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 September 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 0-22705

NEUROCRINE BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**33-0525145**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**
12780 El Camino Real, San Diego, California	**92130**
(Address of principal executive office)	**(Zip Code)**

(858) 617-7600
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.001 par value	NBIX	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 ☒

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 92,093,521 as of October 29, 2019.

NEUROCRINE BIOSCIENCES, INC.

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Part I. Financial Information

Item 1. Financial Statements

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)

(in thousands, except per share data)	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 166,637	$ 141,714
Short-term investments in available-for-sale debt securities	503,525	509,199
Accounts receivable	115,318	57,406
Inventory	10,798	10,864
Other current assets	22,954	18,594
Total current assets	819,232	737,777
Restricted cash	4,706	5,477
Property and equipment, net	40,302	33,869
Long-term investments in available-for-sale debt securities	204,793	216,028
Investment in restricted equity securities	48,915	—
Operating lease assets	61,987	—
Total assets	$ 1,179,935	$ 993,151
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 102,357	$ 86,377
Other current liabilities	13,295	1,856
Total current liabilities	115,652	88,233
Noncurrent operating lease liabilities	74,482	—
Convertible senior notes	403,589	388,496
Other long-term liabilities	11,697	10,231
Deferred rent	—	18,114
Deferred gain on sale of real estate	—	7,312
Total liabilities	605,420	512,386
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value; 220,000 shares authorized; issued and outstanding shares were 92,080 as of September 30, 2019 and 90,797 as of December 31, 2018	92	91
Additional paid-in capital	1,739,517	1,660,361
Accumulated other comprehensive income (loss)	1,606	(1,932)
Accumulated deficit	(1,166,700)	(1,177,755)
Total stockholders' equity	574,515	480,765
Total liabilities and stockholders' equity	$ 1,179,935	$ 993,151

See accompanying notes to the condensed consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF INCOME AND COMPREHENSIVE INCOME
(unaudited)

(in thousands, except per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Product sales, net	$ 198,094	$ 111,291	$ 515,069	$ 279,282
Collaboration revenue	24,000	40,466	29,008	40,466
Total revenues	222,094	151,757	544,077	319,748
Operating expenses:				
Cost of sales	2,229	1,551	4,966	3,355
Research and development	45,278	35,482	144,617	121,417
Acquired in-process research and development	—	—	118,081	—
Selling, general and administrative	84,489	60,401	252,851	179,952
Total operating expenses	131,996	97,434	520,515	304,724
Operating income	90,098	54,323	23,562	15,024
Other (expense) income:				
Interest expense	(8,038)	(7,672)	(23,833)	(22,767)
Unrealized loss on restricted equity securities	(28,450)	—	(5,805)	—
Investment income and other, net	4,797	4,113	13,980	10,776
Total other expense, net	(31,691)	(3,559)	(15,658)	(11,991)
Income before provision for income taxes	58,407	50,764	7,904	3,033
Provision for income taxes	4,618	—	4,892	—
Net income	53,789	50,764	3,012	3,033
Unrealized gain (loss) on available-for-sale debt securities, net of tax	961	753	3,538	(206)
Comprehensive income	$ 54,750	$ 51,517	$ 6,550	$ 2,827
Net income per share, basic	$ 0.59	$ 0.56	$ 0.03	$ 0.03
Net income per share, diluted	$ 0.56	$ 0.52	$ 0.03	$ 0.03
Weighted average common shares outstanding, basic	91,859	90,555	91,440	90,064
Weighted average common shares outstanding, diluted	96,074	96,798	95,231	95,272

See accompanying notes to the condensed consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)

(in thousands)	Nine Months Ended September 30, 2019	2018
Cash Flows from Operating Activities:		
Net income	$ 3,012	$ 3,033
Reconciliation of net income to net cash provided by operating activities:		
Share-based compensation expense	53,945	44,800
Depreciation and amortization	5,361	2,749
Amortization of debt discount	14,057	13,040
Amortization of debt issuance costs	1,036	989
Net (accretion of discounts) amortization of premiums on investments	(1,466)	1,436
Change in fair value of restricted equity securities	5,805	—
Other	792	(482)
Change in operating assets and liabilities:		
Accounts receivable	(57,912)	(23,436)
Inventory	66	(3,907)
Other current assets	(2,180)	(2,714)
Accounts payable and accrued liabilities	12,344	15,577
Other liabilities	14,641	(175)
Net cash provided by operating activities	49,501	50,910
Cash Flows from Investing Activities:		
Purchases of available-for-sale debt securities	(467,090)	(329,289)
Sales and maturities of available-for-sale debt securities	488,823	211,402
Purchase of restricted equity securities	(54,720)	—
Purchases of property and equipment	(11,936)	(18,802)
Proceeds from sales of property and equipment	8	30
Net cash used in investing activities	(44,915)	(136,659)
Cash Flows from Financing Activities:		
Issuance of common stock	20,029	27,748
Net cash provided by financing activities	20,029	27,748
Change in cash and cash equivalents and restricted cash	24,615	(58,001)
Cash and cash equivalents and restricted cash at beginning of period	147,191	259,212
Cash and cash equivalents and restricted cash at end of period	$ 171,806	$ 201,211
Supplemental Disclosure:		
Cash paid for interest	$ 5,822	$ 5,822
Cash paid for income taxes	$ 507	$ —
Non-cash capital expenditures	$ 55	$ 1,802

See accompanying notes to the condensed consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(unaudited)

(in thousands)	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2017	88,794	$ 89	$ 1,572,765	$ (1,850)	$ (1,198,866)	$ 372,138
Net loss	—	—	—	—	(41,818)	(41,818)
Unrealized loss on investments in available-for-sale debt securities	—	—	—	(1,847)	—	(1,847)
Share-based compensation expense	—	—	19,879	—	—	19,879
Issuance of common stock for vested restricted stock units	343	—	—	—	—	—
Issuance of common stock for stock option exercises	745	1	16,134	—	—	16,135
Balance at March 31, 2018	89,882	90	1,608,778	(3,697)	(1,240,684)	364,487
Net loss	—	—	—	—	(5,913)	(5,913)
Unrealized gain on investments in available-for-sale debt securities	—	—	—	888	—	888
Share-based compensation expense	—	—	11,851	—	—	11,851
Issuance of common stock for vested restricted stock units	73	—	—	—	—	—
Issuance of common stock for stock option exercises	448	—	6,123	—	—	6,123
Balance at June 30, 2018	90,403	90	1,626,752	(2,809)	(1,246,597)	377,436
Net income	—	—	—	—	50,764	50,764
Unrealized gain on investments in available-for-sale debt securities	—	—	—	753	—	753
Share-based compensation expense	—	—	13,070	—	—	13,070
Issuance of common stock for vested restricted stock units	4	—	—	—	—	—
Issuance of common stock for stock option exercises	266	1	5,489	—	—	5,490
Balance at September 30, 2018	90,673	91	1,645,311	(2,056)	(1,195,833)	447,513
Balance at December 31, 2018	90,797	$ 91	$ 1,660,361	$ (1,932)	$ (1,177,755)	$ 480,765
Net loss	—	—	—	—	(102,115)	(102,115)
Unrealized gain on available-for-sale debt securities, net of tax	—	—	—	1,699	—	1,699
Share-based compensation expense	—	—	15,764	—	—	15,764
Cumulative-effect adjustment to equity due to adoption of ASU 2016-02	—	—	—	—	8,043	8,043
Issuance of common stock for vested restricted stock units	353	—	—	—	—	—
Issuance of common stock for stock option exercises	95	—	2,581	—	—	2,581
Issuance of common stock for employee stock purchase plan	39	—	2,538	—	—	2,538
Balance at March 31, 2019	91,284	91	1,681,244	(233)	(1,271,827)	409,275
Net income	—	—	—	—	51,338	51,338
Unrealized gain on available-for-sale debt securities, net of tax	—	—	—	878	—	878
Share-based compensation expense	—	—	17,931	—	—	17,931
Issuance of common stock for vested restricted stock units	39	—	—	—	—	—
Issuance of common stock for stock option exercises	213	1	4,283	—	—	4,284
Balance at June 30, 2019	91,536	92	1,703,458	645	(1,220,489)	483,706
Net income	—	—	—	—	53,789	53,789
Unrealized gain on available-for-sale debt securities, net of tax	—	—	—	961	—	961
Share-based compensation expense	—	—	20,250	—	—	20,250
Issuance of common stock for vested restricted stock units	15	—	—	—	—	—
Issuance of common stock for stock option exercises	490	—	13,164	—	—	13,164
Issuance of common stock for employee stock purchase plan	39	—	2,645	—	—	2,645
Balance at September 30, 2019	92,080	$ 92	$ 1,739,517	$ 1,606	$ (1,166,700)	$ 574,515

See accompanying notes to the condensed consolidated financial statements.

1. Organization and Significant Accounting Policies

Description of Business. Neurocrine Biosciences, Inc. (Neurocrine, we, our or us) is a neuroscience-focused, biopharmaceutical company with more than 25 years of experience discovering and developing life-changing treatments for people with serious, challenging and under-addressed neurological, endocrine and psychiatric disorders. We specialize in targeting and interrupting disease-causing mechanisms involving the interconnected pathways of the nervous and endocrine systems.

Our portfolio includes United States Food and Drug Administration (FDA)-approved treatments for tardive dyskinesia (TD) and endometriosis and clinical development programs in multiple therapeutic areas including Parkinson's disease, congenital adrenal hyperplasia, uterine fibroids and polycystic ovary syndrome. Our treatment for endometriosis and our product candidates for uterine fibroids and polycystic ovary syndrome are partnered with AbbVie, Inc. (AbbVie). Additionally, we have a collaboration and license agreement with Voyager Therapeutics, Inc. (Voyager), focused on the development and commercialization of four programs using Voyager's proprietary gene therapy platform, including one clinical development program for advanced Parkinson's disease patients, VY-AADC.

Basis of Presentation. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and with the instructions of the Securities and Exchange Commission (SEC) on Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by GAAP for complete financial statements. In the opinion of management, the condensed consolidated financial statements include all adjustments necessary, which are of a normal and recurring nature, for the fair presentation of our financial position and of the results of operations and cash flows for the periods presented. The accompanying unaudited condensed consolidated financial statements include the accounts of Neurocrine and our wholly owned subsidiaries.

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2018, included in our Annual Report on Form 10-K (2018 Form 10-K) filed with the SEC. The results of operations for the interim period shown in this report are not necessarily indicative of the results that may be expected for any other interim period or for the full year. The condensed consolidated balance sheet at December 31, 2018, has been derived from the audited financial statements as of that date, but does not include all of the information and footnotes required by GAAP for complete financial statements.

There were no significant changes to our significant accounting policies as disclosed in the 2018 Form 10-K.

Recently Adopted Accounting Pronouncements.

ASU 2016-02. In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-02, "Leases (Topic 842)", which requires lessees to recognize leases on the balance sheet and disclose key information about leasing arrangements. ASU 2016-02 establishes a right-of-use (ROU) model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. ASU 2016-02 also requires disclosures to meet the objective of enabling users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. On January 1, 2019, we adopted ASU 2016-02 using the modified retrospective transition method. Under this transition method, we recognized and measured leases that existed at the application date in our condensed consolidated balance sheet as of January 1, 2019.

Arrangements that are determined to be operating leases at inception are included in operating lease assets, noncurrent operating lease liabilities, and other current liabilities in our condensed consolidated balance sheets.

ROU assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease ROU assets and operating lease liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As none of our operating leases provide an implicit rate, we use our incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The operating lease ROU asset is adjusted for any prepaid or accrued lease payments and any lease incentives received. Operating lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term. We have lease agreements with lease and non-lease components, which we have elected to account for as a single lease component. Further, we have elected to recognize our short-term lease payments in profit or loss on a straight-line basis over the associated lease term and variable lease payments in the period in which the obligation for those payments is incurred. Short-term and variable lease payments were not material for the nine months ended September 30, 2019.

In connection with the adoption of ASU 2016-02, we elected the package of practical expedients requiring no reassessment of whether any expired or existing contracts are or contain leases, the lease classification of any expired or existing leases, or initial direct costs for any existing leases. We also made accounting policy elections not to apply the recognition requirements under ASU 2016-02 to any of our short-term leases and to account for each separate lease and associated nonlease components as a single lease component for all of our leases.

In preparation for implementation of ASU 2016-02, we finalized key accounting assessments and updated processes to appropriately recognize and present the associated financial information. Based on these efforts, the adoption of ASU 2016-02 resulted in the recognition of (1) ROU assets of $50.0 million and operating lease liabilities of $70.9 million, resulting from leases of office and laboratory space; (2) the derecognition of deferred rent of $20.9 million for certain lease incentives received; and (3) a cumulative-effect adjustment of $8.0 million to the opening balance of the accumulated deficit as of January 1, 2019, resulting from the recognition of an existing deferred gain on sale of real estate. The comparative prior period information continues to be reported under the accounting standards in effect during those periods. Further, we expect the adoption of ASU 2016-02 to be immaterial to our condensed consolidated statements of income and comprehensive income and statements of cash flows on an ongoing basis.

ASU 2018-07. In June 2018, the FASB issued ASU 2018-07, “Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting”, which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees and applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor’s own operations by issuing share-based payment awards. On January 1, 2019, we adopted ASU 2018-07 using the modified retrospective transition method with no impact on our condensed consolidated financial statements. Further, we expect the adoption of ASU 2018-07 to be immaterial to our condensed consolidated balance sheets, statements of income and comprehensive income, and statements of cash flows on an ongoing basis.

2. Significant Collaboration and Licensing Agreements

Voyager. We entered into a collaboration and license agreement with Voyager, a clinical-stage gene therapy company, which became effective in March 2019. The agreement is focused on the development and commercialization of four programs using Voyager’s proprietary gene therapy platform. The four programs consist of the VY-AADC program for Parkinson’s disease, the VY-FXN01 program for Friedreich’s ataxia and the rights to two programs to be determined by the parties in the future.

In connection with the agreement, we paid Voyager $115.0 million upfront and purchased $50.0 million of Voyager’s common stock at $11.9625 per share, representing approximately 4.2 million shares. Pursuant to the terms of the agreement, Voyager may also be entitled to an additional $1.7 billion in development, regulatory and commercial milestone payments across the four programs, as well as royalties on net sales of any collaboration product.

Pursuant to development plans agreed to by us and Voyager, unless Voyager exercises its co-development and co-commercialization rights as provided for in the agreement, we will be responsible for all development costs. Further, upon the occurrence of a specified event for each program, we will assume responsibility for the development, manufacturing, and commercialization activities of such program.

We accounted for the transaction as an asset acquisition as the set of acquired assets did not constitute a business. Our equity investment in Voyager was recorded at a fair value of $54.7 million after considering Voyager’s stock price on the date of closing and certain lock-up and voting provisions applicable to the acquired shares. The remaining $113.1 million of the purchase price, which includes the applicable transaction costs, was expensed as in-process research and development (IPR&D) in the first quarter of 2019.

In June 2019, we entered into an amendment to the collaboration and license agreement with Voyager. Under the terms of the amendment, we paid Voyager $5.0 million upfront to obtain rights outside the United States (U.S.) to the Friedreich’s ataxia program, VY-FXN01, in connection with the early return of those rights to Voyager pursuant to a restructuring of Voyager’s gene therapy relationship with Sanofi Genzyme. The upfront payment was expensed as IPR&D in the second quarter of 2019.

We may terminate the collaboration and license agreement with Voyager upon 180 days written notice to Voyager prior to the first commercial sale of any collaboration product or upon 1 year after the date of notice if such notice is provided after the first commercial sale of any collaboration product. Unless terminated earlier, the agreement will continue in effect until the expiration of the last to expire royalty term with respect to any collaboration product or the last expiration or termination of any exercised co-development and co-commercialization rights by Voyager as provided for in the agreement.

BIAL – Portela & Ca, S.A. In February 2017, we entered into an exclusive license agreement with BIAL – Portela & Ca, S.A. (BIAL) for the development and commercialization of opicapone for the treatment of human diseases and conditions, including as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients, in the U.S. and Canada. In connection with the agreement, we paid BIAL an upfront license fee of $30.0 million and agreed to make additional regulatory event-based milestone payments of up to $40.0 million, of which $20.0 million has been paid as of September 30, 2019, and up to an additional $75.0 million in commercial event-based milestone payments.

In the second quarter of 2019, we submitted a new drug application (NDA) with the FDA for opicapone as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients. The NDA was accepted by the FDA with a Prescription Drug User Fee Act (PDUFA) target action date of April 26, 2020. The FDA's acceptance of the NDA triggered a milestone payment of $10.0 million, expensed as R&D in the second quarter of 2019 and paid by us to BIAL in the third quarter of 2019.

