dispose of assets to raise capital may be impaired, which could have an adverse effect on our financial flexibility.

If we are unable to comply with certain financial and operating restrictions in the Credit Facility, we may be limited in our business activities and access to credit or may default under the Credit Facility.

Provisions in the Credit Facility impose restrictions or require prior approval on our ability, and the ability of certain of our subsidiaries to, among other things:

- Incur additional debt;
- Make certain investments and acquisitions;
- Guarantee the indebtedness of others or our subsidiaries;

- Create liens or encumbrances;
- Engage in new lines of business;
- Enter into transactions with affiliates;
- Pay cash dividends and make distributions;
- Redeem or repurchase capital shares;
- Sell, lease or transfer certain parts of our business or property;
- Prepay other indebtedness; and
- Acquire new companies and merge or consolidate.

The Credit Facility also contains other customary covenants, including covenants that require us to maintain a minimum cash balance of up to $50 million, dependent on borrowings and levels of sales of Andexxa. We may not be able to comply with these covenants in the future. Our failure to comply with these covenants may result in the declaration of an event of default, which, if not cured or waived, may result in the acceleration of the maturity of indebtedness outstanding under the Credit Facility and would require us to pay all amounts outstanding. If the maturity of our indebtedness is accelerated, we may not have sufficient funds then available for repayment or we may not have the ability to borrow or obtain sufficient funds to replace the accelerated indebtedness on terms acceptable to us or at all. Our failure to repay our indebtedness would result in the Collateral Agent foreclosing on all or a portion of our assets and possibly force us to curtail or cease our operations.

2) RISKS RELATED TO COMMERCIAL AND MARKETING OPERATIONS AND THE DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCTS AND PRODUCT CANDIDATES

Our products may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Our success depends heavily on the launch and commercialization of our products. The commercial success of our products will depend upon their acceptance by the medical community and third-party payors as clinically useful, cost-effective and safe. The degree of market acceptance of any drug depends on a number of factors, such as:

- the prevalence and severity of any side effects;
- efficacy and potential advantages compared to alternative treatments;
- the price we charge for our products;
- interpretations of the results of our clinical trials;
- the willingness of physicians and healthcare organizations to change their current treatment practices;
- the willingness of hospitals and hospital systems to include our products as treatment options;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the willingness of the target patient population to pay for our products, including co-pays under their health coverage plans;
- the strength of marketing and distribution support; and
- the availability of third-party coverage and adequate reimbursement.

Failure to attain market acceptance among the medical community and third-party payors may have an adverse impact on our operations and profitability. If we are not successful in commercializing Andexxa, our future product revenue will suffer, we may incur significant additional losses and our business will be materially harmed.

If we are unable to develop effective sales, marketing and distribution capabilities on our own or through collaborations or other marketing partners, we will not be successful in commercializing our products or our other future products.

We are still in the early stages of developing our sales and marketing infrastructure. To achieve commercial success for our products or any current or potential product candidate, we must continue to develop a sales and marketing organization or outsource these functions to third parties. We plan to market expand our hospital-based sales force in other major markets and work with partners in other parts of the world to commercialize our products globally. There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services.

We also may not be successful entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively, which could damage our reputation. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

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

The development and commercialization of new therapeutic products is highly competitive. We face competition with respect to commercializing our products and developing our current product candidates, and we will face competition with respect to any products that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide.

While there are no therapies other than Andexxa approved specifically as antidotes for Factor Xa inhibitors, we are aware of at least one drug candidate that has been studied in early stage clinical trials as a potential antidote to Factor Xa inhibitors. In addition, Andexxa may compete with the off-label use of other treatments designed to enhance coagulation, such as Fresh Frozen Plasma, 4-factor Prothrombin Complex Concentrates, recombinant activated Factor VII or whole blood. Although there is no approved indication for these products in patients taking Factor Xa inhibitors, physicians may choose to use them because of familiarity, cost or other reasons. In addition, we are aware that several companies have conducted preclinical research on compounds intended to be antidotes for Factor Xa inhibitors.

For Bevyxxa, several large pharmaceutical and biotechnology companies currently market and sell direct or indirect anticoagulants for use in various disease states, including injectable anticoagulants for the prevention of VTE in acutely ill medical patients. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Some of these competitors are or may be attempting to develop therapeutics for our target indications.

In addition, most of our competitors are large pharmaceutical companies that will have a greater ability to reduce prices for their competing drugs in an effort to gain or maintain market share and undermine the value proposition that we might otherwise be able to offer to payors. Bevyxxa is indicated for the prophylaxis of VTE in adult patients hospitalized for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors. The current standard of care for VTE prophylaxis in acute medically ill patients in the United States is a 6- to 14-day administration of enoxaparin, marketed as Lovenox and also available in generic form. Enoxaparin is a low cost therapy that is widely accepted by physicians, patients and third-party payors. As a result of this and other factors, we have faced initial difficulties in marketing Bevyxxa in this patient population. Additionally, our competitors may have the financial and other resources to conduct additional clinical studies in an effort to obtain regulatory approval for use of their drugs for VTE prophylaxis in acutely ill medical patients. For example, Bayer and Janssen recently published results from their Phase 3 MARINER clinical trial evaluating the safety and efficacy of rivaroxaban for up to 45 days post hospital discharge (after enoxaparin in hospital) to reduce the risk of symptomatic VTE in medical ill patients. If the results of Bayer and Janssen's clinical studies support a successful path to regulatory approval, Bevyxxa is expected to face increased competition in the marketplace from a drug that would be used as a different treatment strategy (post discharge only) in an overlapping patient population. Such treatment strategy would not require physicians, patients and third-party payors to replace enoxaparin with a new or higher priced therapy in the hospital.

There are also a number of products in clinical development for hematologic cancer, ophthalmological diseases, allergic rhinitis, allergic asthma and other inflammatory or autoimmune diseases that are potential indications for cerdulatinib or selective SYK inhibitors. Our competitors may develop products that are more effective, safer, more convenient or less costly than any that we are developing or that would render our product candidates obsolete or noncompetitive. Many competing products are in later stages of development than our products and, therefore, may obtain FDA or other regulatory approval for their products before we obtain approval for ours.

Many of our competitors, including a number of large pharmaceutical companies that compete directly with us, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our

competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs.

**** We obtained regulatory approval of Andexxa in the United States through an Accelerated Approval process and in the EU under a conditional approval. Continued approval may be contingent upon the results of ongoing patient studies to demonstrate an improvement in hemostasis.***

The Accelerated Approval regulations allow drugs that are being developed to treat an unmet medical need to be approved substantially based on evidence of an effect on a biomarker endpoint that is considered reasonably likely to predict clinical benefit rather than a clinical endpoint such as survival or irreversible morbidity. Our approval of Andexxa was supported by data from two Phase 3 ANNEXA studies (ANNEXA-R and ANNEXA-A), which evaluated the safety and efficacy of Andexxa in reversing the anticoagulant activity of the Factor Xa inhibitors rivaroxaban and apixaban in healthy volunteers, and interim patient data from our ongoing ANNEXA-4 single-arm, open-label study in patients on a Factor Xa inhibitor experiencing a life threatening or uncontrolled bleeding episode. However, these studies have inherent limitations as compared with a randomized controlled trial. As a condition to approval, the FDA and EMA have required us to conduct a post-marketing randomized controlled trial of Andexxa. This trial will randomize patients to receive either Andexxa or the type of care the enrolling institution would provide in the absence of Andexxa. This study has been opened to enrollment and we expect it to be reported in 2023. We expect the practical implementation and ethical considerations of a randomized controlled trial for Andexxa to present challenges, and we cannot be sure that we will be able to successfully conduct and enroll such a trial in a manner satisfactory, or within the time period required by the FDA and EMA. In addition to the post-marketing study, the EMA has also requested the final study reports for the Annexa-4 study and additional pharmacokinetic data. Further, if the randomized controlled trial is not successful, the FDA and/or EMA could modify or withdraw our marketing approval for Andexxa.

If clinical studies of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our future product candidates.

Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive clinical studies to demonstrate the safety and efficacy of our product candidates in humans. Clinical studies are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. A failure of one or more of our clinical studies could occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, clinical studies that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including the following:

- the number of patients required for clinical studies of our product candidates may be larger than we anticipate, enrollment in these clinical studies may be insufficient or slower than we anticipate or patients may drop out of these clinical studies at a higher rate than we anticipate;
- clinical studies of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs;
- the cost of clinical studies or the manufacturing of our product candidates may be greater than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical studies of our product candidates for various reasons, including unanticipated serious side effects, other unexpected characteristics or unacceptable health risks;
- regulators may not approve our proposed clinical development plans;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical study or conduct a clinical study at a prospective study site;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical studies of our product candidates may be insufficient or inadequate.

If we are required to conduct additional clinical studies or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical studies of our product candidates or other testing, if the results of these studies or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;

- not obtain marketing approval at all;
- obtain approval for indications that are not as broad as intended;
- have the product removed from the market after obtaining marketing approval;
- be subject to additional post-marketing testing requirements; or
- be subject to restrictions on how the product is distributed or used.

Our product development costs may also increase if we experience delays in testing or approvals. We do not know whether any anticipated clinical studies will begin as planned, or whether anticipated or ongoing clinical studies will need to be restructured or will be completed on schedule, or at all. Significant clinical study delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to commercialize our product candidates and harm our business and results of operations.

**** Failure to obtain regulatory approvals in foreign jurisdictions will prevent us from marketing our products internationally. Following the negative decision by the European Commission, we will not obtain marketing approval to commercialize Bevyxxa in the EU at this time, or potentially ever.***

In order to market Bevyxxa or our future products in the European Economic Area ("EEA"), and many other foreign jurisdictions, we must obtain separate regulatory approvals. Specifically, in the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization ("MA"). Before granting the MA, the EMA or the competent authorities of the member states of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

The approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Clinical studies conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. In addition, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to submit for regulatory approvals and even if we submit we may not receive necessary approvals to commercialize our products in any market.

In March 2018, the CHMP issued a negative opinion, recommending that the EMA reject the marketing application for Bevyxxa in the EU. We requested a re-examination of the initial opinion and in July 2018, we received a negative re-examination opinion from the CHMP. The European Commission adopted the CHMP decision in September 2018. Failure to obtain marketing approval of Bevyxxa in the EU will reduce the commercial potential of Bevyxxa and could also have a negative impact on our efforts to commercialize and obtain market acceptance for Bevyxxa in the U.S. market.

If serious adverse side effects are identified with respect to any of our product candidates or either of our approved products, we may need to abandon our development of that product candidate or discontinue sale of that product.

It is impossible to guarantee when or if any of our product candidates will prove safe enough to receive regulatory approval. In addition, there can be no assurance that our clinical studies will identify all relevant safety issues. Known or previously unidentified adverse side effects can adversely affect regulatory approvals or marketing of approved products. In such an event, we might need to abandon marketing efforts or development of that product or product candidate or enter into a partnership to continue development.

While no serious adverse side effects have been observed in our completed healthy subject studies with Andexxa, adverse effects have been observed in our ANNEXA-4 study in bleeding patients. Additionally, there is a risk that adverse events may be reported in our post-marketing randomized controlled trial of Andexxa, additional clinical experience or repeat doses that are determined to have been caused by Andexxa. Some protein-based biologics have encountered problems with immunogenicity, that is, their tendency to trigger an unwanted immune response against themselves. To date, no neutralizing antibodies against Andexxa or antibodies to Factor X or Xa have been detected; however there is still a risk that such antibodies could be identified through our ANNEXA-4 patient study results, additional clinical experience or from repeat doses. In addition, in our ANNEXA-4 patient trial, reversing the anticoagulant activity of Factor Xa inhibitors in patients with life threatening or uncontrolled bleeding who have underlying medical conditions requiring anticoagulation has been associated with thromboembolic events, ischemic events, cardiac arrest and sudden deaths, and the FDA has included a boxed warning in the Andexxa label to this effect.

Bevyxxa, like all currently marketed inhibitors of Factor Xa, carries some risk of life-threatening bleeding. In addition, patients taking Bevyxxa in our clinical studies had an increased rate of gastrointestinal issues, such as diarrhea, nausea and vomiting, and other side effects such as back pain, dizziness, headaches, rashes and insomnia as compared to subjects taking a placebo or an active comparator.

If a regulatory agency discovers adverse events of unanticipated severity or frequency it may impose restrictions on that product or us, including requiring withdrawal of the product from the market. Among other legal and administrative actions, a regulatory agency may:

- mandate modifications to product labelling or promotional materials or require us to provide corrective information to healthcare practitioners;
- suspend any regulatory approvals;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us, our partners or our potential future partners;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require a product recall.

In addition, the occurrence of any of the foregoing, even if promptly remedied, could negatively impact the perception of us or the relevant product among the medical community, patients or third-party payors.

Approval of Andexxa is limited to patients treated with rivaroxaban and apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding, and additional clinical studies and regulatory applications will be required to expand Andexxa indications. We can provide no assurances that such clinical studies or regulatory applications will be successful.

We are developing Andexxa as a universal antidote for patients receiving a Factor Xa inhibitor when reversal of anticoagulation is needed, such as in life-threatening or uncontrolled bleeding or for emergency surgery/urgent procedures. Our approval of Andexxa was limited to patients treated with rivaroxaban and apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. Our studies have not yet included patients requiring emergency surgery or urgent procedures and we do not anticipate obtaining this indication without clinical data. We expect that we will also be required to provide additional clinical data to support addition to our label of other Factor Xa inhibitors, including Bevyxxa, edoxaban and enoxaparin. Additional clinical studies will require additional time and expense and may not prove successful. Limitations in our label for Andexxa will reduce the number of patients for whom Andexxa is indicated and could reduce the size of the anticipated market and our financial prospects. In addition, our label for Andexxa includes a boxed warning that treatment with Andexxa has been associated with serious and life-threatening adverse events, thromboembolic events, ischemic events, cardiac arrest and sudden deaths. This boxed warning may adversely impact market acceptance and the commercial potential of Andexxa. There can be no assurance that further clinical experience will provide a basis to remove this boxed warning.

3) RISKS RELATED TO OUR RELIANCE ON THIRD PARTIES

We rely on single source third-party contract manufacturing organizations to manufacture and supply Andexxa, Bevyxxa and our product candidates for us. If one of our suppliers or manufacturers fails to perform adequately or fulfill our needs, we may be required to incur significant costs and devote significant efforts to find new suppliers or manufacturers. We may also face significant delays in the development and commercialization of our product candidates.

We do not own facilities for clinical-scale or commercial manufacturing of our product candidates and we rely on third-party suppliers to manufacture Andexxa, Bevyxxa and our product candidates. For example, we have contracted with Lonza to manufacture Andexxa bulk drug substance and Baxter International, Inc. to manufacture drug product to support our commercial launch. We rely on Hovione, Limited, to manufacture the active pharmaceutical ingredient for Bevyxxa and Patheon Inc. (part of Thermo Fisher Scientific) to manufacture drug product to supply Bevyxxa. We also rely or expect to rely on other third party providers for raw materials, packaging, labeling and supply chain warehousing and distribution. If we and our suppliers cannot agree to the terms and conditions for them to provide the drug supply necessary for our clinical and commercial needs, or if any single source supplier breaches an agreement with us, or terminates the agreement in response to an alleged breach by us or otherwise becomes unable to fulfill its supply obligations, we would not be able to manufacture and distribute the product candidate until a qualified alternative supplier is identified, which could also significantly disrupt, delay the development of, and impair our ability to commercialize, our product candidates. In addition, lead times for our manufacturing and contractual requirements of our third-party manufacturers require us to estimate product demand in advance. If our forecasts are not accurate, we may experience shortfalls or surplus of product. If we do not manufacture enough product, we may experience stock-outs and interruption of supply of our products. If we manufacture a surplus of product, we may experience spoilage from product expiration and incur manufacturing expenses which were not required. We have fixed manufacturing commitments with our third-party manufacturers which are on a “take-or-pay” basis which could require us to pay for manufacturing costs even if we eventually do not need the capacity forecasted at the time we entered into

such commitments. The financial impact of either stock-outs or a product surplus could be significant with respect to financial commitments and the effect on our financial performance.