Mitsubishi Tanabe Pharma Corporation. In March 2015, we entered into a collaboration and license agreement with Mitsubishi Tanabe Pharma Corporation (MTPC) for the development and commercialization of INGREZZA® (valbenazine) for movement disorders in Japan and other select Asian markets. In connection with the agreement, MTPC made an upfront payment of $30.0 million and agreed to make an additional $85.0 million in development and regulatory event-based milestone payments, payments for the manufacture of pharmaceutical products and royalties on product sales in select territories in Asia.

Since inception of the agreement, we have recognized revenue of $19.8 million associated with the delivery of a technology license and existing know-how and $15.0 million in development event-based milestone payments resulting from MTPC's initiation of Phase II/III clinical trials of INGREZZA in TD in Asia. In accordance with our continuing performance obligations, at the inception of the agreement, $10.2 million of the $30.0 million upfront payment received was originally deferred in connection with our initiation of a clinical trial of valbenazine in Huntington's chorea and will be recognized as revenue over the clinical trial period. In September 2019, we announced the initiation of the KINECT-HD study, a placebo-controlled Phase III study of valbenazine in adult Huntington's disease (HD) patients with chorea. Under the terms of the agreement, any payment we receive is generally non-refundable.

AbbVie. In June 2010, we entered into an exclusive worldwide collaboration with AbbVie to develop and commercialize elagolix and all next-generation gonadotropin-releasing factor antagonists for women's and men's health. In connection with the agreement, AbbVie made an upfront payment of $75.0 million and agreed to make additional development and regulatory event-based milestone payments of up to $480.0 million, of which $135.0 million has been earned as of September 30, 2019, and up to an additional $50.0 million in commercial event-based milestone payments. In the third quarter of 2019, AbbVie submitted an NDA with the FDA for the approval of elagolix in the treatment of uterine fibroids. The NDA was accepted by the FDA with a PDUFA target action date in the second quarter of 2020. The FDA's acceptance of the NDA triggered a milestone payment of $20.0 million, recognized as revenue in the third quarter of 2019 and payable to us by AbbVie in the fourth quarter of 2019.

3. Investments

Available-for-sale (AFS) debt securities are carried at fair value, with any unrealized gains and losses reported in comprehensive income (loss). The cost basis of AFS debt securities is adjusted for the amortization of premiums and accretion of discounts to maturity, as applicable. Such amortization and accretion, as well as any interest and dividends, realized gains and losses and declines in fair value judged to be other-than-temporary, if any, on AFS debt securities are included in investment income and other, net. The cost of AFS debt securities sold is based on the specific identification method. Additionally, investments in equity securities of certain companies that are subject to holding period restrictions longer than 1 year are carried at fair value. Net gains and losses on restricted equity securities are included in other income (expense), net.

Investments consisted of the following:

(in thousands)	September 30, 2019	December 31, 2018
Commercial paper	$ 135,197	$ 94,572
Corporate debt securities	414,951	544,978
Securities of government-sponsored entities	158,170	85,677
Restricted equity securities	48,915	—
Total investments	$ 757,233	$ 725,227

Investments classified as AFS debt securities consisted of the following:

(in thousands)	Contractual Maturity (in years)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Estimated Fair Value
September 30, 2019:					
Classified as current assets:					
Commercial paper	Less than 1	$ 135,156	$ 45	$ (4)	$ 135,197
Corporate debt securities	Less than 1	254,811	577	(21)	255,367
Securities of government-sponsored entities	Less than 1	112,693	272	(4)	112,961
Total short-term available-for-sale debt securities		$ 502,660	$ 894	$ (29)	$ 503,525
Classified as non-current assets:					
Corporate debt securities	1 to 2	$ 159,035	$ 602	$ (53)	$ 159,584
Securities of government-sponsored entities	1 to 2	45,017	192	—	45,209
Total long-term available-for-sale debt securities		$ 204,052	$ 794	$ (53)	$ 204,793
December 31, 2018:					
Classified as current assets:					
Commercial paper	Less than 1	$ 94,617	$ —	$ (45)	$ 94,572
Corporate debt securities	Less than 1	395,385	—	(1,598)	393,787
Securities of government-sponsored entities	Less than 1	20,887	8	(55)	20,840
Total short-term available-for-sale debt securities		$ 510,889	$ 8	$ (1,698)	$ 509,199
Classified as non-current assets:					
Corporate debt securities	1 to 2	$ 151,594	$ 66	$ (469)	$ 151,191
Securities of government-sponsored entities	1 to 2	64,676	162	(1)	64,837
Total long-term available-for-sale debt securities		$ 216,270	$ 228	$ (470)	$ 216,028

The following table presents the estimated fair value and gross unrealized loss position for AFS debt securities, as applicable, aggregated by investment category and length of time that such securities have been in a continuous loss position:

	Less Than 12 Months		12 Months or Greater		Total	
(in thousands)	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
September 30, 2019:						
Commercial paper	$ 28,839	$ (4)	$ —	$ —	$ 28,839	$ (4)
Corporate debt securities	84,753	(63)	42,451	(11)	127,204	(74)
Securities of government-sponsored entities	28,953	(4)	—	—	28,953	(4)
Total	$ 142,545	$ (71)	$ 42,451	$ (11)	$ 184,996	$ (82)
December 31, 2018:						
Commercial paper	$ 51,927	$ (45)	$ —	$ —	$ 51,927	$ (45)
Corporate debt securities	274,696	(746)	234,798	(1,321)	509,494	(2,067)
Securities of government-sponsored entities	4,999	(1)	10,947	(55)	15,946	(56)
Total	$ 331,622	$ (792)	$ 245,745	$ (1,376)	$ 577,367	$ (2,168)

At each reporting date, we perform an evaluation of impairment to determine if any unrealized losses on investments in AFS debt securities are other-than-temporary. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition of the issuer, and our intent and ability to hold the investment until recovery of the amortized cost basis. We intend and have the ability to hold such investments in unrealized loss positions until their amortized cost basis has been recovered. Further, based on our evaluation, we determined that any such unrealized losses were not other-than-temporary at September 30, 2019 and December 31, 2018.

4. Fair Value Measurements

Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs include quoted prices for similar instruments in active markets and/or quoted prices for identical or similar instruments in markets that are not active near the measurement date; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

We classify our cash equivalents and available-for-sale investments as Level 1 or Level 2 within the fair value hierarchy. The fair value of our investment grade corporate debt securities is determined using proprietary valuation models and analytical tools, which utilize market pricing or prices for similar instruments that are both objective and publicly available, such as matrix pricing or reported trades, benchmark yields, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids and offers.

The fair value of our investments in restricted equity securities is determined using an option pricing valuation model and classified as Level 3 within the fair value hierarchy. The most significant assumptions within the option pricing valuation model are the term of the restrictions and the stock price volatility, which is based upon the historical volatility of similar companies. Significant changes in any of those inputs in isolation would result in a significantly higher or lower fair value measurement.

The $517.5 million of 2.25% convertible senior notes due May 15, 2024 (2024 Notes) were recorded at the estimated value of a similar non-convertible instrument on the date of issuance and accretes to the face value of the 2024 Notes over their 7-year term. The fair value of the 2024 Notes, estimated utilizing market quotations from an over-the-counter trading market (Level 2), was $708.7 million at September 30, 2019 and $616.1 million at December 31, 2018.

We did not reclassify any investments between levels in the fair value hierarchy during the nine months ended September 30, 2019 and 2018.

Investments, which were measured at fair value on a recurring basis using the inputs described above, consisted of the following:

(in thousands)	Carrying Value	Fair Value Measurements Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
September 30, 2019:				
Classified as current assets:				
Cash and money market funds	$ 166,637	$ 166,637	$ —	$ —
Certificates of deposit	463	463	—	—
Commercial paper	135,197	—	135,197	—
Securities of government-sponsored entities	112,961	—	112,961	—
Corporate debt securities	255,367	—	255,367	—
Subtotal	670,625	167,100	503,525	—
Classified as long-term assets:				
Cash and money market funds	1,500	1,500	—	—
Certificates of deposit	3,206	3,206	—	—
Securities of government-sponsored entities	45,209	—	45,209	—
Corporate debt securities	159,584	—	159,584	—
Restricted equity securities	48,915	—	—	48,915
Total	929,039	171,806	708,318	48,915
Less cash, cash equivalents and restricted cash	(171,806)	(171,806)	—	—
Total investments	$ 757,233	$ —	$ 708,318	$ 48,915
December 31, 2018:				
Classified as current assets:				
Cash and money market funds	$ 141,714	$ 141,714	$ —	$ —
Commercial paper	94,572	—	94,572	—
Securities of government-sponsored entities	20,840	—	20,840	—
Corporate debt securities	393,787	—	393,787	—
Subtotal	650,913	141,714	509,199	—
Classified as long-term assets:				
Cash and money market funds	1,500	1,500	—	—
Certificates of deposit	3,977	3,977	—	—
Securities of government-sponsored entities	64,837	—	64,837	—
Corporate debt securities	151,191	—	151,191	—
Total	872,418	147,191	725,227	—
Less cash, cash equivalents and restricted cash	(147,191)	(147,191)	—	—
Total investments	$ 725,227	$ —	$ 725,227	$ —

The following table presents a reconciliation of our investment in restricted equity securities, which is measured at fair value on a recurring basis using the significant unobservable inputs (Level 3) described above.

(in thousands)	
Balance at December 31, 2018	$ —
Investment in restricted equity securities	54,720
Net unrealized gain recognized on restricted equity securities during the period	1,680
Balance at March 31, 2019	56,400
Net unrealized gain recognized on restricted equity securities during the period	20,965
Balance at June 30, 2019	77,365
Net unrealized loss recognized on restricted equity securities during the period	(28,450)
Balance at September 30, 2019	$ 48,915

5. Inventory

Inventory consisted of the following:

(in thousands)	September 30, 2019	December 31, 2018
Raw materials	$ 6,461	$ 7,855
Work in process	2,249	2,208
Finished goods	2,088	801
Total inventory	$ 10,798	$ 10,864

6. Restricted Cash

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheet that sum to the total of the same such amounts shown in the condensed consolidated statement of cash flows.

(in thousands)	September 30, 2019	December 31, 2018
Cash and cash equivalents	$ 166,637	$ 141,714
Restricted cash included in other current assets	463	—
Restricted cash	4,706	5,477
Total cash, cash equivalents and restricted cash	$ 171,806	$ 147,191

7. Leases

In December 2007, we closed the sale of our facility and associated real property for a purchase price of $109.0 million. Concurrent with the sale, we retired the entire $47.7 million in mortgage debt previously outstanding with respect to the facility and associated real property and received cash of $61.0 million, net of transaction costs and debt retirement. The ultimate result of this real estate sale was a net deferred gain of $39.1 million, of which the remaining balance was $8.0 million as of December 31, 2018, and which we recognized as a cumulative-effect adjustment to equity upon adoption of Topic 842 on January 1, 2019.

Upon closing of the sale of the facility and associated real property, we entered into an agreement (the original lease) to lease back our corporate headquarters, comprised of two buildings located in San Diego, California, for a term of 12 years. In 2008 through 2011, we entered into a series of subsequent amendments to the original lease, whereby we vacated one of the two buildings and continued to occupy one building (the existing premises). In June 2017, we entered into an amendment to the original lease (the amended lease), whereby we extended its term through December 31, 2029. In August 2019, we entered into an amendment (the 2019 amendment) to the amended lease, whereby we agreed to lease 80,282 square feet of additional office space (the expanded premises) in San Diego, California, for a term of 12 years, and to extend the total term of the original lease to a coterminous date of July 31, 2031.

Under the terms of the 2019 amendment, we will take possession of the expanded premises on a tranche-by-tranche basis as office space currently occupied by third-party tenants becomes available through 2021. Commencing on each applicable tranche lease commencement date and continuing throughout the term of the lease, we will be obligated to pay base annual rent (subject to an annual fixed percentage increase) and our then-applicable portion of the operating expenses and taxes attributable to the expanded premises. Additionally, we will continue to be obligated to pay base annual rent (subject to an annual fixed percentage increase), operating expenses, and taxes attributable to the existing premises.

The 2019 amendment includes two options to extend the term of the lease for a period of 10 years each. We were not reasonably certain to exercise either of these options at lease commencement. As such, neither option was recognized as part of the associated operating lease ROU asset or liability. In connection with the amended lease, in lieu of a cash security deposit, Wells Fargo Bank, N.A. (Wells Fargo) issued a $3.0 million letter of credit on our behalf, which is secured by a deposit of equal amount.

In May 2018, we entered into an agreement to lease 44,718 square feet of office space in San Diego, California, which commenced on July 1, 2018, for a term of 10 years and 10 months. Under the terms of the lease, we pay base annual rent (subject to an annual fixed percentage increase), plus property taxes, and other normal and necessary expenses, such as utilities, repairs, and maintenance. Certain incentives were included in the lease, including $4.2 million in tenant improvement allowances and twelve months of rent abatement. In lieu of a cash security deposit, Wells Fargo issued a $1.0 million letter of credit on our behalf, which is secured by a deposit of $0.7 million. We do not have the right to extend the lease or right of first offer for future rental of adjacent office space owned by the landlord.

For the nine months ended September 30, 2019, our operating lease cost was $5.9 million and cash paid for amounts included in the measurement of lease liabilities for operating cash flows from operating leases was $5.5 million. As of September 30, 2019, we reported operating lease ROU assets and operating lease liabilities of $62.0 million and $82.6 million, respectively. Further, as of September 30, 2019, our operating leases had a weighted average remaining lease term of 11.43 years and a weighted average discount rate of 5.84%.

At September 30, 2019, the approximate future minimum lease payments under operating leases were as follows:

(in thousands)	Operating Leases
Year Ending December 31,	
2019 (3 months remaining)	$ 2,142
2020	8,431
2021	9,026
2022	9,302
2023	9,586
Thereafter	77,068
Total operating lease payments	115,555
Less accreted interest	(32,914)
Total operating lease liabilities	82,641
Less current operating lease liabilities	(8,159)
Noncurrent operating lease liabilities	$ 74,482

Note: Amounts presented in the table above exclude $47.4 million of non-cancelable future minimum lease payments for operating leases that have not yet commenced.

8. Convertible Senior Notes

On May 2, 2017, we completed a private placement of $517.5 million in aggregate principal amount of 2.25% convertible senior notes due 2024 and entered into an indenture agreement (2024 Indenture) with respect to the 2024 Notes. The 2024 Notes accrue interest at a fixed rate of 2.25% per year, payable semiannually in arrears on May 15 and November 15 of each year, beginning on November 15, 2017. The 2024 Notes mature on May 15, 2024. The net proceeds from the issuance of the 2024 Notes were approximately $502.8 million, after deducting commissions and the offering expenses payable by us.

Holders of the 2024 Notes may convert the 2024 Notes at any time prior to the close of business on the business day immediately preceding May 15, 2024, only under the following circumstances:

(i) during any calendar quarter (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than 130% of the conversion price on each applicable trading day;

(ii) during the five business-day period immediately after any five consecutive trading-day period (the measurement period) in which the trading price (as defined in the 2024 Indenture) per $1,000 principal amount of the 2024 Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day;

(iii) upon the occurrence of specified corporate events, including a merger or a sale of all or substantially all of our assets; or

(iv) if we call the 2024 Notes for redemption, until the close of business on the business day immediately preceding the redemption date.

On or after January 15, 2024, until the close of business on the scheduled trading day immediately preceding May 15, 2024, holders may convert their 2024 Notes at any time.

Upon conversion, holders will receive the principal amount of their 2024 Notes and any excess conversion value, calculated based on the per share volume-weighted average price for each of the 30 consecutive trading days during the observation period (as more fully described in the 2024 Indenture). For both the principal and excess conversion value, holders may receive cash, shares of our common stock or a combination of cash and shares of our common stock, at our option.

It is our intent and policy to settle conversions through combination settlement, which essentially involves repayment of an amount of cash equal to the “principal portion” and delivery of the “share amount” in excess of the principal portion in shares of common stock or cash. In general, for each $1,000 in principal, the “principal portion” of cash upon settlement is defined as the lesser of $1,000, and the conversion value during the 25-day observation period as described in the 2024 Indenture. The conversion value is the sum of the daily conversion value which is the product of the effective conversion rate divided by 25 days and the daily volume weighted average price (VWAP) of our common stock. The “share amount” is the cumulative “daily share amount” during the observation period, which is calculated by dividing the daily VWAP into the difference between the daily conversion value (i.e., conversion rate x daily VWAP) and $1,000.

The initial conversion rate for the 2024 Notes is 13.1711 shares of common stock per $1,000 principal amount, which is equivalent to an initial conversion price of approximately $75.92 per share of our common stock. At the initial conversion rate, settlement of the 2024 Notes for shares of our common stock would approximate 6.8 million shares. The conversion rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. The initial conversion price of the 2024 Notes represented a premium of approximately 42.5% to the closing sale price of $53.28 per share of our common stock on the Nasdaq Global Select Market on April 26, 2017, the date that we priced the private offering of the 2024 Notes.

In the event of conversion, holders would forgo all future interest payments, any unpaid accrued interest and the possibility of further stock price appreciation. Upon the receipt of conversion requests, the settlement of the 2024 Notes will be paid pursuant to the terms of the 2024 Indenture. In the event that all of the 2024 Notes are converted, we would be required to repay the $517.5 million in principal value and any conversion premium in any combination of cash and shares of our common stock, at our option.

We may not redeem the 2024 Notes prior to May 15, 2021. On or after May 15, 2021, we may redeem for cash all or part of the 2024 Notes if the last reported sale price (as defined in the 2024 Indenture) of our common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading-day period ending on, and including, the trading day immediately before the date which we provide notice of redemption. The redemption price will equal the sum of (i) 100% of the principal amount of the 2024 Notes being redeemed, plus (ii) accrued and unpaid interest, including additional interest, if any, to, but excluding, the redemption date. No sinking fund is provided for the 2024 Notes.

If we undergo a fundamental change, as defined in the 2024 Indenture, subject to certain conditions, holders of the 2024 Notes may require us to repurchase for cash all or part of their 2024 Notes at a repurchase price equal to 100% of the principal amount of the 2024 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. In addition, if a ‘‘make-whole fundamental change’’ (as defined in the 2024 Indenture) occurs prior to January 15, 2024, we will, in certain circumstances, increase the conversion rate for a holder who elects to convert its notes in connection with the make-whole fundamental change.

The 2024 Notes are our general unsecured obligations that rank senior in right of payment to all of our indebtedness that is expressly subordinated in right of payment to the 2024 Notes, and equal in right of payment to our unsecured indebtedness.

While the 2024 Notes are currently classified as long-term on our condensed consolidated balance sheets, the future convertibility and resulting balance sheet classification of this liability will be monitored at each quarterly reporting date and will be analyzed dependent upon market prices of our common stock during the prescribed measurement periods. In the event that the holders of the 2024 Notes have the election to convert the 2024 Notes at any time during the prescribed measurement period, the 2024 Notes would then be considered a current obligation and classified as such.

We are required to separately account for the liability and equity components of the 2024 Notes as they may be settled entirely or partially in cash upon conversion in a manner that reflects our economic interest cost. The liability component of the instrument was valued in a manner that reflects the market interest rate for a similar nonconvertible instrument at the date of issuance. The initial carrying value of the liability component of $368.3 million was calculated using a 7.5% assumed borrowing rate. The equity component of $149.2 million, representing the conversion option, was determined by deducting the fair value of the liability component from the par value of the 2024 Notes and was recorded in additional paid-in capital on the consolidated balance sheet at the issuance date. That equity component is treated as a discount on the liability component of the 2024 Notes, which is amortized over the seven-year term of the 2024 Notes using the effective interest rate method. The equity component is not re-measured as long as it continues to meet the conditions for equity classification. As of September 30, 2019, the remaining period over which the discount on the liability component will be amortized was approximately 4.7 years.

We allocated the total transaction costs of approximately $14.7 million related to the issuance of the 2024 Notes to the liability and equity components of the 2024 Notes based on their relative values. Transaction costs attributable to the liability component are amortized to interest expense over the seven-year term of the 2024 Notes, and transaction costs attributable to the equity component are netted with the equity component in stockholders’ equity.

The 2024 Notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, the issuance of other indebtedness or the issuance or repurchase of securities by us. The 2024 Indenture contains customary events of default with respect to the 2024 Notes, including that upon certain events of default, 100% of the principal and accrued and unpaid interest on the 2024 Notes will automatically become due and payable.

The 2024 Notes, net of discounts and deferred financing costs, consisted of the following:

(in thousands)	September 30, 2019	December 31, 2018
Principal	$ 517,500	$ 517,500
Deferred financing costs	(7,290)	(8,326)
Debt discount, net	(106,621)	(120,678)
Net carrying amount	$ 403,589	$ 388,496

9. Net Income Per Share

Net income per share was calculated as follows:

(in thousands, except per share data)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Net income - basic and diluted	$ 53,789	$ 50,764	$ 3,012	$ 3,033
Weighted-average common shares outstanding:				
Basic	91,859	90,555	91,440	90,064
Effect of dilutive securities:				
Employee stock purchase program	11	7	22	2
Stock options	2,466	3,352	2,572	3,322
Restricted stock	461	629	392	558
2024 Notes	1,277	2,255	805	1,326
Diluted	96,074	96,798	95,231	95,272
Net income per share:				
Basic	$ 0.59	$ 0.56	$ 0.03	$ 0.03
Diluted	$ 0.56	$ 0.52	$ 0.03	$ 0.03

Convertible debt instruments that may be settled entirely or partly in cash (such as the 2024 Notes) may, in certain circumstances where the borrower has the ability and intent to settle in cash, be accounted for under the treasury stock method. We issued the 2024 Notes with a combination settlement feature, which we have the ability and intent to use upon conversion of the 2024 Notes, to settle the principal amount of debt for cash and the excess of the principal portion in shares of our common stock. As a result, of the approximately 6.8 million shares underlying the 2024 Notes, only the shares required to settle the excess of the principal portion are considered under the treasury stock method.

Shares which have been excluded from diluted per share amounts because their effect would have been anti-dilutive consisted of the following:

(in thousands)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Stock options, restricted stock and convertible senior notes	2,347	882	2,189	823

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations section contains forward-looking statements, which involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below in Part II, Item 1A under the caption "Risk Factors." The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2018 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, which are contained in our Annual Report on Form 10-K for the year ended December 31, 2018, and our Quarterly Report on Form 10-Q for the six months ended June 30, 2019.

Overview

We are a neuroscience-focused biopharmaceutical company with more than 25 years of experience discovering and developing life-changing treatments for people with serious, challenging and under-addressed neurological, endocrine and psychiatric disorders. We specialize in targeting and interrupting disease-causing mechanisms involving the interconnected pathways of the nervous and endocrine systems.

Our portfolio includes United States Food and Drug Administration (FDA)-approved treatments for tardive dyskinesia (TD) and endometriosis and clinical development programs in multiple therapeutic areas including Parkinson's disease, congenital adrenal hyperplasia, uterine fibroids and polycystic ovary syndrome. Our treatment for endometriosis and our product candidates for uterine fibroids and polycystic ovary syndrome are partnered with AbbVie, Inc. (AbbVie). Additionally, we have a collaboration and license agreement with Voyager Therapeutics, Inc. (Voyager) focused on the development and commercialization of four programs using Voyager's proprietary gene therapy platform, including one clinical development program for advanced Parkinson's disease patients, VY-AADC.

In September 2019, we announced the initiation of the KINECT-HD study, a placebo-controlled Phase III study of valbenazine in adult Huntington's disease (HD) patients with chorea. Enrollment of the 120-participant study is expected to commence during the fourth quarter of 2019.

We currently have four major collaborations, two of which involve out-licensing of our proprietary technology to pharmaceutical partners.

Voyager. We entered into a collaboration and license agreement with Voyager, a clinical-stage gene therapy company, which became effective in March 2019. The agreement is focused on the development and commercialization of four programs using Voyager's proprietary gene therapy platform. The four programs consist of the VY-AADC program for Parkinson's disease, the VY-FXN01 program for Friedreich's ataxia and the rights to two programs to be determined by the parties in the future. In June 2019, we entered into an amendment to the collaboration and license agreement with Voyager. Under the terms of the amendment, we paid Voyager $5.0 million upfront to obtain rights outside the United States (U.S.) to the Friedreich's ataxia program, VY-FXN01, in connection with the early return of those rights to Voyager pursuant to a restructuring of Voyager's gene therapy relationship with Sanofi Genzyme.

BIAL – Portela & Ca, S.A. In February 2017, we entered into an exclusive license agreement with BIAL – Portela & Ca, S.A. (BIAL) pursuant to which we in-licensed technology from BIAL for the development and commercialization of opicapone for the treatment of human diseases and conditions in the U.S. and Canada. In the second quarter of 2019, we submitted a new drug application (NDA) with the FDA for opicapone as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients. The NDA was accepted by the FDA with a Prescription Drug User Fee Act target action date of April 26, 2020. The FDA's acceptance of the NDA triggered a milestone payment of $10.0 million, expensed as R&D in the second quarter of 2019 and paid by us to BIAL in the third quarter of 2019.

Mitsubishi Tanabe Pharma Corporation. In March 2015, we entered into a collaboration and license agreement with Mitsubishi Tanabe Pharma Corporation (MTPC) for the development and commercialization of INGREZZA® (valbenazine) for the treatment of movement disorders in Japan and other select Asian markets. Payments to us under this agreement included an up-front license fee of $30.0 million, of which $10.2 million continues to be deferred and will be recognized as revenue over the KINECT-HD study period.

AbbVie. In June 2010, we entered into an exclusive worldwide collaboration with AbbVie to develop and commercialize elagolix and all next-generation gonadotropin-releasing hormone antagonists. In the third quarter of 2019, AbbVie submitted an NDA with the FDA for elagolix for the treatment of heavy menstrual bleeding associated with uterine fibroids in women. The NDA was accepted by the FDA with a PDUFA target action date in the second quarter of 2020. The FDA's acceptance of the NDA triggered a milestone payment of $20.0 million, recognized as revenue in the third quarter of 2019 and payable to us by AbbVie in the fourth quarter of 2019. Additionally, AbbVie intends to initiate a study of elagolix in women with polycystic ovary syndrome.

Results of Operations for the Three and Nine Months Ended September 30, 2019 and 2018

Revenues

The following table presents revenues by category.

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2019**	**2018**	**2019**	**2018**
INGREZZA product sales, net	$ 198,094	$ 111,291	$ 515,069	$ 279,282
Collaboration revenue	24,000	40,466	29,008	40,466
Total revenues	$ 222,094	$ 151,757	$ 544,077	$ 319,748

Product Sales, Net

In April 2017, the FDA approved INGREZZA for the treatment of TD. INGREZZA became available for prescription in late April 2017. Net product sales were $198.1 million and $515.1 million for the three and nine months ended September 30, 2019, respectively, compared with $111.3 million and $279.3 million in the comparable periods last year.

Collaboration Revenue

Collaboration revenue reflects event-based milestones and royalties earned under our collaboration agreement with AbbVie. During the third quarter of 2019, we recognized a $20.0 million event-based milestone as revenue upon the FDA's acceptance of AbbVie's NDA submission of elagolix for the treatment of uterine fibroids. During the third quarter of 2018, we recognized a $40.0 million event-based milestone as revenue upon the FDA's approval of ORILISSA® (elagolix). For the three and nine months ended September 30, 2019, we recognized sales-based royalties of $4.0 million and $9.0 million, respectively, compared with $0.5 million in both of the comparable periods last year. These sales-based royalties are payable to us by AbbVie on quarterly net sales of ORILISSA.

Operating Expenses

Cost of Sales

Cost of sales was $2.2 million and $5.0 million for the three and nine months ended September 30, 2019, respectively, compared with $1.6 million and $3.4 million in the comparable periods last year.

Research and Development

We support our drug discovery and development efforts through the commitment of significant resources to discovery, research and development (R&D) programs, and business development opportunities.

Costs are reflected in the applicable development stage based upon the program status when incurred. Therefore, the same program could be reflected in different development stages in the same reporting period. For several of our programs, the R&D activities are part of our collaborative and other relationships.

Late stage consists of costs incurred related to product candidates in Phase II registrational studies and onwards. Early stage consists of costs incurred related to product candidates in post-investigational new drug application (IND) through Phase II non-registrational studies. Research and discovery consists of pre-IND costs. Milestone expenses reflect payments made in connection with our collaborative and other relationships. Payroll and benefits consists of costs incurred for salaries and wages, payroll taxes, benefits, and share-based compensation associated with employees involved in ongoing R&D activities.

Facilities and other consists of indirect costs incurred in support of overall R&D activities and non-specific programs, including activities that benefit multiple programs, such as management costs, as well as depreciation, information technology, and facility-based expenses. These costs are not allocated to a specific program or stage.

The following table presents R&D expense by category:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2019**	**2018**	**2019**	**2018**
Late stage	$ 11,717	$ 4,959	$ 32,549	$ 15,331
Early stage	6,204	9,915	17,813	28,625
Research and discovery	4,365	2,806	14,538	9,676
Milestone expenses	—	—	10,000	10,000
Payroll and benefits	17,918	14,535	50,717	49,651
Facilities and other	5,074	3,267	19,000	8,133
Total R&D expense	$ 45,278	$ 35,482	$ 144,617	$ 121,416

R&D expense was $45.3 million and $144.6 million for the three and nine months ended September 30, 2019, respectively, compared with $35.5 million and $121.4 million in the comparable periods last year, primarily reflecting funding of development activities in connection with our collaboration with Voyager.

Acquired In-Process Research and Development

In-process research and development (IPR&D) was $118.1 million for the first nine months of 2019. In connection with the payment of the upfront fee pursuant to our collaboration and license agreement with Voyager, we recorded a charge of $113.1 million, accounted for as IPR&D, in the first quarter of 2019. In the second quarter of 2019, we entered into an amendment to the collaboration and license agreement with Voyager, pursuant to which we paid Voyager $5.0 million upfront to obtain rights outside the United States to the Friedreich's ataxia program, VY-FXN01. The upfront payment was expensed as IPR&D in the second quarter of 2019.

Sales, General and Administrative

Sales, general and administrative (SG&A) expense was $84.5 million and $252.9 million for the three and nine months ended September 30, 2019, respectively, compared with $60.4 million and $180.0 million in the comparable periods last year, primarily reflecting the sales force expansion completed in the third quarter of 2018, the national launch of a patient-focused disease state awareness campaign, Talk About TD, and an increase in the Branded Pharmaceutical Drug fee expense.

Other Expense, Net

Other expense, net, was $31.7 million and $15.7 million for the three and nine months ended September 30, 2019, respectively, compared with $3.6 million and $12.0 million in the comparable periods last year, primarily reflecting unrealized losses of $28.5 million and $5.8 million in the three and nine months ended September 30, 2019, respectively, to adjust our equity investment in Voyager to fair value as of September 30, 2019.

Provision for Income Taxes

Our provision for income taxes was $4.6 million and $4.9 million for the three and nine months ended September 30, 2019, respectively, for estimated current state income taxes. We used the year-to-date effective tax rate method to determine our interim income tax expense for state jurisdictions where a reliable estimate of the annual effective tax rate could not be made. The tax provision recorded differs from the statutory rate of 21%, reflecting a full valuation allowance recorded against losses incurred.

Net Income

Net income was $53.8 million, or $0.56 diluted earnings per share, for the third quarter of 2019, compared with $50.8 million, or $0.52 diluted earnings per share, in the comparable period last year, primarily reflecting increased INGREZZA net product sales, partially offset by continued INGREZZA investment and a $28.5 million unrealized loss on our Voyager equity investment. For the first nine months of 2019, net income was $3.0 million, or $0.03 diluted earnings per share, compared with $3.0 million, or $0.03 diluted earnings per share, in the comparable period last year, primarily reflecting increased INGREZZA net product sales, offset by $118.1 million of IPR&D in connection with our collaboration with Voyager.

Liquidity and Capital Resources

At September 30, 2019, our cash and cash equivalents and available-for-sale investments totaled $875.0 million compared with $866.9 million at December 31, 2018.

Net cash provided by operating activities was $49.5 million for the first nine months of 2019, compared with $50.9 million in the comparable period last year, primarily reflecting increased INGREZZA net product sales compared with the same period last year, partially offset by incremental INGREZZA investment and upfront payments of $118.1 million and funding of development activities in the first nine months of 2019 in connection with our collaboration with Voyager.

Net cash used in investing activities was $44.9 million for the first nine months of 2019, compared with $136.7 million in the comparable period last year, reflecting timing differences associated with the purchases and sales and maturities of our available-for-sale investments, as well as changes in our portfolio-mix between cash equivalents and short-term and long-term investment holdings, offset by our $54.7 million equity investment in Voyager in the first quarter of 2019.

Net cash provided by financing activities was $20.0 million for the first nine months of 2019, compared with $27.7 million in comparable period last year.

Shelf Registration Statement

In February 2017, we filed an automatic shelf registration statement which immediately became effective by rule of the Securities and Exchange Commission (SEC). For so long as we continue to satisfy the requirements to be deemed a well-known seasoned issuer, this

shelf registration statement allows us to issue an unlimited number of securities from time to time. We sold no securities under this shelf registration statement in 2018 or the first nine months of 2019.

Convertible Senior Notes

In May 2017, we issued $517.5 million of 2.25% convertible senior notes due May 15, 2024.

Off-Balance Sheet Arrangements

As of September 30, 2019, we did not have any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

There were no changes to our critical accounting policies as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018.