The manufacture of pharmaceutical products in compliance with U.S. and foreign regulatory manufacturing requirements, requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, quality assurance, including stability of the product candidate and quality control testing, shortages of qualified personnel, as well as compliance with strictly enforced regulatory requirements, other federal and state regulatory requirements and foreign regulations. If our manufacturers were to encounter any of these difficulties or otherwise fail to comply with their obligations to us or under applicable regulations and agreements, our ability to provide the drug supply necessary for our clinical studies and commercial needs would be jeopardized. Any delay or interruption in the supply of clinical study materials could delay the completion of our clinical studies, increase the costs associated with maintaining our clinical study programs and, depending upon the period of delay, require us to commence new studies at significant additional expense or terminate the studies completely.

All manufacturers of our product candidates must comply with regulatory manufacturing requirements enforced by the U.S. and foreign regulatory authorities through their facilities inspection programs. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our product candidates may be unable to comply with these manufacturing requirements and with other FDA, state and foreign regulatory requirements. The FDA or similar foreign regulatory agencies may also implement new standards at any time, or change their interpretation and enforcement of existing standards for manufacturing, packaging or testing of products. We have limited control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure, the ability to import product into countries, or recall or withdrawal of product approval. If the safety of any product supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay or interruption of clinical studies, regulatory submissions, approvals or commercialization of our product candidates, entail higher costs or adversely affect our reputation.

Although alternative sources of supply exist, the number of third-party suppliers with the necessary manufacturing and regulatory expertise and facilities to manufacture biologics is limited, and it could be expensive and take a significant amount of time to arrange for alternative suppliers, which could have a material adverse effect on our business. New suppliers of any product candidate would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing the product candidate. Obtaining the necessary regulatory approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party intellectual property rights could result in a significant interruption of supply and could require the new manufacturer to bear significant additional costs which may be passed on to us.

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

We do not independently conduct clinical studies of our product candidates. We rely on third parties, such as contract research organizations ("CROs"), clinical data management organizations, medical institutions and clinical investigators, to perform this function. Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. We remain responsible for ensuring that each of our clinical studies is conducted in accordance with the general investigational plan and protocols for the study.

Moreover, the regulatory authorities require us to comply with standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical studies to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of patients in clinical studies are protected. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical studies in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully develop our products and our product candidates.

We also rely on other third parties to store and distribute supplies for our clinical studies. Any performance failure on the part of our existing or future distributors could delay clinical development or regulatory approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

We may enter into collaborations that place the development and commercialization of our products and product candidates outside our control, require us to relinquish important rights or may otherwise be on terms unfavorable to us, and if our collaborations are not successful, our product candidates may not reach their full market potential.

We may enter into additional collaboration agreements with third parties with respect to our product candidates for the commercialization of the candidates both inside and outside the United States, or for other purposes. For example, we have out-licensed development and commercial rights to Andexxa in Japan. In addition, depending on our capital requirements, development and commercialization costs, need for additional therapeutic expertise and other factors, it is possible that we will enter into broader development and commercialization arrangements with respect to our product candidates. Our likely collaborators for any distribution, marketing, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We will have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend in part on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to any such collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical study results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical studies, provide insufficient funding for a clinical study program, stop a clinical study, abandon a product candidate, repeat or conduct new clinical studies or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our product candidates or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property.

Any termination or disruption of our collaboration with potential collaborators could result in delays in the development and commercialization of our product candidates, increases in our costs to develop and commercialize the product candidate, or the termination of development of a product candidate.

4) RISKS RELATED TO THE OPERATION OF OUR BUSINESS

Our future success depends on our ability to retain our key executives, and if we are not able to retain these members of our management, or retain or recruit additional management and other key personnel, our business will suffer.

Recruiting and retaining leadership and other key personnel is critical to our success. We are highly dependent on our President and Chief Executive Officer and the other principal members of our executive and leadership teams. We may not be able to attract and retain management and other key personnel in the future, due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Francisco Bay Area. We also may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar

personnel. We also experience competition for the hiring of personnel from universities, research institutions and technology companies. In addition, we rely on consultants and advisors to assist us in formulating our business strategies. Our consultants and advisors may also perform services for companies other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Under the terms of their employment, our executives may terminate their employment with us at any time. The loss of the services of any of these people could impede the achievement of our research, development and commercialization objectives.

We expect to expand our development, regulatory and sales and marketing capabilities in the U.S. and Europe, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, in the U.S. and Europe, particularly in the areas of drug development, regulatory affairs, quality, commercial compliance, medical affairs, and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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

As a public company, we incur significant legal, accounting and other expenses. For example, the Sarbanes-Oxley Act, and rules of the Securities and Exchange Commission ("SEC") and those of The Nasdaq Stock Market, or the Nasdaq, have imposed various requirements on public companies including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel have and will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations are continuously being revised, have increased and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. In addition, we are required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting. Our compliance with Section 404 of the Sarbanes-Oxley Act, as applicable, requires us to incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to continue to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. If we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources.

Our ability to successfully implement our business plan and comply with Section 404 of the Sarbanes-Oxley Act, as applicable, requires us to be able to prepare timely and accurate financial statements. We expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our auditors as required under Section 404 of the Sarbanes-Oxley Act. 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, and current and potential stockholders may lose confidence in our financial reporting. This, in turn, could have an adverse impact on trading prices for our common stock, and could adversely affect our ability to access the capital markets.

Product liability lawsuits and claims against us could cause us to incur substantial liabilities and could limit product sales.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical studies, and the commercial manufacturing, distribution and sale of Andexxa and Bevyxxa. For example, the manufacturers of currently marketed Factor Xa inhibitors and other manufacturers of anticoagulants have faced substantial litigation due to certain alleged bleeding risks.

In addition, in our ANNEXA-4 patient trial, reversing the anticoagulant activity of Factor Xa inhibitors in patients with underlying medical conditions requiring anticoagulation has been associated with thromboembolic events, ischemic events, cardiac arrest and sudden deaths, and the FDA has included a boxed warning in the Andexxa label to this effect. If we cannot successfully defend ourselves against claims that Andexxa, Bevyxxa or our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation and significant negative media attention;
- withdrawal of patients from clinical studies or cancellation of studies;
- significant costs to defend the related litigation;
- substantial monetary awards to patients;
- loss of revenue; and
- the inability to commercialize any additional products that we may develop.

We may not have sufficient insurance coverage for future product liability claims. We may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation in the industry, significantly increase our expenses, and reduce product sales. Product liability claims in excess of our insurance coverage would be paid out of cash reserves, harming our financial condition and operating results.

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

Because we have limited financial and managerial resources, we focus on sales, marketing and research programs and products and product candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other products or product candidates or other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products.

If we do not accurately evaluate the commercial potential or target market for a particular product or product candidate, we may relinquish valuable rights through collaboration, licensing, or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials. In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

Our operations could be subject to earthquakes, power shortages, telecommunications failures, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions. The occurrence of

any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our corporate headquarters is located in California near major earthquake faults. Our operations and financial condition could suffer in the event of a major earthquake, fire or other natural or manmade disaster.

A variety of risks associated with international operations could materially adversely affect our business. If any product candidates that we may develop are approved for commercialization outside the United States, we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price control;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

In connection with our Andexxa and Bevyxxa development and commercialization, we are currently utilizing certain suppliers outside of the United States, which subjects us to certain of the above risks.

We may be subject to information technology system failures, network disruptions and breaches in data security.

We are increasingly dependent upon information technology systems and infrastructure to conduct critical operations and generally operate our business, which includes using information technology systems to process, transmit and store electronic information in our day-to-day operations, including customer, employee and company data. The size and complexity of our computer systems make them potentially vulnerable to breakdown, malicious intrusion and random attack. We also store certain information with third parties. Our information systems and those of our third-party vendors are subjected to computer viruses or other malicious codes, unauthorized access attempts, and cyber- or phishing-attacks and also are vulnerable to an increasing threat of continually evolving cybersecurity risks and external hazards. Disruption, degradation, or manipulation of these systems and infrastructure through intentional or accidental means could impact key business processes. Cyber-attacks against the Company's systems and infrastructure could result in exposure of confidential information, the modification of critical data, and/or the failure of critical operations. Likewise, improper or inadvertent employee behavior, including data privacy breaches by employees and others with permitted access to our systems, may pose a risk that sensitive data may be exposed to unauthorized persons or to the public. Any such breach could compromise our networks, and the information stored therein could be accessed, publicly disclosed, lost or stolen. Such attacks could result in our intellectual property and other confidential information being lost or stolen, disruption of our operations, and other negative consequences, such as increased costs for security measures or remediation costs, and diversion of management attention. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical study data from completed or ongoing clinical studies for any of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed. In addition, with planned operations in EU, we will need to comply with the General Data Protection Regulation ("GDPR") provisions relating to personal data, use of third party processors, data breach notifications and transfer of personal data out of the EU to the United States. The GDPR imposes large penalties for noncompliance and has the potential to increase our responsibility and liability in relation of personal data that we process, including in clinical trials, and we are required to put in place and maintain additional mechanisms to ensure compliance with the GDPR, including increased company and vendor technology and data management measures and cybersecurity investments.