Interest Rate Risk

We are exposed to interest rate risk on our short-term investments. The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in highly liquid and high-quality government and other debt securities. To minimize our exposure due to adverse shifts in interest rates, we invest in short-term securities and ensure that the maximum average maturity of our investments does not exceed 12 months. If a 10% change in interest rates were to have occurred on September 30, 2019, it would not have had a material effect on the fair value of our investment portfolio as of that date. Due to the short holding period of our investments, we have concluded that we do not have a material financial market risk exposure.

Recently Issued Accounting Pronouncements

For a summary of new accounting pronouncements which may be applicable to us, see Note 1 to the condensed consolidated financial statements included in this report.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements that involve a number of risks and uncertainties. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, these forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements.

Forward-looking statements can be identified by the use of forward-looking words such as “believes,” “expects,” “hopes,” “may,” “will,” “plan,” “intends,” “estimates,” “could,” “should,” “would,” “continue,” “seeks,” “proforma,” or “anticipates,” or other similar words (including their use in the negative), or by discussions of future matters such as the development of new products, technology enhancements, possible changes in legislation and other statements that are not historical. These statements include but are not limited to statements under the captions “Risk Factors,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” as well as other sections in this report. You should be aware that the occurrence of any of the events discussed under the heading in Part II titled “Item 1A. Risk Factors” and elsewhere in this report could substantially harm our business, results of operations and financial condition and that if any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock.

The cautionary statements made in this report are intended to be applicable to all related forward-looking statements wherever they may appear in this report. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. Except as required by law, we assume no obligation to update our forward-looking statements, even if new information becomes available in the future.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

A discussion of our exposure to, and management of, market risk appears in Part I, Item 2 of this Quarterly Report on Form 10-Q under the heading “Interest Rate Risk.”

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 required by the Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the timelines specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the quarter covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of any changes to our internal control over financial reporting that occurred during our last fiscal quarter and that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Our evaluation did not identify significant changes in our internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934) that occurred during the quarter ended September 30, 2019, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Item 1A. Risk Factors

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report on Form 10-Q and those we may make from time to time. If any of the following risks actually occur, our business, operating results, prospects or financial condition could be harmed. Additional risks not presently known to us, or that we currently deem immaterial, may also affect our business operations. The risk factors set forth below with an asterisk (*) contain changes to the risk factors set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

Risks Related to Our Company

We may not be able to continue to successfully commercialize INGREZZA, or any of our product candidates if they are approved in the future.

Our ability to produce INGREZZA revenues consistent with expectations ultimately depends on our ability to sell our products and secure adequate third-party reimbursement if and when they are approved by the FDA. Our experience in marketing and selling pharmaceutical products began with INGREZZA's approval in 2017, when we hired our sales force and established our distribution and reimbursement capabilities, all of which are necessary to successfully commercialize INGREZZA. We have continued to invest in our commercial infrastructure and distribution capabilities in the past two years, including our sales force expansion in late 2018. While our team members and consultants have experience marketing and selling pharmaceutical products, we may face difficulties related to managing the rapid growth of our personnel and infrastructure, and there can be no guarantee that we will be able to maintain the personnel, systems, arrangements and capabilities necessary to successfully commercialize INGREZZA or any product candidate approved by the FDA in the future. If we fail to maintain successful marketing, sales and reimbursement capabilities or fail to enter into successful marketing arrangements with third parties, our product revenues may suffer.

If physicians and patients do not continue to accept INGREZZA or do not accept any of our other products, or our sales and marketing efforts are not effective, we may not generate sufficient revenue.

The commercial success of INGREZZA or any of our other products, if approved for marketing, will depend upon the acceptance of those products as safe and effective by the medical community and patients.

The market acceptance of INGREZZA or any of our other products could be affected by a number of factors, including:

- the timing of receipt of marketing approvals for indications;
- the safety and efficacy of the products;
- the pricing of our products;
- the availability of healthcare payor coverage and adequate reimbursement for the products;
- public perception regarding any gene therapy products we may develop;
- the success of existing competitor products addressing our target markets or the emergence of equivalent or superior products; and
- the cost-effectiveness of the products.

If the medical community and patients do not ultimately accept our products as being safe, effective, superior and/or cost-effective, we may not generate sufficient revenue.

We depend on our current collaborators for the development and commercialization of several of our products and product candidates and may need to enter into future collaborations to develop and commercialize certain of our product candidates.

Our strategy for fully developing and commercializing ORILISSA is dependent upon maintaining our current collaboration agreement with AbbVie. This collaboration agreement provides for significant future payments should certain development, regulatory and commercial milestones be achieved, and royalties on future sales of elagolix. Under this agreement, AbbVie is responsible for, among other things, conducting clinical trials and obtaining required regulatory approvals for elagolix; as well as manufacturing and commercialization of ORILISSA.

Because of our reliance on AbbVie, the commercialization and continued development of ORILISSA could be substantially delayed, and our ability to receive future funding could be substantially impaired, if AbbVie:

- does not successfully commercialize ORILISSA for endometriosis;
- fails to gain regulatory approval of elagolix for uterine fibroids, and if applicable, successfully launch and commercialize elagolix for that indication;
- does not conduct its collaborative activities in a timely manner;
- does not devote sufficient time and resources to our partnered program;
- terminates its agreement with us;

- develops, either alone or with others, products that may compete with elagolix;
- disputes our respective allocations of rights to any products or technology developed during our collaboration; or
- merges with a third party that wants to terminate our agreement.

In March 2015, we entered into a collaboration and license agreement with MTPC to develop and commercialize INGREZZA in Japan and other select Asian markets. We will rely on MTPC to achieve certain development, regulatory and commercial milestones which, if achieved, could generate significant future revenue for us. Our collaboration with MTPC is subject to risks and uncertainties similar to those described above. In addition, we may need to enter into other out-licensing collaborations to assist in the development and commercialization of other product candidates we are developing now or may develop in the future, and any such future collaborations would be subject to similar risks and uncertainties.

Effective in March 2019, we entered into a collaboration and license agreement with Voyager for the research, development and commercialization of four programs including Voyager's Parkinson's disease program, or AADC Program, Voyager's Friedreich's ataxia program, or FA Program, and two programs to be determined by us and Voyager at a later date, or the Discovery Programs. Pursuant to development plans to be agreed to by the parties, which will be overseen by a joint steering committee, Voyager has operational responsibility, subject to certain exceptions, for the conduct of the AADC Program, FA Program and Discovery Programs prior to specified transition events for each program. We have agreed to be responsible for all costs incurred by Voyager in conducting these activities for each program in accordance with an agreed budget. Upon the occurrence of specified events for each program, we have agreed to assume responsibility for development, manufacturing and commercialization activities for such program. Voyager might not be successful in achieving the goals set forth in the development plan prior to the occurrence of the specified events that give rise to us assuming responsibility for development, manufacturing and commercialization activities for such program. Further, Voyager's objectives in connection with the collaboration may not be consistent with our best interests. Voyager could take actions that may be adverse to us, or it could halt, slow, or deprioritize its development and commercialization efforts under the collaboration. We could also experience disagreements or delays involving the determination of one or both of the Discovery Programs. In any such instances, our ability to commercialize any product candidate related to the AADC Program, FA Program or Discovery Programs could be delayed or prohibited.

These issues and possible disagreements with AbbVie, MTPC, Voyager, or any future corporate collaborators could lead to delays in the collaborative research, development or commercialization of our product candidates. Furthermore, disagreements with these parties could require or result in litigation or arbitration, which would be time-consuming and expensive. If any of these issues arise, it may delay the development and commercialization of drug candidates and, ultimately, our generation of product revenues.

Use of our approved products or those of our collaborators, including INGREZZA and ORILISSA, could be associated with side effects or adverse events.

As with most pharmaceutical products, use of our approved products or those of our collaborators, including INGREZZA and ORILISSA, could be associated with side effects or adverse events which can vary in severity (from minor adverse reactions to death) and frequency (infrequent or prevalent). Side effects or adverse events associated with the use of our products or those of our collaborators may be observed at any time, including after a product is commercialized, and reports of any such side effects or adverse events may negatively impact demand for our or our collaborators' products or affect our or our collaborators' ability to maintain regulatory approval for such products. Side effects or other safety issues associated with the use of our approved products or those of our collaborators could require us or our collaborators to modify or halt commercialization of these products or expose us to product liability lawsuits which will harm our business. We or our collaborators may be required by regulatory agencies to conduct additional studies regarding the safety and efficacy of our products which we have not planned or anticipated. Furthermore, there can be no assurance that we or our collaborators will resolve any issues related to any product related adverse events to the satisfaction of the FDA or any regulatory agency in a timely manner or ever, which could harm our business, prospects and financial condition.

We currently depend on a limited number of third-party suppliers. The loss of these suppliers, or delays or problems in the supply of INGREZZA, could materially and adversely affect our ability to successfully commercialize INGREZZA.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of process controls required to consistently produce the active pharmaceutical ingredients and the finished product in sufficient quantities while meeting detailed product specifications on a repeated basis. Manufacturers of pharmaceutical products may encounter difficulties in production, such as difficulties with production costs and yields, process controls, quality control and quality assurance, including testing of stability, impurities and impurity levels and other product specifications by validated test methods, and compliance with strictly enforced U.S., state, and non-U.S. regulations. We depend on a limited number of suppliers for each of the production of INGREZZA and its active pharmaceutical ingredients. If our third-party suppliers for INGREZZA encounter these or any other manufacturing, quality or compliance difficulties, we may be unable to meet commercial demand for INGREZZA, which could materially and adversely affect our ability to successfully commercialize INGREZZA. We also depend on BIAL, and its suppliers, for the production of opicapone drug substance and drug product.

In addition, if our suppliers fail or refuse to supply us with INGREZZA or its active pharmaceutical ingredient for any reason, it would take a significant amount of time and expense to qualify a new supplier. The FDA and similar international regulatory bodies must approve manufacturers of the active and inactive pharmaceutical ingredients and certain packaging materials used in pharmaceutical products. The loss of a supplier could require us to obtain regulatory clearance and to incur validation and other costs associated with the transfer of the active pharmaceutical ingredients or product manufacturing processes. If there are delays in qualifying new suppliers or facilities or a new supplier is unable to meet FDA or a similar international regulatory body's requirements for approval, there could be a shortage of INGREZZA, which could materially and adversely affect our ability to successfully commercialize INGREZZA. If BIAL is unable or refuses to supply us with opicapone drug product for any reason, or does not meet FDA or international regulators' requirements for approval, we have limited opportunity to qualify a new supplier. This could materially and adversely affect our ability to obtain regulatory approval for opicapone or successfully commercialize opicapone.

We have no manufacturing capabilities. If third-party manufacturers of INGREZZA or any of our product candidates fail to devote sufficient time and resources to our concerns, or if their performance is substandard, our clinical trials and product introductions may be delayed, and our costs may rise.

We have in the past utilized, and intend to continue to utilize, third-party manufacturers to produce the drug compounds we use in our clinical trials and for the commercialization of our products. We have limited experience in manufacturing products for commercial purposes and do not currently have any manufacturing facilities. Consequently, we depend on, and will continue to depend on, several contract manufacturers for all production of products for development and commercial purposes, including INGREZZA and opicapone. If we are unable to obtain or retain third-party manufacturers, we will not be able to develop or commercialize our products, including INGREZZA and opicapone. The manufacture of our products for clinical trials and commercial purposes is subject to specific FDA regulations, including current Good Manufacturing Practice regulations. Our third-party manufacturers, including BIAL and its suppliers, might not comply with FDA regulations relating to manufacturing our products for clinical trials and commercial purposes or other regulatory requirements now or in the future. In addition, the manufacture of gene therapy products, which will be necessary under our collaboration and license agreement with Voyager, is technically complex and necessitates substantial expertise and capital investment. Our reliance on contract manufacturers also exposes us to the following risks:

- contract manufacturers may encounter difficulties in achieving volume production, quality control or quality assurance, and also may experience shortages in qualified personnel. As a result, our contract manufacturers might not be able to meet our clinical schedules or adequately manufacture our products in commercial quantities when required;
- switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly on acceptable terms, or at all;
- our contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store or distribute our products; and
- drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the U.S. Drug Enforcement Administration, and other agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

Our current dependence upon third parties for the manufacture of our products may reduce our profit margin, if any, on the sale of INGREZZA, opicapone, or our future products and our ability to develop and deliver products on a timely and competitive basis.

Governmental and third-party payors may impose sales and pharmaceutical pricing controls on our products or limit coverage and/or reimbursement for our products that could limit our product revenues and delay sustained profitability.

Our ability to commercialize any products successfully, including INGREZZA, will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available. The continuing efforts of government and third-party payors to contain or reduce the costs of health care through various means may reduce our potential revenues. These payors' efforts could decrease the price that we receive for any products we may develop and sell in the future.

Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available regardless of whether they are approved by the FDA for that particular use.

Government authorities and other third-party payors are developing increasingly sophisticated methods of controlling healthcare costs, such as by limiting coverage and the amount of reimbursement for particular medications. Further, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the U.S. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. In addition, communications from government officials regarding health care costs and pharmaceutical pricing could have a negative impact on our stock price, even if such communications do not ultimately impact coverage or reimbursement decisions for our products.

There may also be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize INGREZZA or any other product candidate for which we obtain marketing approval. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved 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.

We are substantially dependent on BIAL for the development and commercialization of opicapone, including the receipt of regulatory approval for opicapone as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients.

In February 2017, we entered into a license agreement with BIAL for the development and commercialization of opicapone for the treatment of human diseases and conditions, including Parkinson’s disease, in the U.S. and Canada. In June 2019, we submitted an NDA with the FDA for opicapone as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients. The FDA has indicated that the Prescription Drug User Fee Act target date, on which the FDA is expected to complete its review of the opicapone NDA for Parkinson's disease, is April 26, 2020. Our strategy for developing and commercializing opicapone, including the receipt of regulatory approval for opicapone, is dependent upon maintaining our current collaboration with BIAL. Under the terms of our agreement with BIAL, although we are responsible for the management of all opicapone development and commercialization activities, we depend on BIAL and its suppliers to supply all drug product and investigation medicinal product for the development and commercialization of opicapone. Bial relies on third-party contract manufacturers to produce opicapone. These contract manufacturers may encounter difficulties in achieving volume production, quality control, or quality assurance. As a result, these contract manufacturers may not be able to adequately produce opicapone in commercial quantities when required, which may impact our ability to deliver opicapone on a timely basis. In addition, we and BIAL have established a joint steering committee with overall coordination and strategic oversight over activities under the agreement and to provide a forum for regular exchange of information, and BIAL has the right to co-promote licensed products during certain periods of time and to engage in certain marketing-related activities in cooperation with us. Because of our substantial reliance on BIAL, any failure by BIAL to timely or fully comply with its obligations under our agreement, any disagreement with BIAL, or any decision by BIAL to not devote sufficient time and resources to our collaboration, could substantially delay and/or prohibit our ability to develop and commercialize opicapone.

We are subject to ongoing obligations and continued regulatory review for INGREZZA, which may result in significant additional expense and market withdrawal. Additionally, our other product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

We received FDA regulatory approval for INGREZZA in April 2017. This approval and other regulatory approvals for any of our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. With respect to the FDA’s approval of INGREZZA for TD, we are subject to certain post-marketing requirements and commitments. Failure to comply with these post-marketing requirements and commitments could result in withdrawal of our marketing approval for INGREZZA. In addition, with respect to INGREZZA, and any product candidate that the FDA or a comparable foreign regulatory authority approves, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current Good Manufacturing Practices for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency (especially for a product, such as INGREZZA, which has been administered in a relatively limited patient population to date), or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

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

The FDA’s policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of any of our product candidates or future indications for currently approved products. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability on a sustained basis.

Because the development of our product candidates is subject to a substantial degree of technological uncertainty, we may not succeed in developing any of our product candidates.

All of our product candidates are currently in research or clinical development with the exceptions of INGREZZA, which has been approved by the FDA for TD, and ORILISSA (partnered with AbbVie), which has been approved by the FDA for the management of moderate to severe endometriosis pain in women. Only a small number of research and development programs ultimately result in commercially successful drugs. In addition, to date the FDA has granted regulatory approval for only a very limited number of gene therapy products. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons. These reasons include the possibilities that the potential products may:

- be found ineffective or cause harmful side effects during preclinical studies or clinical trials;
- fail to receive necessary regulatory approvals on a timely basis or at all;
- be precluded from commercialization by proprietary rights of third parties;
- be difficult to manufacture on a large scale; or
- be uneconomical to commercialize or fail to achieve market acceptance.

If any of our product candidates encounters any of these potential problems, we may never successfully market that product candidate.

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

Before obtaining regulatory approval for the sale of any of our potential products, we must subject these product candidates to extensive preclinical and clinical testing to demonstrate their safety and efficacy for humans. Clinical trials are expensive, time-consuming and may take years to complete.

In connection with the clinical trials of our product candidates, we face the risks that:

- the FDA or similar foreign regulatory authority may not allow an IND application or foreign equivalent filings required to initiate human clinical studies for our drug candidates or the FDA may require additional preclinical studies as a condition of the initiation of Phase I clinical studies, or additional clinical studies for progression from Phase I to Phase II, or Phase II to Phase III, or for NDA approval;
- the product candidate may not prove to be effective or as effective as other competing product candidates;
- we may discover that a product candidate may cause harmful side effects or results of required toxicology studies may not be acceptable to the FDA;
- the results may not replicate the results of earlier, smaller trials;
- the FDA or similar foreign regulatory authorities may require use of new or experimental endpoints that may prove insensitive to treatment effects;
- we or the FDA or similar foreign regulatory authorities may suspend the trials;
- the results may not be statistically significant;
- patient recruitment may be slower than expected;
- the FDA may not accept the data from any trial or trial site outside of the U.S.;
- patients may drop out of the trials; and
- regulatory requirements may change.

These risks and uncertainties impact all of our clinical programs. For example, any of the clinical, regulatory or operational events described above could change our planned clinical and regulatory activities for the opicapone program in Parkinson’s disease and/or our NBI-74788 program for the treatment of congenital adrenal hyperplasia, or CAH. Additionally, any of these events described above could result in suspension of a program and/or obviate any filings for necessary regulatory approvals.

In addition, late-stage clinical trials are often conducted with patients having the most advanced stages of disease. During the course of treatment, these patients can die or suffer other adverse medical effects for reasons that may not be related to the pharmaceutical agent being tested but which can nevertheless adversely affect clinical trial results. Any failure or substantial delay in completing clinical trials for our product candidates may severely harm our business.

Even if the clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

If we are unable to retain and recruit qualified scientists or if any of our key senior executives discontinues his or her employment with us, it may delay our development efforts or impact our commercialization of INGREZZA or any product candidate approved by the FDA.

We are highly dependent on the principal members of our management and scientific staff. The loss of any of these people could impede the achievement of our objectives, including the successful commercialization of INGREZZA or any product candidate approved by the FDA. Furthermore, recruiting and retaining qualified scientific personnel to perform research and development work in the future, along with personnel with experience marketing and selling pharmaceutical products, is critical to our success. We may be unable to attract and retain personnel on acceptable terms given the competition among biotechnology, pharmaceutical and health care companies, universities and non-profit research institutions for experienced scientists and individuals with experience marketing and selling pharmaceutical products. We may face particular retention challenges in light of the recent rapid growth in our personnel and infrastructure and the perceived impact of those changes upon our corporate culture. In addition, we rely on a significant number of consultants to assist us in formulating our research and development strategy and our commercialization strategy. Our consultants may have commitments to, or advisory or consulting agreements with, other entities that may limit their availability to us.

If the market opportunities for our products and product candidates are smaller than we believe they are, our revenues may be adversely affected, and our business may suffer.

Certain of the diseases that INGREZZA and our product candidates are being developed to address are in underserved and underdiagnosed populations. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who will seek treatment utilizing our products or product candidates, may not be accurate. If our estimates of the prevalence or number of patients potentially on therapy prove to be inaccurate, the market opportunities for INGREZZA and our product candidates may be smaller than we believe they are, our prospects for generating expected revenue may be adversely affected and our business may suffer.

Gene therapy treatments, which we are developing pursuant to our collaboration and license agreement with Voyager, may be perceived as unsafe or may result in unforeseen adverse events. Negative public opinion and increased regulatory scrutiny of gene therapy may adversely affect our ability to initiate or continue clinical development or obtain regulatory approvals for gene therapy product candidates or the commercialization of gene therapy products.

Gene therapy remains a novel technology, with few gene therapy products approved to date in the U.S. Public perception may be influenced by claims that gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. As part of our collaboration and license agreement with Voyager, a Phase II clinical trial of VY-AADC is being conducted. There is no guarantee that this program or other collaboration gene therapy product candidates will not be placed on clinical hold by the FDA, as has been the case for many gene therapy clinical programs. Even if we are able to successfully complete clinical development of a gene therapy product and obtain commercial approval, the success of our collaboration with Voyager will depend upon physicians who specialize in the treatment of genetic diseases targeted by gene therapy product candidates, prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are familiar and for which greater clinical data may be available. More restrictive government regulations or negative public opinion related to gene therapy products may delay or impair the development and commercialization of our gene therapy product candidates or demand for any gene therapy products we develop.

The limited precedent for gene therapy approvals makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for the product candidates we are developing through our collaboration with Voyager.

The FDA has limited experience in the review and approval of gene therapy products. The limited precedent for gene therapy approvals makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for the product candidates we are developing through our collaboration with Voyager.

Regulatory requirements governing gene therapy products have changed frequently and may continue to change in the future. As a result, the regulatory review process may take longer or cost more than we anticipate, including requirements for additional preclinical studies or clinical trials, and delay or prevent approval and commercialization of our gene therapy product candidates we are developing through our collaboration with Voyager. While the FDA has issued draft guidance for the development of gene therapies and proposed rules that would streamline certain requirements to which gene therapies are currently subject, it remains to be seen as to whether such initiatives will ultimately increase the speed of drug development in gene therapies such as the product candidates we are developing through our collaboration with Voyager.

Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations and prospects would be harmed.

We do not and will not have access to all information regarding the products and product candidates we licensed to AbbVie.

We do not and will not have access to all information regarding ORILISSA, including potentially material information about commercialization plans, medical information strategies, clinical trial design and execution, safety reports from clinical trials, safety reports, regulatory affairs, process development, manufacturing and other areas known by AbbVie. In addition, we have confidentiality obligations under our agreement with AbbVie. Thus, our ability to keep our shareholders informed about the status of ORILISSA will be limited by the degree to which AbbVie keeps us informed and allows us to disclose such information to the public. If AbbVie fails to keep us informed about commercialization efforts related to ORILISSA, or the status of the clinical development or regulatory approval pathway of other product candidates licensed to it, we may make operational and/or investment decisions that we would not have made had we been fully informed, which may materially and adversely affect our business and operations.

The independent clinical investigators and contract research organizations that we rely upon to conduct our clinical trials may not be diligent, careful or timely, and may make mistakes, in the conduct of our trials.

We depend on independent clinical investigators and contract research organizations (CROs) to conduct our clinical trials under their agreements with us. The investigators are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If our independent investigators fail to devote sufficient time and resources to our drug development programs, or if their performance is substandard, or not in compliance with Good Clinical Practices, it may delay or prevent the approval of our FDA applications and our introduction of new drugs. The CROs we contract with for execution of our clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Failure of the CROs to meet their obligations could adversely affect clinical development of our products. Moreover, these independent investigators and CROs may also have relationships with other commercial entities, some of which may compete with us. If independent investigators and CROs assist our competitors at our expense, it could harm our competitive position.

****We face intense competition, and if we are unable to compete effectively, the demand for our products may be reduced.***

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition in the development and marketing of our products and product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies.

Competition may also arise from, among other things:

- other drug development technologies;
- methods of preventing or reducing the incidence of disease, including vaccines; and
- new small molecule or other classes of therapeutic agents.

Developments by others may render our product candidates or technologies obsolete or noncompetitive.

We are commercializing and performing research on or developing products for the treatment of several disorders including endometriosis, TD, uterine fibroids, essential tremor, classic congenital adrenal hyperplasia, pain, Parkinson’s disease, Friedreich’s ataxia, and other neurological and endocrine-related diseases and disorders, and there are a number of competitors to our products and product candidates. If one or more of our competitors’ products or programs are successful, the market for our products may be reduced or eliminated.

- With respect to INGREZZA for TD, we compete with Teva Pharmaceutical Industries, which received FDA approval for AUSTEDO to treat TD in August 2017, and several clinical development-stage programs targeting TD and related movement disorders. Additionally, there are a number of commercially available medicines used to treat TD off-label, such as Xenazine (tetrabenazine) and generic equivalents, and various antipsychotic medications (e.g., clozapine), anticholinergics, benzodiazepines (off-label), and botulinum toxin.
- In endometriosis, ORILISSA competes with several FDA-approved products for the treatment of endometriosis, uterine fibroids, infertility, and central precocious puberty. Additionally, there is also competition from surgical interventions. Approximately 130,000 hysterectomies are performed in the U.S. annually as a direct result of endometriosis, as well as a significant number of laparoscopic procedures to ablate endometrial explants. Separate from these options, there are many programs in clinical development which serve as potential future competition. Lastly, there are numerous medicines used to treat the symptoms of disease (vs. endometriosis directly) which may also serve as competition: oral contraceptives, NSAIDs and other pain medications including opioids.
- With respect to opicapone for Parkinson’s disease, there are currently two FDA-approved COMT inhibitors. Opicapone would compete directly with these two drugs and their generic equivalents. Additionally, there are a number of alternative adjunctive treatment options (FDA-approved and in clinical development) for Parkinson’s patients which would compete with opicapone, including various L-dopa preparations, dopamine agonists, MAO-B inhibitors and others. In terms of potential future competition, there are several programs in late-stage clinical development.
- As for congenital adrenal hyperplasia, or CAH, high doses of corticosteroids are the current standard of care to both correct the endogenous cortisol deficiency as well as reduce the excessive ACTH levels. In the U.S. alone, there are more than two dozen companies manufacturing steroid-based products. Additionally, there are several companies developing medicinal treatments for CAH.

- Our development programs using Voyager's proprietary gene therapy platform (VY-AADC for Parkinson's disease and VY-FXN01 for Friedreich's Ataxia) may in the future compete with development-stage programs being pursued by numerous companies.

Compared to us, many of our competitors and potential competitors have substantially greater:

- capital resources;
- research and development resources, including personnel and technology;
- regulatory experience;
- preclinical study and clinical testing experience;
- manufacturing, marketing and distribution experience; and
- production facilities.

We license some of our core technologies and drug candidates from third parties. If we default on any of our obligations under those licenses, or violate the terms of these licenses, we could lose our rights to those technologies and drug candidates or be forced to pay damages.

We are dependent on licenses from third parties for some of our key technologies. These licenses typically subject us to various commercialization, reporting and other obligations. If we fail to comply with these obligations, we could lose important rights. If we were to default on our obligations under any of our licenses, we could lose some or all of our rights to develop, market and sell products covered by these licenses. For example, BIAL may terminate our license agreement, pursuant to which we have rights to develop and commercialize opicapone, if we fail to use commercially reasonable efforts, fail to submit an NDA for a licensed product by a specified date, or otherwise breach the license agreement. Pursuant to our collaboration and license agreement with Voyager, Voyager can terminate the agreement if we challenge the validity or enforceability of certain Voyager intellectual property rights or if we commit a material breach in whole or in part of the agreement and do not cure such breach within the agreed upon cure period. In addition, if we were to violate any of the terms of our licenses, we could become subject to damages. Likewise, if we were to lose our rights under a license to use proprietary research tools, it could adversely affect our existing collaborations or adversely affect our ability to form new collaborations. We also face the risk that our licensors could, for a number of reasons, lose patent protection or lose their rights to the technologies we have licensed, thereby impairing or extinguishing our rights under our licenses with them.

Our indebtedness and liabilities could limit the cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations.

To date, we have sold $517.5 million aggregate principal amount of 2.25% convertible senior notes due May 15, 2024 (2024 Notes). We may also incur additional indebtedness to meet future financing needs. Our indebtedness could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things:

- increasing our vulnerability to adverse economic and industry conditions;
- limiting our ability to obtain additional financing;
- requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for other purposes;
- limiting our flexibility to plan for, or react to, changes in our business;
- diluting the interests of our existing stockholders as a result of issuing shares of our common stock upon conversion of the 2024 Notes; and
- placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital.

Our business may not generate sufficient funds, and we may otherwise be unable to maintain sufficient cash reserves, to pay amounts due under the 2024 Notes and any additional indebtedness that we may incur. In addition, our cash needs may increase in the future. In addition, any future indebtedness that we may incur may contain financial and other restrictive covenants that limit our ability to operate our business, raise capital or make payments under our other indebtedness. If we fail to comply with these covenants or to make payments under our indebtedness when due, then we would be in default under that indebtedness, which could, in turn, result in that and our other indebtedness becoming immediately payable in full.

The conditional conversion feature of the 2024 Notes, if triggered, may adversely affect our financial condition, operating results, or liquidity.

In the event the conditional conversion feature of the 2024 Notes is triggered, holders of 2024 Notes will be entitled to convert their 2024 Notes at any time during specified periods at their option. If one or more of the holders of the 2024 Notes elects to convert their notes, unless we satisfy our conversion obligation by delivering only shares of our common stock, we would be required to settle all or a portion of our conversion obligation through the payment of cash, which could adversely affect our liquidity. The conditional convertibility of the 2024 Notes will be monitored at each quarterly reporting date and analyzed dependent upon market prices of our common stock during the prescribed measurement periods.

We have a history of losses and expect to increase our expenses for the foreseeable future, and we may never achieve sustained profitability.

Since our inception, we have incurred significant net losses and negative cash flow from operations. As a result of historical operating losses, we had an accumulated deficit of approximately $1.2 billion as of December 31, 2018.

In April 2017, we received FDA approval of INGREZZA for TD, and in July 2018, our partner AbbVie received FDA approval for ORILISSA for management of moderate to severe endometriosis pain in women. However, we have not yet obtained regulatory approvals for any other product candidates. Even if we succeed in commercializing INGREZZA or developing and commercializing any of our other product candidates, we may not be profitable. We also expect to continue to incur significant operating and capital expenditures as we:

- commercialize INGREZZA for TD;
- seek regulatory approvals for our product candidates;
- develop, formulate, manufacture and commercialize our product candidates;
- in-license or acquire new product development opportunities;
- implement additional internal systems and infrastructure; and
- hire additional clinical, scientific, sales and marketing personnel.

We expect to increase our expenses and other investments in the coming years as we fund our operations, in-licensing or acquisition opportunities, and capital expenditures. While we were profitable for the three months ended September 30, 2019, our future operating results and profitability may fluctuate from period to period due to the factors described above, and we will need to generate significant revenues to achieve and maintain profitability and positive cash flow on a sustained basis. We may not be able to generate these revenues, and we may never achieve profitability on a sustained basis in the future. Our failure to maintain or increase profitability on a sustained basis could negatively impact the market price of our common stock.

We have recently increased the size of our organization and will need to continue to increase the size of our organization. We may encounter difficulties with managing our growth, which could adversely affect our results of operations.

As of September 30, 2019, we had approximately 670 full-time employees. Although we have substantially increased the size of our organization, we may need to add additional qualified personnel and resources, especially now that we have a commercial sales force. Our current infrastructure may be inadequate to support our development and commercialization efforts and expected growth. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees, and may take time away from running other aspects of our business, including development and commercialization of our product candidates.

Our future financial performance and our ability to commercialize INGREZZA and any other product candidates that receive regulatory approval will depend, in part, on our ability to manage any future growth effectively. In particular, as we commercialize INGREZZA, we will need to support the training and ongoing activities of our sales force and will likely need to continue to expand the size of our employee base for managerial, operational, financial and other resources. To that end, we must be able to successfully:

- manage our development efforts effectively;
- integrate additional management, administrative and manufacturing personnel;
- further develop our marketing and sales organization; and
- maintain sufficient administrative, accounting and management information systems and controls.

We may not be able to accomplish these tasks or successfully manage our operations and, accordingly, may not achieve our research, development, and commercialization goals. Our failure to accomplish any of these goals could harm our financial results and prospects.

We may be subject to claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is commonplace in the biotechnology industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Because our operating results may vary significantly in future periods, our stock price may decline.

Our quarterly revenues, expenses and operating results have fluctuated in the past and are likely to fluctuate significantly in the future. Our financial results are unpredictable and may fluctuate, for among other reasons, due to seasonality of commercial sales of INGREZZA, royalties from out-licensed products, the impact of Medicare Part D coverage, our achievement of product development objectives and milestones, clinical trial enrollment and expenses, research and development expenses and the timing and nature of contract manufacturing and contract research payments. In addition, in April 2017 we received regulatory approval from the FDA for INGREZZA in TD and our revenues will be dependent on our ability to sell INGREZZA and to secure adequate third-party reimbursement. A high portion of our costs are predetermined on an annual basis, due in part to our significant research and

development costs. Thus, small declines in revenue could disproportionately affect financial results in a quarter. While we were profitable for the three months ended September 30, 2019, our future operating results and profitability may fluctuate from period to period, and even if we become profitable on a quarterly or annual basis, we may not be able to sustain or increase our profitability. Moreover, as our company and our market capitalization have grown, our financial performance has become increasingly subject to quarterly and annual comparisons with the expectations of securities analysts or investors. The failure of our financial results to meet these expectations, either in a single quarterly or annual period over a sustained period time, could cause our stock price to decline.