5) RISKS RELATED TO INTELLECTUAL PROPERTY

If we fail to comply with our obligations in our intellectual property licenses from third parties, we could lose license rights that are important to our business.

We are a party to intellectual property license agreements with third parties, including with respect to Bevyxxa, cerdulatinib, and other early stage programs, and we expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that our future license agreements will impose, various supply, support, diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate these agreements or pursue other remedies, in which event we may not be able to develop and market any product that is covered by these agreements or be liable for damages. Termination of licenses or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms or our not having sufficient intellectual property rights to operate our business. The occurrence of such events could materially harm our business.

Our ability to successfully commercialize our technology and products may be materially adversely affected if we are unable to obtain and maintain effective intellectual property rights for our technologies and product candidates.

Our success depends in large part on our and our licensors' ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and products. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or products that we license from third parties. Therefore, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. In addition, if our current or future licensors, licensees, or collaboration partners fail to establish or maintain such patents and other intellectual property rights, or lose rights to those patents and other intellectual property rights, such rights may be reduced or eliminated.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and products that are important to our business. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technologies or from developing competing products and technologies.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unresolved. In recent years patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued that protect our technology or products or that effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa. Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned and licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

The Leahy-Smith America Invents Act, or the America Invents Act ("AIA") implemented significant changes to United States patent law. The AIA could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We have been and may again become involved in opposition, derivation, reexamination, *inter partes review*, post-grant review, or other proceedings challenging our patent rights or the patent rights of our licensors, and the outcome of any proceedings are highly uncertain. For example, in November 2013, Zentiva k.s. and Günter SÖLCH separately filed papers with the European Patent Office opposing European Patent 2101760, assigned to Millennium to which we have an exclusive license. The European Patent Office decided in favor of revoking the European patent. Portola has appealed this revocation. Should any of these proceedings or appeals be unsuccessful, this could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner, or by successfully seeking to narrow or invalidate our patents or render them unenforceable. The issuance of a patent is not conclusive as to its inventorship scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us, and may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our owned or licensed U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. Similar extensions as compensation for patent term lost during regulatory review processes are also available in certain foreign countries and territories, such as in Europe under a Supplementary Patent Certificate. However, we may not be granted an extension in the United States and/or foreign countries and territories because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, 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. For example, we have applied for patent term extensions at the U.S. Patent and Trademark Office (USPTO) within the applicable deadline after receiving approval for Andexxa and Bevyxxa, but have not yet received a final determination. If we are unable to obtain patent term extension or the term of any such extension is shorter than what we request or we fail to choose the most optimal patents to extend, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

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

Competitors or other parties may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. 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, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our products and product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights or intellectual property of third parties. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding third party intellectual property rights with respect to our products, product candidates, and technology, including interference proceedings before the USPTO. An interference proceeding is a proceeding before the USPTO to determine the priority among multiple patents or patent applications. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. Any litigation involving defense against claims of infringement, misappropriation or other violation of proprietary or intellectual property rights, regardless of the merit of such claims, would involve substantial litigation expense and would be a substantial diversion of management time. If we are found to infringe a third-party's intellectual property rights, we could be required to pay substantial damages, including treble damages and attorneys' fees if we are found to be willfully infringing a third party's patents. We may also be required to indemnify parties with whom we have contractual relationships against such claims. If a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. We also could be required to

obtain a license from such third-party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all.

Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. A finding of infringement could prevent us from commercializing our products or product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business.

We may be unable to protect the confidentiality of our trade secrets, thus harming our business and competitive position.

In addition to our patented technology and products, we rely upon trade secrets, including unpatented know-how, technology and other proprietary information to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and consultants that obligate them to assign their inventions to us. However, it is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees, consultants or collaborators that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could be disclosed, misappropriated or otherwise become known or be independently discovered by our competitors. In addition, intellectual property laws in foreign countries may not protect our intellectual property to the same extent as the laws of the United States. If our trade secrets are disclosed or misappropriated, it would harm our ability to protect our rights and have a material adverse effect on our business.

We may be subject to claims that our employees have wrongfully used or disclosed intellectual property of their former employers. Intellectual property litigation or proceedings could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property-related proceedings could have a material adverse effect on our ability to compete in the marketplace.

6) RISKS RELATED TO GOVERNMENT REGULATION

The regulatory approval process is expensive, time consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. We will not be permitted to market our product candidates in the United States until we receive approval of an NDA or a BLA, from the FDA. Obtaining approval of an NDA or BLA can be a lengthy, expensive and uncertain process that may not be successful. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including the following:

- warning letters;
- civil or criminal penalties and fines;
- injunctions;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical studies;

- voluntary or mandatory product recalls and publicity requirements;
- refusal to accept or approve applications for marketing approval of new drugs or biologics or supplements to approved applications submitted by us;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of our products or import bans.

Prior to receiving approval to commercialize any of our product candidates in the United States or abroad, we must demonstrate with substantial evidence from well-controlled clinical studies, and to the satisfaction of the FDA and other regulatory authorities abroad, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical studies can be interpreted in different ways. Even if we and our collaboration partners believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering any of our product candidates to humans may produce undesirable side effects, which could interrupt, delay or cause suspension of clinical studies of our product candidates and result in the FDA or other regulatory authorities denying approval of our product candidates for any or all targeted indications.

Regulatory approval of an NDA or BLA is not guaranteed, and the approval process is expensive and may take several years. The regulatory authorities also have substantial discretion in the approval process. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical studies, or perform additional preclinical studies and clinical studies. The number of preclinical studies and clinical studies that will be required for FDA approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address and the regulations applicable to any particular product candidate. The FDA can delay, limit or deny approval of a product candidate for many reasons, including, but not limited to, the following:

- a product candidate may not be deemed safe or effective;
- FDA officials may not find the data from preclinical studies and clinical studies sufficient;
- the FDA may find our manufacturing data insufficient to support approval
- the FDA might not approve our or our third-party manufacturer's processes or facilities; or
- the FDA may change its approval policies or adopt new regulations.

If any of our product candidates fails to demonstrate safety and efficacy in clinical studies or does not gain regulatory approval, our business and results of operations will be materially and adversely harmed.

Unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives in the U.S., Europe and other foreign jurisdictions could harm our business.

There is increasing pressure on biotechnology companies to reduce healthcare costs. In the U.S., these pressures come from a variety of sources, such as managed care groups, institutional, and government purchasers. Increased purchasing power of entities that negotiate on behalf of federal healthcare programs and private sector beneficiaries could increase pricing pressures in the future. Such pressures may also increase the risk of litigation or investigation by the government regarding pricing calculations. The biotechnology industry will likely face greater regulation and political and legal action in the future.

The regulations that govern marketing approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Some countries, including many EU member countries, require approval of the sale price of a product before it can be marketed. In many countries, including EU member 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. In some foreign markets, including the EU member countries, current standard of care and/or competitive products may be used as a benchmark or reference to determine pricing and reimbursement level for novel products such as Andexxa. To the extent that comparators are available at lower prices than our anticipated pricing for Andexxa, the pricing and reimbursement level of our products in the EU could be negatively impacted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenue we are able to generate from the sale of the product in that country, or even reduce the commercial viability of the product to an extent that prevents the launch altogether.

Adverse pricing limitations may hinder our ability to recoup our investment in Andexxa, Bevyxxa or one or more product candidates, even if our product candidates obtain regulatory approval. Adverse pricing limitations prior to approval will also adversely affect us

by reducing our commercial potential. Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and reimbursement for these products and related treatments becomes available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will cover and establish reimbursement levels. For example, in October 2018, CMA granted reimbursement for the NTAP to Andexxa, and in August 2019, CMS announced it would increase the reimbursement amount for the NTAP to Andexxa from 50% to 65% of the wholesale acquisition cost of the standard dose, effective October 1, 2019. While NTAP is expected to remain in effect for a period of two to three years, is no assurance, however, that this reimbursement will continue in the future at the same rate, if at all.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We are engaged in ongoing negotiations with hospitals and third-party payors regarding coverage, reimbursement and formulary placement. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

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

Healthcare reform measures could hinder or prevent the commercial success of our products or our product candidates.