U.S. federal income tax reform could adversely affect our business and financial condition.

On December 22, 2017, U.S. federal income tax legislation was signed into law (H.R. 1, "An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018", informally titled the Tax Cuts and Jobs Act, or the Tax Act). The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, repeal of the alternative minimum tax for corporations, limitation of the tax deduction for interest expense to 30% of adjusted taxable income (except for certain small businesses), limitation of the deduction for net operating losses generated in taxable years beginning after December 31, 2017, to 80% of current year taxable income, elimination of most carrybacks of net operating losses arising in taxable years ending after December 31, 2017, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the Tax Act. The impact of the Tax Act on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Our ability to use net operating loss carryforwards and certain other tax attributes may be limited.

Our net operating loss, or NOL, carryforwards generated in tax years ending on or prior to December 31, 2017, are only permitted to be carried forward for 20 years under applicable U.S. tax law. Under the Tax Act, our federal NOLs generated in tax years ending after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs generated in tax years beginning after December 31, 2017, is limited. It is uncertain if and to what extent various states will conform to the Tax Act. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We do not believe we have experienced any previous ownership changes, but the determination is complex and there can be no assurance we are correct. Furthermore, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control.

As a result, our pre-2018 NOL carryforwards may expire prior to being used and our NOL carryforwards generated thereafter will be subject to a percentage limitation and, if we undergo an ownership change (or if we previously underwent such an ownership change), our ability to use all of our pre-change NOLs and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes may be limited. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, we may be unable to use all or a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

Our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of the newly enacted federal income tax law, changes in the mix of our profitability from state to state, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

The price of our common stock is volatile.

The market prices for securities of biotechnology and pharmaceutical companies historically have been highly volatile, and the market for these securities has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Furthermore, especially as we and our market capitalization have grown, the price of our common stock has been increasingly affected by quarterly and annual comparisons with the valuations and recommendations of the analysts who cover our business. If our results do not meet these analysts' forecasts, the expectations of our investors or the financial guidance we provide to investors in any period, which is based on assumptions that may be incorrect or that may change from quarter to quarter, the market price of our common stock could decline. Over the course of the last 12 months, the price of our common stock has ranged from approximately $126.00 per share to approximately $65.00 per share. The market price of our common stock may fluctuate in response to many factors, including:

- sales of INGREZZA and ORILISSA;
- the status and cost of our post-marketing commitments for INGREZZA;
- the results of our clinical trials;
- reports of safety issues related to INGREZZA or ORILISSA;
- developments concerning new and existing collaboration agreements;
- announcements of technological innovations or new therapeutic products by us or others;
- general economic and market conditions, including economic and market conditions affecting the biotechnology industry;
- developments in patent or other proprietary rights;
- developments related to the FDA;
- future sales of our common stock by us or our stockholders;
- comments by securities analysts;
- additions or departures of key personnel;
- fluctuations in our operating results;
- potential litigation matters;
- government regulation;
- government and third-party payor coverage and reimbursement;
- failure of any of our product candidates, if approved, to achieve commercial success; and
- public concern as to the safety of our drugs.

If we cannot raise additional funding, we may be unable to complete development of our product candidates or establish commercial and manufacturing capabilities in the future.

We may require additional funding to effectively commercialize INGREZZA, to continue our research and product development programs, to conduct preclinical studies and clinical trials, for operating expenses, to pursue regulatory approvals for our product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims, if any, and the cost of product in-licensing and any possible acquisitions. In addition, we may require additional funding to establish manufacturing and marketing capabilities in the future. We believe that our existing capital resources, together with investment income, and future payments due under our strategic alliances, will be sufficient to satisfy our current and projected funding requirements for at least the next 12 months. However, these resources might be insufficient to conduct research and development programs, the cost of product in-taking and possible acquisitions, fully commercialize products and operate the company to the full extent currently planned. If we cannot obtain adequate funds, we may be required to curtail significantly our commercial plans or one or more of our research and development programs or obtain funds through additional arrangements with corporate collaborators or others that may require us to relinquish rights to some of our technologies or product candidates.

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

- the commercial success of INGREZZA and/or ORILISSA;
- debt service obligations on the 2024 Notes;
- continued scientific progress in our R&D and clinical development programs;
- the magnitude and complexity of our research and development programs;
- progress with preclinical testing and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in filing and pursuing patent applications, enforcing patent claims, or engaging in interference proceedings or other patent litigation;
- competing technological and market developments;
- the establishment of additional strategic alliances;
- developments related to any future litigation;
- the cost of commercialization activities and arrangements, including manufacturing of our product candidates; and
- the cost of product in-licensing and any possible acquisitions.

We intend to seek additional funding through strategic alliances and may seek additional funding through public or private sales of our securities, including equity securities. For example, for so long as we continue to satisfy the requirements to be deemed a well-known seasoned issuer, we can utilize a shelf registration statement currently on file with the SEC, to allow us to issue an unlimited number of securities from time to time. In addition, during the second quarter of 2017, we issued the 2024 Notes and we have previously financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. Additional equity or debt financing might not be available on reasonable terms, if at all. Any additional equity financings will be dilutive to our stockholders and any additional debt financings may involve operating covenants that restrict our business.

Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, new SEC regulations and Nasdaq rules, are creating uncertainty for companies such as ours. These laws, regulations and standards are subject to varying interpretations in some cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, our efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased sales, general and administrative expenses and management time related to compliance activities. If we fail to comply with these laws, regulations and standards, our reputation may be harmed, and we might be subject to sanctions or investigation by regulatory authorities, such as the SEC. Any such action could adversely affect our financial results and the market price of our common stock.

Risks Related to Our Industry

****Health care reform measures and other recent legislative initiatives could adversely affect our business.***

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payors to contain or reduce the costs of health care. In the U.S., comprehensive health care reform legislation was enacted by the Federal government and we expect that there will continue to be a number of federal and state proposals to implement government control over the pricing of prescription pharmaceuticals. In addition, increasing emphasis on reducing the cost of health care in the U.S. will continue to put pressure on the rate of adoption and pricing of prescription pharmaceuticals. Moreover, in some foreign jurisdictions, pricing of prescription pharmaceuticals is already subject to government control. Additionally, other recent federal and state legislation imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements of this new legislation, manufacturers are required to provide certain information regarding the drug product provided to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding distribution of the drug product. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, notification and purchaser license verification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Additionally, in March 2010, Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, was signed into law, which was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the ACA of importance to our potential drug candidates are:

- an annual, nondeductible fee on any entity that manufactures, or imports, specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer’s Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer’s Medicaid rebate liability;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer’s outpatient drugs to be covered under Medicare Part D;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Some of the provisions of the ACA have yet to be fully implemented, and there have been legal and political challenges to certain aspects of the ACA. Since January 2017, two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA have been put into place. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. On January 22, 2018, a continuing resolution was enacted on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-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, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In December 2018, the Centers for Medicare and Medicaid Services, or CMS, published a new final rule permitting further collections and payments to and from certain ACA-qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a U.S. District Court Judge in Texas ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act. While such U.S. District Court Judge, as well as the current presidential administration and 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 ACA will impact the ACA and our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 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, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, which will be fully implemented in 2019. At this time, it is unclear how the introduction of the Medicare quality payment program will impact overall physician reimbursement. Also, there has been heightened governmental scrutiny recently over 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 current presidential administration's budget proposals for fiscal years 2019 and 2020 contains further drug price control measures that could be enacted during the 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. Further, the current presidential administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on certain of these measures and, additionally, is immediately implementing others under its existing authority. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain sustained profitability or commercialize our drugs.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

We are currently unable to predict what additional legislation or regulation, if any, relating to the health care industry may be enacted in the future or what effect recently enacted federal legislation or any such additional legislation or regulation would have on our business. The pendency or approval of such proposals or reforms could result in a decrease in our stock price or limit our ability to raise capital or to enter into collaboration agreements for the further development and commercialization of our programs and products.

Any relationships with healthcare professionals, principal investigators, consultants, customers (actual and potential) and third-party payors in connection with our current and future business activities are and will continue to be subject, directly or indirectly, to federal and state healthcare laws. If we are unable to comply, or have not fully complied, with such laws, we could face penalties, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations.

Our business operations and activities may be directly, or indirectly, subject to various federal and state healthcare laws, including without limitation, fraud and abuse laws, false claims laws, data privacy and security laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers. These laws may restrict or prohibit a wide range of business activities, including, but not limited to, research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. These laws may impact, among other things, our current

activities with principal investigators and research subjects, as well as current and future sales, marketing, patient co-payment assistance and education programs.

Such laws include:

- the federal Anti-Kickback Statute which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalties laws, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, which also imposes obligations, including mandatory contractual terms, on certain types of individuals and entities, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to payments or other transfers of value made to physicians and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members; and
- analogous state, local, and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private 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 laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures or drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; state and local "drug takeback" laws and regulations; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. While our interactions with healthcare professionals, including our speaker programs and other arrangements, such as our contributions to patient assistance programs, have been structured to comply with these laws and related guidance, it is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws. If our operations or activities 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, without limitation, significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

In addition, any sales of our product once commercialized outside the U.S. will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

We could face liability if a regulatory authority determines that we are promoting INGREZZA, or any of our product candidates that receives regulatory approval, for "off-label" uses.

A company may not promote "off-label" uses for its drug products. An off-label use is the use of a product for an indication that is not described in the product's FDA-approved label in the U.S. or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. A company that is found to have promoted off-label use of its product may be subject to significant liability, including civil and criminal sanctions. We intend to comply with the requirements and restrictions of the FDA and other regulatory agencies with respect to our promotion of our products, including INGREZZA, but we cannot be sure that the FDA or other regulatory agencies will agree that we have not violated their restrictions. As a result, we may be subject to criminal and civil liability. In addition, our management's attention could be diverted to handle any such alleged violations. If the FDA or any other governmental agency initiates an enforcement action against us, or if we are the subject of a *qui tam* suit brought by a private plaintiff on behalf of the government, and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects, and reputation.

If we are unable to protect our intellectual property, our competitors could develop and market products based on our discoveries, which may reduce demand for our products.

Our success will depend on our ability to, among other things:

- obtain patent protection for our products;
- preserve our trade secrets;
- prevent third parties from infringing upon our proprietary rights; and
- operate without infringing upon the proprietary rights of others, both in the U.S. and internationally.

Because of the substantial length of time and expense associated with bringing new products through the development and regulatory approval processes in order to reach the marketplace, the pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Accordingly, we intend to seek patent protection for our proprietary technology and compounds. However, we face the risk that we may not obtain any of these patents and that the breadth of claims we obtain, if any, may not provide adequate protection of our proprietary technology or compounds.

We also rely upon unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, through confidentiality agreements with our commercial collaborators, employees and consultants. We also have invention or patent assignment agreements with our employees and some, but not all, of our commercial collaborators and consultants. However, if our employees, commercial collaborators or consultants breach these agreements, we may not have adequate remedies for any such breach, and our trade secrets may otherwise become known or independently discovered by our competitors.

In addition, although we own a number of patents, the issuance of a patent is not conclusive as to its validity or enforceability, and third parties may challenge the validity or enforceability of our patents. We cannot assure you how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court or in other proceedings. It is possible that a competitor may successfully challenge our patents or that challenges will result in limitations of their coverage. Moreover, competitors may infringe our patents or successfully avoid them through design innovation. To prevent infringement or unauthorized use, we may need to file infringement claims, which are expensive and time-consuming. In addition, in an infringement proceeding a court may decide that a patent of ours is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. Interference proceedings declared by the U.S. Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patent applications or those of our licensors. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and be a distraction to management. We cannot assure you that we will be able to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the U.S.

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

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

In the EU, orphan exclusivity may be reduced to six years if the drug no longer satisfies the original designation criteria or can be lost altogether if the marketing authorization holder consents to a second orphan drug application or cannot supply enough drug, or when a second applicant demonstrates its drug is “clinically superior” to the original orphan drug. We may not be successful obtaining orphan drug designations for any indications and, even if we succeed, such orphan drug designations may fail to result in or maintain orphan drug exclusivity upon approval, which would harm our competitive position.

The technologies we use in our research as well as the drug targets we select may infringe the patents or violate the proprietary rights of third parties.

We cannot assure you that third parties will not assert patent or other intellectual property infringement claims against us or our collaborators with respect to technologies used in potential products. If a patent infringement suit were brought against us or our collaborators, we or our collaborators could be forced to stop or delay developing, manufacturing or selling potential products that are claimed to infringe a third party’s intellectual property unless that party grants us or our collaborators rights to use its intellectual property. In such cases, we could be required to obtain licenses to patents or proprietary rights of others in order to continue to commercialize our products. However, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all. Even if our collaborators or we were able to obtain rights to the third party’s intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees and independent contractors, such as principal investigators, consultants, commercial partners and vendors, or by employees of our commercial partners could include failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws, to report financial information or data accurately, to maintain the confidentiality of our trade secrets or the trade secrets of our commercial partners, or to disclose unauthorized activities to us. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. Employee and independent contractor misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Any action against our employees, independent contractors, principal investigators, consultants, commercial partners or vendors for violations of these laws could result in significant civil, criminal, and administrative penalties, fines, and imprisonment.

****We face potential product liability exposure far in excess of our insurance coverage.***

The use of any of our potential products in clinical trials, and the sale of any approved products, including INGREZZA, may expose us to liability claims. These claims might be made directly by consumers, health care providers, pharmaceutical companies or others selling our products. We have product liability insurance coverage for our clinical trials in the amount of $35.0 million per occurrence and $35.0 million in the aggregate. In addition, we have product liability insurance related to the sale of INGREZZA in the amount of $35.0 million per occurrence and $35.0 million in the aggregate. However, our insurance may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability from any current or future clinical trials or approved products. A successful product liability claim, or series of claims, brought against us would decrease our cash reserves and could cause our stock price to fall. Furthermore, regardless of the eventual outcome of a product liability claim, any product liability claim against us may decrease demand for our approved products, including INGREZZA, damage our reputation, result in regulatory investigations that could require costly recalls or product modifications, cause clinical trial participants to withdrawal, result in costs to defend the related litigation, decrease our revenue, and divert management's attention from managing our business.

Our activities involve hazardous materials, and we may be liable for any resulting contamination or injuries.

Our research activities involve the controlled use of hazardous materials. We cannot eliminate the risk of accidental contamination or injury from these materials. If an accident occurs, a court may hold us liable for any resulting damages, which may harm our results of operations and cause us to use a substantial portion of our cash reserves, which would force us to seek additional financing.

Cyber security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect and store confidential and sensitive electronic information on our networks and in our data centers. This information includes, among other things, our intellectual property and proprietary information, the confidential information of our collaborators and licensees, and the personally identifiable information of our employees. It is important to our operations and business strategy that this electronic information remains secure and is perceived to be secure. The size and complexity of our information technology systems, and those of third-party vendors with whom we contract, and the volume of data we retain, make such systems potentially vulnerable to breakdown, malicious intrusion, security breaches and other cyber-attacks. Information security risks have significantly increased in recent years in part due to the proliferation of new technologies and the increased sophistication and activities of organized crime, hackers, terrorists and other external parties, including foreign state actors. A security breach or privacy violation that leads to disclosure or modification of or prevents access to personally identifiable information or other protected information could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, resulting in increased costs or loss of revenue. Similarly, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. As cyber threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security vulnerabilities. While we have implemented security measures to protect our data security and information technology systems, such measures may not prevent such events. Significant disruptions of our information technology systems or breaches of data security could have a material adverse effect on our business, financial condition and results of operations.

Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could have a material adverse effect on our business, financial condition or results of operations.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. For example, the EU's General Data Protection Regulation, or GDPR, imposes strict obligations on the processing of personal data, including personal health data, and the free movement of such data. The GDPR applies to any company established in the EU as well as any company outside the EU that processes personal data in connection with the offering of goods or services to individuals in the EU or the monitoring of their behavior. The GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, obligations relating to: processing health and other sensitive data; obtaining consent of individuals; providing notice to individuals regarding data processing activities; responding to data subject requests; taking certain measures when engaging third-party processors; notifying data subjects and regulators of data breaches; implementing safeguards to protect the security and confidentiality of personal data; and transferring personal data to countries outside the EU, including the U.S. The GDPR imposes substantial fines for breaches of data protection requirements, which can be up to four percent of global revenue or 20 million euros, whichever is greater, and it also confers a private right of action on data subjects for breaches of data protection requirements. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business practices or lead to government enforcement actions, private litigation or significant penalties against us and could have a material adverse effect on our business, financial condition or results of operations.