In the United States, there have been and we expect there will continue to be a number of legislative and regulatory changes to the healthcare system in ways that could affect our future revenue and profitability and the future revenue and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. Legislative proposals have been introduced by members of Congress to overhaul provisions of the Patient Protection and Affordable Care Act, to allow commercial-level re-importation of prescription medications from Canada or other countries and to enable Medicare to negotiate drug prices with biopharmaceutical manufacturers. Congressional focus on drug pricing has increased since the Democrats took control of the U.S. House of Representatives in November 2018. For example, in January 2019, the chair of the House Oversight and Reform Committee sent letters to twelve different biopharmaceutical manufacturers, seeking documents and detailed information about such companies' drug pricing. Both that committee and the Senate Finance Committee held committee hearings in January 2019 on the topic of drug pricing and have indicated that further committee hearings on the topic are likely.

In addition, since January 2017, the President has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On January 22, 2018, the President signed a continuing resolution on appropriations for fiscal year 2018 delaying the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018 ("BBA"), among other

things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Presidential administration and the Centers for Medicare & Medicaid Services, or CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business. Moreover, several attempts have been made to reduce the length of exclusivity for biologic therapies, via federal government budget proposals and proposed legislation. For example, the Price Relief, Innovation, and Competition for Essential Drugs Act, introduced in 2016, would have reduced exclusivity for biological drugs from 12 to seven years. We cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, or Budget Control Act, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, which triggered the legislation's automatic reduction to several government programs, including aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in April 2013, and due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. While some of these and other proposed measures may require additional authorization to become effective, Congress and the Presidential administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- our ability to set a price we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

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

Pharmaceutical companies are heavily regulated by federal, state and local regulations in the countries in which business activities occur. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to laws and regulations governing healthcare fraud and abuse, advertising and other promotional activities, data privacy and patient rights by both the federal government and the states in which we conduct our business, as well as by healthcare regulators in the EU and other foreign jurisdictions where we may market our products. The regulations that may affect our ability to operate include, without limitation:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;

- the federal Physician Payments Sunshine Act or Open Payments Program provisions and the implementing regulations which will require, among other things, extensive tracking of physician and teaching hospital payments, maintenance of a payments database, and public reporting of the payment data;
- the federal civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- federal and state laws governing data privacy and the EU general data privacy regulation ("GDPR");
- the Foreign Corrupt Practices Act and similar statutes and regulations in foreign jurisdictions, which makes it unlawful for certain classes of persons and entities to make payments to foreign government officials to assist in obtaining or retaining business;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;
- the Drug Quality and Security Act which requires manufacturers and other distribution parties to create systems to trace certain prescription drugs as they are distributed in the United States;
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require pharmaceutical companies to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require the reporting of information related to drug pricing; and state and local laws requiring the registration of pharmaceutical sales and medical representatives; and
- EU member states' laws and the industry self-regulation codes of conduct governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices.

The Affordable Care Act, among other things, amended the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to substantial penalties, including civil and criminal penalties, damages, fines, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, integrity oversight and reporting obligations to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

The United Kingdom's planned withdrawal from the EU may have a negative effect on our business, global economic conditions, and financial markets.

As a result of the United Kingdom's vote to leave the EU, the EMA is relocating its headquarters from London to Amsterdam. Since a significant proportion of the regulatory framework in the United Kingdom is derived from EU directives and regulations, Brexit could materially impact the regulatory regime with respect to the approval of product candidates, disrupt the manufacture of our products and product candidates in the United Kingdom or the EU, disrupt the importation and export of active substances and other components of drug formulations, and disrupt the supply chain for clinical trial product and final authorized formulations. While negotiations continue regarding the terms of the United Kingdom's withdrawal from the EU, the specific impact to the supervision, regulation and supply of medicines in the United Kingdom and Europe remain unclear. The cumulative effect of disruptions to the regulatory framework or supply chains may add considerably to the development lead time to, and expense of, marketing

authorization and commercialization of products in the EU and/or the United Kingdom. In view of the uncertainty surrounding the Brexit implementation, we are unable to predict the effects of such disruption to the regulatory framework and supply chain in Europe.

7) RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

Our stock price may be volatile, and investors in our common stock could incur substantial losses.

Our stock price has fluctuated in the past and may be volatile in the future. The stock market in general, and the market for biotechnology companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investment in our stock. The market price for our common stock may be influenced by many factors, including the following:

- the timing and amount of revenues generated from sale of our products or product candidates;
- our ability to meet the expectations of investors related to the commercialization of our products and product candidates;
- regulatory actions or decisions, including the timing and outcome of any potential future FDA or EMA decision, or other products or product candidates, including those of our competitors;
- inaccurate sales or cash forecasting of our products or product candidates;
- changes in laws or regulations;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- results of clinical trials or regulatory actions with respect to our products or product candidates;
- market conditions in the pharmaceutical and biotechnology sectors;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- general economic, industry and market conditions; and
- the other risks described in this “Risk factors” section.

These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. In addition, following our update call on September 5, 2017, at least three plaintiffs’ securities litigation firms publicly announced that they are investigating potential securities fraud claims that they may wish to make against us. Such litigation, if instituted against us, could result in substantial costs and diversion of management’s attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

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

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts may cease to publish research on our company at any time in their discretion. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline. In addition, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If our operating results fail to meet the forecasts of analysts, our stock price will likely decline.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for

their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions include the following:

- our board of directors is divided into three classes with staggered three-year terms which may delay or prevent a change of our management or a change in control;
- our board of directors has the right to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- our stockholders may not act by written consent or call special stockholders' meetings; as a result, a holder, or holders, controlling a majority of our capital stock would not be able to take certain actions other than at annual stockholders' meetings or special stockholders' meetings called by the board of directors, the chairman of the board, the chief executive officer or the president;
- our certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- stockholders must provide advance notice and additional disclosures in order to nominate individuals for election to the board of directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company; and
- our board of directors may issue, without stockholder approval, shares of undesignated preferred stock; the ability to issue undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our agreements with our executive officers may require us to pay severance benefits to any of those persons who are terminated in connection with a change in control of us, which could harm our financial condition or results or discourage third parties from seeking business combinations.

Our executive officers are parties to agreements that contain change in control and severance provisions and acceleration of vesting of equity awards. The accelerated vesting of equity awards could result in dilution to our existing stockholders and harm the market price of our common stock. The payment of these severance benefits could harm our financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

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

We have never declared or paid cash dividends on our common stock. 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 our existing debt agreement precludes us from paying dividends and future debt agreements or other restrictive covenants may also preclude us from paying dividends in the future. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of Portola Pharmaceuticals, Inc.	8-K	001-35935	3.1	5/28/2013
3.2	Certificate of Amendment to the Portola Pharmaceuticals, Inc. Amended and Restated Certificate of Incorporation	8-K	001-35935	3.1	6/11/2018
3.3	Amended and Restated Bylaws of Portola Pharmaceuticals, Inc.	8-K	001-35935	3.2	5/28/2013
4.1	Reference is made to Exhibits 3.1 through 3.3.				
4.2	Form of Common Stock Certificate of Portola Pharmaceuticals, Inc.	S-1	333-187901	4.1	5/17/2013
4.5	Warrant to Purchase Shares of Common Stock by and between the registrant and Laurence Shushan and Magdalena Shushan Acosta, Trustees, The Laurence and Magdalena Shushan Family Trust, Under Agreement Dated October 8, 1997, dated December 15, 2006	10-Q	001-35935	4.7	11/06/2013
4.6	Warrant to Purchase Shares of Common Stock by and between Portola Pharmaceuticals, Inc., and HCP Life Science Assets TRS, LLC, dated December 15, 2006	10-Q	001-35935	4.8	11/06/2013
4.7	Warrant to Purchase Shares of Common Stock by and between Portola Pharmaceuticals, Inc., and Bristow Investments, L.P., dated December 15, 2006	10-Q	001-35935	4.9	11/06/2013
10.5*+	Amended and Restated Portola Pharmaceuticals, Inc. Non-Employee Director Compensation Policy				
10.51*	Sixth Amendment To Lease dated June 28, 2019				
31.1*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d- 14(a) of the Securities Exchange Act of 1934, as amended				
31.2*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d- 14(a) of the Securities Exchange Act of 1934, as amended				
32.1*	Certification of Principal Executive Officers and Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (1)				
101.INS*	XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH*	XBRL Taxonomy Extension Schema Document				

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
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				

* Filed herewith

\+ Management contract or compensatory plan

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

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.