Item 6. Exhibits

Exhibit Number	Description
3.1	Certificate of Incorporation, as amended(1)
3.2	Bylaws, as amended(2)
4.1	Form of Common Stock Certificate (3)
4.2	Indenture, dated as of May 2, 2017, by and between Neurocrine and U.S. Bank National Association, as Trustee(4)
4.3	Form of Note representing Neurocrine's 2.25% Convertible Notes due 2024(5)
10.1	Third Amendment to Amended and Restated Lease between the Company and Kilroy Realty, L.P. dated August 7, 2019
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
32*	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	Inline 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	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibit 101.INS

(1) Incorporated by reference to Exhibit 3.1 of our Quarterly Report on Form 10-Q dated November 5, 2018
(2) Incorporated by reference to Exhibit 3.2 of our Quarterly Report on Form 10-Q dated November 5, 2018
(3) Incorporated by reference to our Registration Statement on Form S-1 (Registration No. 333-03172)
(4) Incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K dated May 2, 2017
(5) Incorporated by reference to Exhibit 99.1 of our Current Report on Form 8-K dated May 2, 2017
* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of Neurocrine Biosciences, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Except as specifically noted above, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K have a Commission File Number of 000-22705.

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.

NEUROCRINE BIOSCIENCES, INC.

Dated: November 4, 2019

/s/ Matthew C. Abernethy

Matthew C. Abernethy

Chief Financial Officer

(Duly authorized officer and Principal Financial Officer)

Exhibit 10.1

THIRD AMENDMENT TO AMENDED AND RESTATED LEASE

This THIRD AMENDMENT TO AMENDED AND RESTATED LEASE ("**Third Amendment**") is made and entered into as of August 7, 2019, by and between KILROY REALTY, L.P., a Delaware limited partnership ("**Landlord**"), and NEUROCRINE BIOSCIENCES, INC., a Delaware corporation ("**Tenant**").

RECITALS:

A. Landlord (as successor-in-interest to DMH CAMPUS INVESTORS, LLC, a Delaware limited liability company) and Tenant are parties to that certain Amended and Restated Lease dated as of November 1, 2011 (the "**Original Lease**"), as amended by that certain First Amendment to Amended and Restated Lease dated as of June 5, 2017 (the "**First Amendment**"), and that certain Second Amendment to Amended and Restated Lease dated September 29, 2017 (the "**Second Amendment**") (the Original Lease, First Amendment, and Second Amendment are, collectively, the "**Lease**"), pursuant to which Tenant leases a currently deemed total of 140,591 rentable square feet of space (subject to a stipulated re-measured increase on January 1, 2020, to a deemed total of 141,091 rentable square feet of space (the "**Remeasurement**"), as more particularly set forth in the First Amendment, the "**12780 Premises**") comprising the entirety of the building (the "**12780 Building**") located at 12780 El Camino Real, San Diego, California.

B. Landlord and Tenant are also parties to that certain Lease dated as of December 28, 2017 (the "**12790 Lease**"), pursuant to which Tenant leases 7,545 rentable square feet of space commonly known as Suite 150 (the "**Short Term Premises**" or "**Suite 150**")) located on the first (1st) floor of the building (the "**12790 Building**") located at 12790 El Camino Real, San Diego, California, the term of which is scheduled to expire on January 31, 2020 (the "**12790 Lease Expiration Date**").

C. The parties desire to amend the Lease to expand the existing premises to include all of the 12780 Premises and the "12790 Premises" (which "**12790 Premises**" shall mean and be collectively comprised of (i) Suite 150, (ii) that certain space containing 5,016 rentable square feet of space on the first (1st) floor of the 12790 Building commonly known as Suite 110 ("**Suite 110**"), (iii) that certain space containing 1,957 rentable square feet of space on the first (1st) floor of the 12790 Building commonly known as Suite 130 ("**Suite 130**"), (iv) that certain space containing 17,596 rentable square feet of space on the first (1st) floor of the 12790 Building commonly known as Suite 100 ("**Suite 100**"), (v) that certain space containing 27,837 rentable square feet of space on the second (2nd) floor of the 12790 Building commonly known as Suite 200 ("**Suite 200**" , and together with Suite 100, the "**KM Tranche**") which KM Tranche collectively contains 45,433 rentable square feet of space), and (vi) that certain space containing 27,876 rentable square feet of space on the third (3rd) floor of the 12790 Building commonly known as Suite 300 ("**Suite 300**")) and to extend the total term to a coterminous date, and to incorporate further amendments on the terms and conditions set forth in this Third 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 Third Amendment.

2. **Premises**.

2.1 **Modification of Premises**. Landlord and Tenant hereby agree to expand the existing 12780 Premises to include the entirety of the 12790 Building (the "**12790 Premises**"). Landlord and Tenant acknowledge and agree that the 12790 Premises has been measured in accordance with the standards set forth by the Building Owners and Managers Association – ANSI/BOMA Z65.1-2018 ("**BOMA**"), the rentable area of such 12790 Premises shall be conclusively deemed to total 87,944 rentable square feet of space (the tranche-by-tranche breakdown for which is set forth in the below schedule). Landlord and Tenant acknowledge that, excepting only Tenant's occupancy of Suite 150 pursuant to the 12790 Lease, the balance of the 12790 Building is currently occupied by third-party tenants. Within five (5) business days following the vacation of the corresponding portions of the 12790 Building by such third-party tenants (the estimated dates for which are set forth in the below schedule), Landlord shall deliver possession of such portion of the 12790 Premises to Tenant (each, a "**Delivery Date**") and, upon the corresponding date (the "**Tranche Lease Commencement Date**") which is one hundred fifty (150) days following the corresponding Delivery Date (subject to a day-for-day extension for force majeure events and Landlord Delays), Tenant shall lease from Landlord and Landlord shall lease to Tenant, such portion of the 12790 Premises. Upon each such Tranche Lease Commencement Date, the corresponding portion of the 12790 Premises shall be added to, and included in, the 12790 Premises.

Tranche, RSF and Estimated Turnover Schedule of 12790 Premises

Suite Number	Estimated Delivery Date[o]	Estimated Tranche Lease Commencement Date	Rentable Square Footage
Suite 150	February 1, 2020*	February 1, 2020*	7,662
Suite 300	December 1, 2019**	May 1, 2020	27,876
Suite 200	February 1, 2021***	July 1, 2021	27,837
Suite 100	February 1, 2021***	July 1, 2021	17,596
Suite 110 (Allen G)	February 1, 2021***	July 1, 2021	5,016
Suite 130 (Frank K)	December 1, 2019	May 1, 2020	1,957
			87,944
			(total for entire 12790 Premises)

[o] Despite such estimated Delivery Dates, Landlord agrees to utilize commercially reasonable efforts, without incurring material cost or expense (except as may be incurred in relocating a tenant or evicting a hold-over tenant), to expedite the vacation of the corresponding tranche of the 12790 Premises by the third parties currently occupying such tranche.

* The concurrent, deemed delivery and commencement date for the Suite 150 portion of the 12790 Premises (i.e., Suite 150) shall be the date (i.e., February 1, 2020) immediately following the corresponding 12790 Lease Expiration Date, provided however, Tenant shall not be required to pay the Monthly Rental otherwise attributable to Suite 150 during the "Suite 150 Abatement Period," as defined in and pursuant to the terms of Section 4.7.1 below. Landlord hereby acknowledges that Tenant shall be entitled to use the Improvement Allowance for improvements to Suite 150 following the execution and delivery of this Third Amendment.

** Notwithstanding such estimated Delivery Date above, to the extent Landlord is unable to cause possession of Suite 300 to be delivered to Tenant on or before January 1, 2020 (such outside delivery date, the "**Suite 300 Deadline**"), then Tenant shall be entitled to a one day extension of the "12790 Abatement Period" (as that term is defined in Section 4.7.2 below) for each day between and including the Suite 300 Deadline and the date of actual delivery of Suite 300 to Tenant (and such extension shall be in addition to the extensions set forth in the immediately below paragraph).

*** Notwithstanding such estimated Delivery Dates, to the extent Landlord is unable to cause possession of both the KM Tranche and Suite 110 to be delivered to Tenant on or before February 1, 2021, then the "12790 Rent Abatement Period" set forth in Section 4.7.2 of this Third Amendment shall be extended by one (1) month (to a total of eight (8) months). In addition, if Landlord does not deliver possession of the entire KM Tranche and Suite 110 to Tenant on or before March 1, 2021 (such outside delivery date, the "**KM Deadline**"), then Tenant shall be entitled to a one day extension of the 12790 Abatement Period for each day between and including the KM Deadline and the date of actual delivery of both the KM Tranche and Suite 110 to Tenant (and such extension shall be in addition to the one (1) month extension pursuant to the foregoing sentence).

2.2 **Remeasurement of Suite 150; Stipulated RSF of Premises**. Landlord and Tenant hereby acknowledge and agree that Suite 150, the 12790 Building and the Project have been remeasured. Landlord and Tenant agree that, effective as of February 1, 2020, notwithstanding any contrary provision contained in the Lease, Suite 150 shall be deemed to contain 7,662 rentable square feet of space. Subject to the penultimate grammatical sentence of Section 1 of the Work Letter, throughout the Expansion Term, neither the 12780 Premises, the corresponding 12780 Building, the 12790 Premises nor the 12790 Building will be subject to remeasurement or modification by Landlord or Tenant prior to the Expansion Term Expiration Date (as that term is defined in Section 3.1 below); provided, however, that should Tenant exercise its right to further extend the term of the Lease, Landlord shall have the right to remeasure the entire Premises in accordance with then-prevailing standards set forth by the Building Owners and Managers Association applicable to single-tenant buildings, but such remeasurement shall only become effective from and after the Expansion Term Expiration Date.

2.3 **Condition of the 12780 Premises**. Landlord and Tenant acknowledge that Tenant has been occupying the 12780 Premises pursuant to the Lease and, therefore, Tenant continues to accept such 12780 Premises in its presently existing, "as is" condition. Except as expressly set forth below and in the Work Letter, Landlord shall not be obligated to provide or pay for any improvement work or services related to the improvement of the 12780 Premises, subject to Landlord's ongoing repair and maintenance obligations as and to the extent set forth in the Lease, including, without limitation, Landlord's obligation to repair, improve and replace Capital Items in the 12780 Premises in accordance with the Lease. Notwithstanding the foregoing, concurrent with construction of the Improvements (as defined in **Exhibit B**), Tenant shall cause certain Building Systems within the 12780 Premises to be repaired and/or replaced, specifically including, but not limited to, those items set forth on **Exhibit G**, and Landlord and Tenant shall reasonably and mutually agree upon any additional repairs or replacements based upon the report prepared by TK1SC dated 4-9-2019 for Project # 2017-0745 (the "**12780 Work**"), which 127890 Work shall be at Landlord's sole cost and expense, up to a maximum amount of $2,200,000.00; provided,

however, (i) such Landlord contribution shall be subject to inclusion, and shall be included, as a Capital Expense in accordance with Article 4 of the Original Lease, (ii) Landlord retains the right to reasonably modify the scope of such work as necessary to ensure proper integration with the Building systems and compatibility with Landlord's systems in the Project and other property owned by Landlord or its affiliates, and (iii) Tenant hereby agrees that Landlord shall not be required to reimburse Tenant or pay Contractor until the calendar year 2020, regardless of when Tenant performs such 12780 Work. Tenant will contract with Contractor (as defined in Section 4.1.1 of the Work Letter) to perform the 12780 Work, and Landlord will, upon the receipt of invoices approved by Landlord and Tenant for the 12780 Work, deliver a check to Tenant made jointly payable to Contractor and Tenant, or directly to Contractor at Landlord's sole discretion.

2.4 **Condition of 12790 Premises**. Landlord and Tenant acknowledge that Tenant has been occupying Suite 150 pursuant to the 12790 Lease and, therefore, Tenant continues to accept such Short Term Premises in its presently existing, "as is" condition. Landlord and Tenant further acknowledge and agree that Landlord has provided Tenant an opportunity to examine the balance of the 12790 Building and, subject to Landlord's express obligations set forth in the Work Letter, Tenant agrees to accept such remainder of the 12790 Premises in its then-existing, "as is" condition. Except as expressly set forth in the Work Letter, Landlord shall not be obligated to provide or pay for any improvement work or services related to the improvement of the 12790 Premises, subject to Landlord's ongoing repair and maintenance obligations as and to the extent set forth in the Lease including, without limitation, Landlord's obligation to repair, improve and replace Capital Items in the 12790 Premises in accordance with the Lease.

2.5 **Project Common Area Improvements**. Notwithstanding the foregoing, Landlord shall, at Landlord's sole cost and expense (as opposed to inclusion as an Operating Expense), use commercially reasonable and diligent efforts to improve those Common Area components of the Project as identified on, and in accordance with, **Exhibit C-1** attached hereto (the "**Common Area Improvements**") which Landlord shall use commercially reasonable efforts to perform on or before July 1, 2021 (other than the fitness center and the completion of the remainder of the "Common Amenity Space" (as that term is defined in Section 4.8.4 below), all of which shall be completed within the timeframe set forth in Section 4.8.4 below). If Landlord does not make the Common Area Improvements (other than the fitness center and the Common Amenity Space) available for use by Tenant by January 1, 2022 (such outside date, the "**Common Area Improvements Deadline**"), then Tenant shall be entitled to a per diem penalty of $3,500.00 per day for each day between and including the Common Area Improvements Deadline and the date of that the Common Area Improvements (other than the fitness center) are actually made available for use by Tenant. The Common Area Improvements will be available for use by Tenant during the Term, in common with tenants of the Project and the One Paseo Office Center Buildings (as defined in Section 4.8.4).

3. **Term**.

3.1 **Expansion Term**. The "**Expansion Term**" shall commence on February 1, 2020 (i.e., upon the Tranche Lease Commencement Date for the Suite 150 portion of the 12790 Premises), and shall continue until the earlier of (a) July 31, 2031, and (b) the last day of the calendar month in which the one hundred twenty-seventh (127th) monthly anniversary of the Tranche Lease Commencement Date applicable to the KM Tranche portion of the 12790 Premises

occurs (the "**Expansion Term Expiration Date**"), unless extended or sooner terminated as provided in the Lease, as hereby amended. The parties acknowledge that the Expansion Term Expiration Date is anticipated to be July 31, 2031, based upon an anticipated Tranche Lease Commencement Date of July 1, 2021 for the corresponding portion of the 12790 Premises. For purposes of this Third Amendment, the term "**Expansion Year**" with respect to each tranche of the 12790 Premises shall mean each consecutive twelve (12) calendar month period during the Expansion Term; provided, however, that the first Expansion Year shall commence on the applicable Tranche Lease Commencement Date for the applicable portion of the 12790 Premises and end on the last day of the month in which the first anniversary of such Tranche Lease Commencement Date occurs (or if the applicable Tranche Lease Commencement Date is the first day of a calendar month, then the first Expansion Year shall commence on the applicable Tranche Lease Commencement Date and end on the day immediately preceding the first anniversary of the applicable Tranche Lease Commencement Date), and the second and each succeeding Expansion Year shall commence on the first day of the next calendar month; and further provided that the last Expansion Year shall end on the Expansion Term Expiration Date.

3.2 **Extension of Lease of 12780 Premises to Coterminous with Expansion Term**. Pursuant to the Lease, the existing Term of the 12780 Premises is scheduled to expire on December 31, 2029. Landlord and Tenant hereby agree to extend the Term of the 12780 Premises for a period of approximately nineteen (19) months, from January 1, 2030 until the Expansion Term Expiration Date (the "**12780 Extended Term**"), on the terms and conditions set forth in the Lease, as hereby amended by this Third Amendment, unless extended or sooner terminated as provided in the Lease.

3.3 **Remaining Options to Extend Term**. Landlord and Tenant acknowledge and agree that neither the Expansion Term nor the 12780 Extended Term shall be deemed to represent the first of Tenant's two (2) options to extend the Term as provided in Section 2.2 of the Original Lease, and accordingly, Tenant shall retain and continue to have both of such two (2) options to extend the Term (i.e., the for a period of ten (10) years each) with regard to the entire Premises, which option shall otherwise be in accordance with, and pursuant to the terms of, Section 2.2 of the Original Lease.

3.4 **No Prior Surrender Obligations**. Notwithstanding anything to the contrary in the Lease or the 12790 Lease, Landlord shall not require Tenant, whether at the end of the Expansion Term (as the same may be subsequently extended), the expiration of the 12790 Lease, the expiration of the existing Term of the 12780 Premises, or following any earlier termination of the Lease, to remove any existing leasehold improvements, tenant improvements, or additions existing within the 12780 Premises or 12790 Premises as of the date of this Third Amendment.

4. **Rent**.