PORTOLA PHARMACEUTICALS, INC.

Date: August 7, 2019

By: /s/ Mardi C. Dier
Mardi C. Dier
Chief Financial and Business Officer
(Principal Financial Officer)

Date: August 7, 2019

By: /s/ Scott Garland
Scott Garland
President and Chief Executive Officer
(Principal Executive Officer)

AMENDED AND RESTATED PORTOLA PHARMACEUTICALS, INC.
NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

The Compensation Committee (the "***Compensation Committee***") of the Board of Directors (the "***Board***") of Portola Pharmaceuticals, Inc. (the "***Company***") has approved the amendment and restatement of the following compensation policy (the "***Policy***") for non-employee directors of the Company. For purposes of this Policy, a "***Non-Employee Director***" is a director who has not served as an employee or executive officer of the Company or its affiliates or otherwise provided services to the Company or its affiliates in a capacity other than as a director during the preceding year, provided that a director who has served as an "interim executive officer" as permitted under Nasdaq regulations may still qualify as a Non-Employee Director.

1. Cash Compensation. Each Non-Employee Director will receive the following cash compensation:

(a) Annual cash compensation in an amount equal to $50,000, accruing and payable on a quarterly basis at the end of each calendar quarter of service, as an annual retainer for his or her Board service.

(b) In addition to the cash compensation set forth in paragraph 1(a) immediately above, each chairperson, vice-chairperson and lead director of the Board will earn an additional annual payment in an amount equal to $25,000, accruing and payable on a quarterly basis at the end of each calendar quarter of service, as a retainer for his or her service as chairperson, vice-chairperson and/or lead director, as applicable, of the Board.

(c) Audit Committee. In addition to the compensation provided under any other provision of this Policy, each Non-Employee Director serving on the Audit Committee of the Board (the "***Audit Committee***") will receive the following compensation:

(i) The chairperson of the Audit Committee will receive annual cash compensation in an amount equal to $20,000, accruing and payable on a quarterly basis at the end of each calendar quarter of service, as an annual retainer for his or her service as chairperson of the Audit Committee.

(ii) The other members of the Audit Committee will receive annual cash compensation in an amount equal to $10,000, accruing and payable on a quarterly basis at the end of each calendar quarter of service, as an annual retainer for his or her Audit Committee service.

(d) Compensation Committee. In addition to the compensation provided under any other provision of this Policy, each Non-Employee Director serving on the Compensation Committee will receive the following compensation:

(i) The chairperson of the Compensation Committee will receive annual cash compensation in an amount equal to $20,000, accruing and payable on a quarterly basis at the end of each calendar quarter of service, as an annual retainer for his or her

service as chairperson of the Compensation Committee.

(ii) The other members of the Compensation Committee will receive annual cash compensation in an amount equal to $8,000, accruing and payable on a quarterly basis at the end of each calendar quarter of service, as an annual retainer for his or her Compensation Committee service.

(e) Nominating and Corporate Governance Committee. In addition to the compensation provided under any other provision of this Policy, each Non-Employee Director serving on the Nominating and Corporate Governance Committee of the Board (the "***Nominating and Corporate Governance Committee***") will receive the following compensation:

(i) The chairperson of the Nominating and Corporate Governance Committee will receive annual cash compensation in an amount equal to $15,000, accruing and payable on a quarterly basis at the end of each calendar quarter of service, as an annual retainer for his or her service as chairperson of the Nominating and Corporate Governance Committee.

(ii) The other members of the Nominating and Corporate Governance Committee will receive annual cash compensation in an amount equal to $5,000, accruing and payable on a quarterly basis at the end of each calendar quarter of service, as an annual retainer for his or her Nominating and Corporate Governance Committee service.

(f) Research and Development Advisory Committee. In addition to the compensation provided under any other provision of this Policy, each Non-Employee Director serving on the Research and Development Advisory Committee of the Board (the "***Research and Development Committee***") will receive the following compensation:

(i) The chairperson of the Research and Development Committee will receive annual cash compensation in an amount equal to $15,000, accruing and payable on a quarterly basis at the end of each calendar quarter of service, as an annual retainer for his or her service as chairperson of the Research and Development Committee.

(ii) The other members of the Research and Development Committee will receive annual cash compensation in an amount equal to $5,500, accruing and payable on a quarterly basis at the end of each calendar quarter of service, as an annual retainer for his or her Research and Development Committee service.

(g) Commercial Advisory Committee. In addition to the compensation provided under any other provision of this Policy, each Non-Employee Director serving on the Commercial Advisory Committee of the Board (the "***Commercial Committee***") will receive the following compensation:

(i) The chairperson of the Commercial Committee will receive annual cash compensation in an amount equal to $15,000, accruing and payable on a quarterly basis at the end of each calendar quarter of service, as an annual retainer for his or her service as chairperson of the Commercial Committee.

(ii) The members of the Commercial Committee will receive annual cash compensation in an amount equal to $5,500, accruing and payable on a quarterly basis at the end of each calendar quarter of service, as an annual retainer for his or her Commercial Committee service.

2. Equity Compensation. Each Non-Employee Director will receive the following equity awards under the Company's 2013 Equity Incentive Plan (the "***Plan***") as consideration for service on the Board. Each equity award granted under this Policy will be made in accordance with the Plan and shall individually be approved by the Board or the Compensation Committee. Vesting of all equity awards granted under this Policy is subject to the applicable Non-Employee Director's "***Continuous Service***" (as defined in the Plan) from the date of grant through each applicable vesting date. Each equity award granted under this Policy will be granted with an exercise price equal to the fair market value of the Company's common stock on the date of grant and will be subject to the Company's standard form of Option Agreement, as most recently adopted by the Board for use under this Policy. The exact number of shares to be granted in each equity award granted under this Policy will be subject to adjustment based on the review by the Board or Compensation Committee of the market value of the grant implied by the percentages given below at the time of grant.

(a) New Non-Employee Directors Equity Award. For each new Non-Employee Director that joins the Board, the Board or Compensation Committee will grant such new Non-Employee Director (i) an initial stock option to purchase 12,000 shares of the Company's common stock, and (ii) an award of 6,000 Restricted Stock Units. Such initial option grant will vest, subject to Continuous Service, on a monthly basis for the 36-month period following the date of grant, and such initial Restricted Stock Units shall vest, subject to Continuous Service, annually over a three year period following the year in which the Restricted Stock Unit is granted.

(b) Annual Equity Award. Each year, the Board or Compensation Committee will grant each continuing Non-Employee Director an equity award ("***Annual Grant***") with a targeted equity value of $250,000 split evenly between stock options ("***Annual Option Grant***") and restricted stock units ("***Annual RSU Grant***"). Subject to the such Non-Employee Director's Continuous Service, each Annual Option Grant shall vest in equal increments monthly over a period of twelve months from the first day of the month following the date of grant. Each Annual RSU Grant shall vest in full on March 1st of the year following the year in which the Annual RSU Grant is granted. To be eligible to receive an Annual Grant, a Non-Employee Director must have (i) served on the Board as of December 31 of the prior year, or (ii) served on the Board for six (6) or more months by the date of the Company's annual meeting of stockholders.

Exhibit 10.51

SIXTH AMENDMENT TO LEASE

This SIXTH AMENDMENT TO LEASE ("**Sixth Amendment**") is made and entered into as of June 28, 2019 (the "**Effective Date**"), by and between BRITANNIA POINTE GRAND LIMITED PARTNERSHIP, a Delaware limited partnership ("**Landlord**"), and PORTOLA PHARMACEUTICALS, INC., a Delaware corporation ("**Tenant**").

R E C I T A L S :

A. Landlord and Tenant entered into the Lease dated December 15, 2006 (the "**Original Lease**"), as amended by the Confirmation of Portola's Exercise of Option to Extend Lease dated December 11, 2008 (the "**Confirmation**"), the First Amendment to Lease dated May 21, 2010 (the "**First Amendment**"), the Second Amendment to Lease dated March 14, 2014 (the "**Second Amendment**"), the Third **Amendment** to Lease dated May 18, 2015 (the "**Third Amendment**"), the Fourth Amendment to Lease dated December 22, 2017 (the "**Fourth Amendment**") and the Fifth Amendment to Lease dated October 29, 2018 (the "**Fifth Amendment**") (the Original Lease, as so amended, shall be collectively referred to herein as the "**Lease**"), whereby Landlord leases to Tenant and Tenant leases from Landlord those certain premises consisting of 83,475 rentable square feet of space (collectively, the "**Premises**") comprised of (A) (i) approximately 51,641 rentable square feet of space consisting of the entirety of the office building (the "**270 Building**") located at 270 East Grand Avenue, South San Francisco, California, and (ii) approximately 9,739 rentable square feet of space known as Suite 90 in the office building located at 250 East Grand Avenue (the "**250 Building**"), approximately 5,710 rentable square feet of space known as Suite 35 in the 250 Building, and approximately 6,855 rentable square feet of space known as Suites 40 and 55 in the 250 Building (such space described in this item (A), the "**Original Premises**"), and (B) approximately 9,530 square feet of space commonly known as Suite 26 in the 250 Building (the "**Suite 26**"). The 250 building and 270 Building are located in the office project currently known as "Britannia Pointe Grand Business Park" (the "**Project**").

B. The parties desire to amend the Lease on the terms and conditions set forth in this Sixth Amendment.

A G R E E M E N T :

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. **Terms**. All capitalized terms when used herein shall have the same respective meanings as are given such terms in the Lease unless expressly provided otherwise in this Sixth Amendment.

2. **Condition of the Premises**. Landlord and Tenant acknowledge that Tenant has been occupying the Premises pursuant to the Lease, and therefore Tenant continues to accept the Premises in its presently existing, "as is" condition. Except as otherwise set forth in the Tenant Work Letter attached hereto as **Exhibit A**, Landlord shall not be obligated to provide or pay for any improvement work or services related to the improvement of the Premises. Tenant also acknowledges that neither Landlord nor any agent of Landlord has made any representation or warranty regarding the condition of the Premises, the Building, or the Project or with respect to the suitability of the same for the conduct of Tenant's business.

3. **Lease Term.**

3.1. **Extended Term**. Pursuant to the Lease, the term of Tenant's lease with respect to the Original Premises is scheduled to expire on March 31, 2020. Landlord and Tenant hereby agree to extend the term of Tenant's lease with respect to the Original Premises only for a period of three (3) years (the "**Extended Term**"), from April 1, 2020, through March 31, 2023 (the "**Extended Term Expiration Date**"), on the terms and conditions set forth in the Lease, as hereby amended by this Sixth Amendment, unless sooner terminated as provided in the Lease. Notwithstanding the foregoing, the term of Tenant's lease for Suite 26 shall continue as set forth in the Lease (i.e., shall expire on December 31, 2019 pursuant to the Fifth Amendment) and shall remain unmodified by this Sixth Amendment.

3.2. **Option Term**. The Option Term set forth in Section 3.2 of the First Amendment shall continue to apply as of the end of the Extended Term (i.e., March 31, 2023), provided that any such extension by Tenant shall be effective as to the Original Premises only (i.e., the same shall not apply to Suite 26) and shall be for a period of eight (8) years (rather than three (3) years as currently set forth therein).

4. **Rent.**

4.1. **Minimum Rental for Original Premises**. During the Extended Term, Tenant shall pay Minimum Rental for the Original Premises as follows, and otherwise shall pay Minimum Rental in accordance with the terms of the Lease:

Period During Extended Term	Annual Minimum Rental	Monthly Installment of Minimum Rental	Monthly Rental Rate per Square Foot
April 1, 2020 – March 31, 2021	$4,436,700.00	$369,725.00	$5.00
April 1, 2021 – March 31, 2022	$4,591,984.50	$382,665.38	$5.18
April 1, 2022 – March 31, 2023	$4,752,703.96	$396,058.66	$5.36

4.2. **Operating Expenses for Original Premises**. During the Extended Term, Tenant shall continue to be obligated to pay, as additional rent, Tenant's Operating Cost Share in connection with the Original Premises in accordance with the terms of Section 7 of the Original Lease, as amended by Section 5 of the First Amendment and Section 5 of the Third Amendment.

4.3. **Minimum Rental and Operating Expenses for Suite 26**. Notwithstanding any provision to the contrary contained herein or in the Lease, Tenant shall continue to pay Minimum Rental and Tenant's Operating Cost Share of Operating Expenses in connection with Suite 26 in accordance with the terms of the Lease (i.e., until the expiration of the term of tenant's lease of Suite 26 on December 31, 2019).

5. **Early Termination Right**. Landlord and Tenant acknowledge and agree that

Section 8 of the Second Amendment is hereby deleted and of no further force or effect.

6. **Further Expansion and Relocation**. Landlord and Tenant acknowledge and agree that Section 9 of the Second Amendment is hereby deleted and of no further force or effect. In the event that Landlord and Tenant fully execute and deliver a new lease agreement (the "**New Lease**") for other space in the Project or in a project owned by an affiliate of Landlord during the Extended Term which New Lease satisfies the following conditions: (i) a term for such New Lease which extends beyond the Extended Term Expiration Date (i.e., extends beyond March 31, 2023), and (ii) the premises under such New Lease contains no less than 100,000 rentable square feet of space, and (iii) provided that Tenant is not then in default of this Lease beyond the applicable notice and cure periods, then Tenant shall have the right to terminate this Lease without the payment of any penalty or termination fee (and without restoration costs for the Original Premises) upon not less than thirty (30) days' prior written notice to Landlord (the " **Tenant Termination Notice**"). Such Tenant Termination Notice shall set forth the termination date of this Lease (the "**Tenant Early Termination Date**"). To the extent Tenant exercises its right to terminate this Lease, pursuant to the terms of this Section 6, then this Lease shall terminate effective as of the Tenant Early Termination Date with the same force and effect as if the Lease were scheduled to expire in accordance with its terms as of such Tenant Early Termination Date, subject to the provisions of this Lease which expressly survive the expiration or earlier termination of this Lease.

7. **Right of First Offer**. Landlord hereby grants to the named Tenant in this Sixth Amendment (the "**Original Tenant**"), or an assignee under a Permitted Transfer (a "**Permitted Transfer Assignee**"), a one-time right of first offer with respect to Suite 26 (following the expiration of the "Suite 26 Extended Term" (as that term is defined in Section 2 of the Fifth Amendment) and the terms of this Section 7 below) and that certain space commonly known as Suite 65 in the 250 Building (the "**First Offer Space**"), which First Offer Space is shown on **Exhibit B** attached hereto. Notwithstanding the foregoing, Landlord and Tenant acknowledge that Tenant's right of first offer with respect to Suite 26 shall not commence until the expiration or earlier termination of the initial lease entered into by Landlord following the expiration of the Suite 26 Extended Term (including renewals of any such lease, irrespective of whether any such renewal is currently set forth in such lease or is subsequently granted or agreed upon, and regardless of whether such renewal is consummated pursuant to a lease amendment or a new lease). Further, such first offer right of Tenant shall commence only following the expiration or earlier termination of the existing leases of the remainder of the First Offer Space (including renewals of any such lease, irrespective of whether any such renewal is currently set forth in such lease or is subsequently granted or agreed upon, and regardless of whether such renewal is consummated pursuant to a lease amendment or a new lease). Such right of first offer shall be subordinate to all rights of other tenants of the Project, which rights relate to the First Offer Space and are set forth in leases of space in the Project existing as of the date hereof, including, without limitation, any expansion, first offer, first refusal, first negotiation and other rights, regardless of whether such rights are executed strictly in accordance with their respective terms or pursuant to a lease amendment or a new lease (the "**Superior Rights**"). In connection with the foregoing, Landlord hereby agrees that any expansion, first offer, first refusal, first negotiation and other similar rights which relate to the First Offer Space and are granted in leases of space in the Project following the date of this Sixth Amendment shall not be Superior Rights. Notwithstanding any contrary provision in the lease of any Superior Right Holder, such rights of any Superior Right Holder shall continue to be Superior Rights in the event that such Superior Right Holder's lease is renewed or otherwise modified (and irrespective of whether any such renewal is currently set forth in such lease or is subsequently granted or agreed upon, and regardless of whether such renewal is consummated

pursuant to a lease amendment or a new lease). All such tenants of the First Offer Space (including the initial tenant of Suite 26 following expiration of the Suite 26 Extended Term), and all such third party tenants in the Project holding Superior Rights, are collectively referred to as the "**Superior Right Holders**". Tenant's right of first offer shall be on the terms and conditions set forth in this Section 7.

7.1. **Procedure for Offer.** Subject to the terms of this Section 7, Landlord shall notify Tenant (the **"First Offer Notice"**) from time to time when the First Offer Space or any portion thereof will become available for lease to third parties, subject to the rights of any Superior Right Holder. Pursuant to such First Offer Notice, Landlord shall offer to lease to Tenant the then available First Offer Space. The First Offer Notice shall describe the space so offered to Tenant and the base rent, and other fundamental material economic terms upon which Landlord is willing to lease such space to Tenant.

7.2. **Procedure for Acceptance.** If Tenant wishes to exercise Tenant's right of first offer with respect to the space described in the First Offer Notice, then within seven (7) business days of delivery of the First Offer Notice to Tenant, Tenant shall deliver notice to Landlord (the **"First Offer Exercise Notice"**) of Tenant's election to exercise its right of first offer with respect to the entire space described in the First Offer Notice on the terms contained in such notice. If Tenant does not so notify Landlord within such seven (7) business day period, then Landlord shall be free to lease the space described in the First Offer Notice to anyone to whom Landlord desires on any terms Landlord desires. Notwithstanding anything to the contrary contained herein, Tenant must elect to exercise its right of first offer, if at all, with respect to all of the space offered by Landlord to Tenant at any particular time, and Tenant may not elect to lease only a portion thereof.

7.3. **Construction In First Offer Space.** Tenant shall take the First Offer Space in its "as is" condition (provided that Landlord shall deliver the First Offer Space in vacant, broom clean condition), and the construction of improvements in the First Offer Space shall comply with the terms of Article 9 of the Original Lease. Any improvement allowance to which Tenant may be entitled and any work to be performed by Landlord shall be as set forth in the First Offer Notice.

7.4. **Amendment to Lease.** If Tenant timely exercises Tenant's right to lease the First Offer Space as set forth herein, then Landlord and Tenant shall within thirty (30) days thereafter execute an amendment to the Lease for such First Offer Space upon the terms and conditions as set forth in the First Offer Notice and this Section 7. The rentable square footage of any First Offer Space leased by Tenant shall be determined by Landlord in accordance with Landlord's then current standard of measurement for the Building. Tenant shall commence payment of rent for the First Offer Space, and the term of Tenant's lease of the First Offer Space shall commence, upon the date of delivery of the First Offer Space to Tenant (the **"First Offer Commencement Date"**) and shall terminate on the date set forth in the First Offer Notice.

7.5. **Termination of Right of First Offer.** Tenant's rights under this Section 7 shall be personal to the Original Tenant and any Permitted Transfer Assignee and may only be exercised by the Original Tenant and any Permitted Transfer Assignee (and not any other assignee, sublessee or other transferee of the Original Tenant's interest in the Lease) if the Original Tenant and any Permitted Transfer Assignee occupies not less than eighty percent (80%) of the Premises. The right of first offer granted herein shall terminate as to particular First Offer Space upon Tenant's failure to timely exercise its right of first offer with respect to such particular First Offer Space. Tenant shall not have the right to lease First Offer Space, as provided in this Section 7, if, as of the date of the attempted exercise of any right of first offer by Tenant, or, at Landlord's option, as of the scheduled date of delivery of such First Offer Space to Tenant, Tenant is in default under the Lease (beyond the expiration of any applicable notice and cure period set forth in the Lease, as amended), as amended, or Tenant has previously been in default under the Lease (beyond the expiration of any applicable notice and cure period set forth in the Lease, as amended).

8. **Broker**. Landlord and Tenant hereby warrant to each other that they have had no dealings with any real estate broker or agent in connection with the negotiation of this Sixth Amendment other than CBRE, Inc. (the "**Broker**"), and that they know of no other real estate broker or agent who is entitled to a commission in connection with this Sixth Amendment. Each party agrees to indemnify and defend the other party against and hold the other party harmless from any and all claims, demands, losses, liabilities, lawsuits, judgments, costs and expenses (including without limitation reasonable attorneys' fees) with respect to any leasing commission or equivalent compensation alleged to be owing on account of any dealings with any real estate broker or agent, other than the Broker, occurring by, through, or under the indemnifying party. The terms of this Section 8 shall survive the expiration or earlier termination of the term of the Lease, as hereby amended.

9. **California Required Disclosures**. For purposes of Section 1938 of the California Civil Code, Landlord hereby discloses to Tenant, and Tenant hereby acknowledges, that the Project, Building and Premises have not undergone inspection by a Certified Access Specialist (CASp).

10. **No Further Modification**. Except as specifically set forth in this Sixth Amendment, all of the terms and provisions of the Lease shall remain unmodified and in full force and effect.

[SIGNATURES FOLLOW ON NEXT PAGE]

IN WITNESS WHEREOF, this Sixth Amendment has been executed as of the day and year first above written.

"**LANDLORD**"

BRITANNIA POINTE GRAND
LIMITED PARTNERSHIP,
a Delaware limited partnership,

By: /s/ Scott Bohn
Name: Scott Bohn
Its: Senior Vice President

"**TENANT**"

PORTOLA PHARMACEUTICALS, INC.,
a Delaware corporation

By: /s/ Scott Garland
Name: Scott Garland
Its: CEO

By: _____
Name: _____
Its: _____

EXHIBIT A

TENANT WORK LETTER

Landlord and Tenant acknowledge that Tenant has been occupying the Premises pursuant to the Lease. Except as specifically set forth herein, Landlord shall not be obligated to construct or install any improvements or facilities of any kind in the Premises, and Tenant shall continue to accept the Premises in its currently-existing, "as-is" condition. Notwithstanding the foregoing, Tenant shall be entitled to a one-time tenant improvement allowance (the "**Tenant Improvement Allowance**") equal to $739,450.00 (*i.e.*, approximately $10.00 per rentable square feet of the Original Premises) for the costs relating to the design and construction of Tenant's improvements which are permanently affixed to the Original Premises (the "**Tenant Improvements**"). The Tenant Improvement Allowance will be disbursed in accordance with Landlord's standard disbursement procedures, including, without limitation, following Landlord's receipt of (i) evidence (i.e., invoices or other documentation reasonably satisfactory to Landlord) of payment for the Tenant Improvements, and (ii) fully executed, unconditional lien releases from all contractors, subcontractors, laborers, materialmen, and suppliers used by Tenant in connection with the Tenant Improvements. The Tenant Improvements shall be constructed in accordance with the terms and conditions of Article 9 of the Original Lease. In no event shall Landlord be obligated to disburse any portion of the Tenant Improvement Allowance subsequent to the date which is twelve (12) months following the Effective Date, nor shall Landlord be obligated to disburse any amount in excess of the Tenant Improvement Allowance in connection with the construction of the Tenant Improvements. No portion of the Tenant Improvement Allowance, if any, remaining after the construction of the Tenant Improvements shall be available for use by Tenant.

Exhibit 31.1

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

I, Mardi Dier, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Portola 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 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;

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

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

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

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

Date: August 7, 2019

/s/ Mardi Dier
Mardi Dier
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.2

Certification of Principal Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Scott Garland, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Portola 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 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;

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

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

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

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

Date: August 7, 2019

/s/ Scott Garland
Scott Garland
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Mardi Dier, Chief Financial Officer of Portola Pharmaceuticals, Inc. (the "Company"), and Scott Garland, President and Chief Executive Officer of the Company, each hereby certifies that, to the best of his or her knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2019, to which this Certification is attached as Exhibit 32.1 (the "Quarterly Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

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

In Witness Whereof, the undersigned have set their hands hereto as of the 7th day of August, 2019.

/s/ Mardi C. Dier	/s/ Scott Garland
Mardi C. Dier	Scott Garland
Chief Financial Officer	*President and Chief Executive Officer*
(Principal Financial Officer)	*(Principal Executive Officer)*

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Portola 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 Form 10-Q), irrespective of any general incorporation language contained in such filing.