4.1 **12780 Premises**. Prior to January 1, 2030, Tenant shall continue to pay Monthly Rental with regard to the 12780 Premises pursuant to the terms of the Lease. Notwithstanding anything to the contrary set forth in the Lease, commencing on January 1, 2030, and continuing through the Expansion Term Expiration Date (contemplated to be July 31, 2031), Tenant shall continue to escalate at a rate of three percent (3%) per annum, pursuant to which Tenant pay the Monthly Rental for the 12780 Premises as follows:

Period During 12780 Extended Term	Annualized Rental	Monthly Rental	Monthly Rental Rate per Square Foot
January 1, 2030 – December 31, 2030	$8,702,269.44	$725,189.12	$5.14
January 1, 2031 – Expansion Term Expiration Date	$8,963,337.48	$746,944.79	$5.29

4.2 **Monthly Rental for Suite 150**. Commencing on February 1, 2020 and continuing throughout the Expansion Term, Tenant shall pay to Landlord Monthly Rental for Suite 150 as follows:

Period During Expansion Term	Annualized Rental	Monthly Rental◊◊	Monthly Rental Rate per Square Foot
February 1, 2020 – January 31, 2021	$390,762.00	$32,563.50	$4.25
February 1, 2021 – January 31, 2022	$402,484.86	$33,540.41	$4.38*
February 1, 2022 – January 31, 2023	$414,559.41	$34,546.62	$4.51*
February 1, 2023 – January 31, 2024	$426,996.19	$35,583.02	$4.64*
February 1, 2024 – January 31, 2025	$439,806.07	$36,650.51	$4.78*
February 1, 2025 – January 31, 2026	$453,000.26	$37,750.02	$4.93*
February 1, 2026 – January 31, 2027	$466,590.26	$38,882.52	$5.07*
February 1, 2027 – January 31, 2028	$480,587.97	$40,049.00	$5.23*
February 1, 2028 – January 31, 2029	$495,005.61	$41,250.47	$5.38*
February 1, 2029 – January 31, 2030	$509,855.78	$42,487.98	$5.55*
February 1, 2030 – January 31, 2031	$525,151.45	$43,762.62	$5.71*
February 1, 2031 – Expansion Term Expiration Date	$540,906.00	$45,075.50	$5.88*

◊ The schedule above is subject to the 12790 Rent Abatement and the Suite 150 Rent Abatement set forth in Section 4.7 of this Third Amendment, below.

◊◊ The initial Monthly Rental amount was calculated by multiplying the initial Monthly Rental Rate per Square Foot amount by the number of rentable square feet of space in Suite 150, and the Annualized Rent amount was calculated by multiplying the initial Monthly Rental amount by twelve (12). In all subsequent Monthly Rental payment periods during the Expansion Term commencing on February 1, 2021, the calculation of each Monthly Rental amount reflects an annual increase of three percent (3%) and each Annualized Rent amount was calculated by multiplying the corresponding Monthly Rental amount by twelve (12).

* The amounts identified in the column entitled "Monthly Rental Rate per Square Foot" are rounded amounts provided for informational purposes only.

4.3 **Monthly Rental for KM Tranche**. Commencing on the Tranche Lease Commencement Date for the KM Tranche and continuing throughout the Expansion Term, Tenant shall pay to Landlord Monthly Rental for the KM Tranche as follows (provided that on or before the Tranche Lease Commencement Date for the KM Tranche, Tenant shall pay to Landlord the Monthly Rental payable for the KM Tranche for the first full month of the Expansion Term applicable to the KM Tranche):

KM Tranche Expansion Year	Annualized Rental	Monthly Rental◊◊	Monthly Rental Rate per Square Foot
1	$2,317,083.00	$193,090.25	$4.25
2	$2,386,595.49	$198,882.96	$4.38*
3	$2,458,193.35	$204,849.45	$4.51*
4	$2,531,939.16	$210,994.93	$4.64*
5	$2,607,897.33	$217,324.78	$4.78*
6	$2,686,134.25	$223,844.52	$4.93*
7	$2,766,718.28	$230,559.86	$5.07*
8	$2,849,719.83	$237,476.65	$5.23*
9	$2,935,211.42	$244,600.95	$5.38*
10	$3,023,267.76	$251,938.98	$5.55*
11 (through Expansion Term Expiration Date)	$3,113,965.80	$259,497.15	$5.71*

◊ The schedule above is subject to the 12790 Rent Abatement set forth in Section 4.7.2 of this Third Amendment, below.

◊◊ The initial Monthly Rental amount was calculated by multiplying the initial Monthly Rental Rate per Square Foot amount by the number of rentable square feet of space in the KM Tranche, and the Annualized Rent amount was calculated by multiplying the initial Monthly Rental amount by twelve (12). In all subsequent Monthly Rental payment periods during the Expansion Term commencing on first day of Expansion Year 2 for the KM Tranche, the calculation of each Monthly Rental amount reflects an annual increase of three percent (3%) and each Annualized Rent amount was calculated by multiplying the corresponding Monthly Rental amount by twelve (12).

* The amounts identified in the column entitled "Monthly Rental Rate per Square Foot" are rounded amounts provided for informational purposes only.

4.4 **Monthly Rental for Suite 110**. Commencing on the Tranche Lease Commencement Date for Suite 110 and continuing throughout the Expansion Term, Tenant shall pay to Landlord Monthly Rental for Suite 110 as follows (provided that on or before the Tranche Lease Commencement Date for Suite 110, Tenant shall pay to Landlord the Monthly Rental payable for Suite 110 for the first full month of the Expansion Term applicable to Suite 110):

Suite 110 Expansion Year	Annualized Rental	Monthly Rental◊◊	Monthly Rental Rate per Square Foot
1	$255,816.00	$21,318.00	$4.25
2	$263,490.48	$21,957.54	$4.38*
3	$271,395.19	$22,616.27	$4.51*
4	$279,537.05	$23,294.75	$4.64*
5	$287,923.16	$23,993.60	$4.78*
6	$296,560.86	$24,713.40	$4.93*
7	$305,457.68	$25,454.81	$5.07*
8	$314,621.41	$26,218.45	$5.23*
9	$324,060.06	$27,005.00	$5.38*
10	$333,781.86	$27,815.15	$5.55*
11 (through Expansion Expiration Date)	$343,795.31	$28,649.61	$5.71*

◊ The schedule above is subject to the 12790 Rent Abatement set forth in Section 4.7.2 of this Third Amendment, below.

◊◊ The initial Monthly Rental amount was calculated by multiplying the initial Monthly Rental Rate per Square Foot amount by the number of rentable square feet of space in Suite 110, and the Annualized Rent amount was calculated by multiplying the initial Monthly Rental amount by twelve (12). In all subsequent Monthly Rental payment periods during the Expansion Term commencing on first day of Expansion Year 2 for Suite 110, the calculation of each Monthly Rental amount reflects an annual increase of three percent (3%) and each Annualized Rent amount was calculated by multiplying the corresponding Monthly Rental amount by twelve (12).

* The amounts identified in the column entitled "Monthly Rental Rate per Square Foot" are rounded amounts provided for informational purposes only.

4.5 **Monthly Rental for Suite 130**. Commencing on the Tranche Lease Commencement Date for Suite 130 and continuing throughout the Expansion Term, Tenant shall pay to Landlord Monthly Rental for Suite 130 as follows (provided that on or before the Tranche Lease Commencement Date for Suite 130, Tenant shall pay to Landlord the Monthly Rental payable for Suite 130 for the first full month of the Expansion Term applicable to Suite 130):

Suite 130 Expansion Year	Annualized Rental	Monthly Rental◊◊	Monthly Rental Rate per Square Foot
1	$99,807.00	$8,317.25	$4.25
2	$102,801.21	$8,566.77	$4.38*
3	$105,885.25	$8,823.77	$4.51*
4	$109,061.80	$9,088.48	$4.64*
5	$112,333.66	$9,361.14	$4.78*
6	$115,703.67	$9,641.97	$4.93*
7	$119,174.78	$9,931.23	$5.07*
8	$122,750.02	$10,229.17	$5.23*
9	$126,432.52	$10,536.04	$5.38*
10	$130,225.50	$10,852.12	$5.55*
11	$134,132.26	$11,177.69	$5.71*
12 (through Expansion Expiration Date)	$138,156.23	$11,513.02	$5.88*

◊ The schedule above is subject to the 12790 Rent Abatement set forth in Section 4.7.2 of this Third Amendment, below.

◊◊ The initial Monthly Rental amount was calculated by multiplying the initial Monthly Rental Rate per Square Foot amount by the number of rentable square feet of space in Suite 130, and the Annualized Rent amount was calculated by multiplying the initial Monthly Rental amount by twelve (12). In all subsequent Monthly Rental payment periods during the Expansion Term commencing on first day of Expansion Year 2 for Suite 130, the calculation of each Monthly Rental amount reflects an annual increase of three percent (3%) and each Annualized Rent amount was calculated by multiplying the corresponding Monthly Rental amount by twelve (12).

* The amounts identified in the column entitled "Monthly Rental Rate per Square Foot" are rounded amounts provided for informational purposes only.

4.6 **Monthly Rental for Suite 300**. Commencing on the Tranche Lease Commencement Date for the KM Tranche and continuing throughout the Expansion Term, Tenant shall pay to Landlord Monthly Rental for the KM Tranche as follows (provided that on or before the Tranche Lease Commencement Date for the KM Tranche, Tenant shall pay to Landlord the Monthly Rental payable for the KM Tranche for the first full month of the Expansion Term applicable to the KM Tranche):

Suite 300 Expansion Year	Annualized Rental	Monthly Rental◊◊	Monthly Rental Rate per Square Foot
1	$1,421,676.00	$118,473.00	$4.25
2	$1,464,326.28	$122,027.19	$4.38*
3	$1,508,256.07	$125,688.01	$4.51*
4	$1,553,503.75	$129,458.65	$4.64*
5	$1,600,108.86	$133,342.41	$4.78*
6	$1,648,112.13	$137,342.68	$4.93*
7	$1,697,555.49	$141,462.96	$5.07*
8	$1,748,482.16	$145,706.85	$5.23*
9	$1,800,936.62	$150,078.05	$5.38*
10	$1,854,964.72	$154,580.39	$5.55*
11	$1,910,613.66	$159,217.81	$5.71*
12 (through Expansion Expiration Date)	$1,967,932.07	$163,994.34	$5.88*

◊ The schedule above is subject to the 12790 Rent Abatement set forth in Section 4.7.2 of this Third Amendment, below.

◊◊ The initial Monthly Rental amount was calculated by multiplying the initial Monthly Rental Rate per Square Foot amount by the number of rentable square feet of space in Suite 300, and the Annualized Rent amount was calculated by multiplying the initial Monthly Rental amount by twelve (12). In all subsequent Monthly Rental payment periods during the Expansion Term commencing on first day of Expansion Year 2 for Suite 300, the calculation of each Monthly Rental amount reflects an annual increase of three percent (3%) and each Annualized Rent amount was calculated by multiplying the corresponding Monthly Rental amount by twelve (12).

* The amounts identified in the column entitled "Monthly Rental Rate per Square Foot" are rounded amounts provided for informational purposes only.

4.7 **Abated Monthly Rental**.

4.7.1 **Suite 150 Abated Monthly Rental**. During the three (3) month period commencing on February 1, 2020 and ending on April 30, 2020 (the "**Suite 150 Rent Abatement Period**"), Tenant shall not be obligated to pay any Monthly Rental otherwise attributable to Suite 150 during such Suite 150 Rent Abatement Period (the "**Suite 150 Rent Abatement**"). Landlord and Tenant acknowledge that the aggregate amount of the Suite 150 Rent Abatement equals $97,690.50 (*i.e.*, $32,563.50 per month). Tenant acknowledges and agrees that during such Suite 150 Rent Abatement Period, such abatement of Monthly Rental for the Suite 150 Premises shall have no effect on Tenant's rental obligations with regard to the 12780 Premises, nor on the calculation of any future increases in Monthly Rental, Operating Expenses or Taxes payable by Tenant pursuant to the terms of the Lease, which increases shall be calculated without regard to such Suite 150 Rent Abatement. Additionally, Tenant shall be obligated to pay all Additional Rental during the Suite 150 Rent Abatement Period. Tenant acknowledges and agrees that the foregoing Suite 150 Rent Abatement has been granted to Tenant as additional consideration for entering into this Third Amendment, and for agreeing to pay the rent and perform the terms and conditions otherwise required under the Lease (as hereby amended). If Tenant shall be in default under the Lease (as hereby amended) and shall fail to cure such default within the notice and cure period, if any, permitted for cure pursuant to the Lease (as hereby amended), or if the Lease (as hereby amended) is terminated for any reason, other than as the result of casualty or condemnation, then the dollar amount of the unapplied portion of the Suite 150 Rent Abatement as of such default or termination shall be converted to a credit to be applied to the Monthly Rental applicable at the end of the Expansion Term and Tenant shall immediately be obligated to begin paying Monthly Rental for the Premises in full.

4.7.2 **12790 Premises Abated Monthly Rental**. Provided that Tenant is not then in default of the Lease (as hereby amended) (beyond the expiration of any applicable notice and cure period set forth in the Lease, as amended), then during the seven (7) month period commencing on first calendar month following the month in which the Tranche Lease Commencement Date attributable to the KM Tranche occurs (the "**12790 Rent Abatement Period**"), Tenant shall not be obligated to pay any Monthly Rental otherwise attributable to the 12790 Premises during such 12790 Rent Abatement Period (the "**12790 Rent Abatement**"). Landlord and Tenant acknowledge that the aggregate amount of the 12790 Rent Abatement equals $2,616,334.00. Tenant acknowledges and agrees that during such 12790 Rent Abatement Period, such abatement of Monthly Rental for the 12790 Premises shall have no effect on Tenant's rental obligations with regard to the 12780 Premises, nor on the calculation of any future increases in Monthly Rental, Operating Expenses or Taxes payable by Tenant pursuant to the terms of the Lease, which increases shall be calculated without regard to such 12790 Rent Abatement. Additionally, Tenant shall be obligated to pay all Additional Rental during the 12790 Rent Abatement Period. Tenant acknowledges and agrees that the foregoing 12790 Rent Abatement has been granted to Tenant as additional consideration for entering into this Third Amendment, and for agreeing to pay the rent and perform the terms and conditions otherwise required under the Lease (as hereby amended). If Tenant shall be in default under the Lease (as hereby amended) and shall fail to cure such default within the notice and cure period, if any, permitted for cure pursuant to the Lease (as hereby amended), or if the Lease (as hereby amended) is terminated for any reason, other than as the result of casualty or condemnation, then the dollar amount of the unapplied portion of the 12790 Rent Abatement as of such default or termination shall be converted to a credit to be applied to the Monthly Rental applicable at the end of the Expansion Term and Tenant shall immediately be obligated to begin paying Monthly Rental for the Premises in full.

4.8 **Operating Expenses and Taxes**.

4.8.1 **12780 Premises**. Prior to and during the Expansion Term, Tenant shall continue to be obligated to pay 100% of the annual Operating Expenses and Taxes attributable to the 12780 Premises in accordance with the terms of the Lease.

4.8.2 **12790 Premises**. Commencing on the applicable Tranche Lease Commencement Date, and continuing throughout the Expansion Term, Tenant shall be obligated to pay Tenant's then-applicable "12790 Pro Rata Share" of the annual Operating Expenses and Taxes attributable to the 12790 Premises in accordance with the terms of the Lease (as hereby amended).

4.8.3 **12790 Pro Rata Share**. Tenant's "**12790 Pro Rata Share**" shall mean the pro-rata portion of 12790 Building which then constitutes, from time-to-time, the 12790 Premises. Landlord and Tenant acknowledge and agree that, initially, Tenant's 12790 Pro Rata Share of the 12790 Building shall be 8.71% (i.e., the 7,662 rsf attributable to the Suite 150 portion of the 12790 Premises divided by the 87,944 rsf of the 12790 Building). Thereafter, on each Tranche Lease Commencement Date, Tenant's 12790 Pro Rata Share shall increase to the resulting percentage represented by a fraction, the numerator of which shall be the then-applicable rentable square footage of the 12790 Premises, and the denominator is the 87,944 rsf of the 12790 Building.

4.8.4 **Common Amenity Space; Allocation of Operating Expenses and Taxes**. Landlord and Tenant acknowledge and agree that, in addition to the Common Area Improvements set forth in Section 2.5 above, Landlord is constructing certain Common Area amenities for which the approximate intended project scope is set forth in **Exhibit C-2** attached hereto (the "**Common Amenity Space**"), which Common Amenity Space will benefit both the Project and the immediately adjacent office buildings being constructed by Landlord (the "**One Paseo Office Center Buildings**," commonly known as 12830 & 12860 El Camino Real). Landlord shall endeavor to keep Tenant reasonably informed with respect to Landlord's construction plans for the Common Amenity Space. Accordingly, and otherwise in accordance with the penultimate paragraph of Section 4.3 of the Original Lease, the parties further acknowledge and agree that each of the 12780 Building, 12790 Building and the third Project building commonly known as 12770 El Camino Real (the "**12770 Building**") will, along with the One Paseo Office Center Buildings, include an equitable allocation of the costs associated with the Common Amenity Space and non-exclusive services provided therein to the extent made available to Tenant based on the respective square footages of the One Paseo Office Center Buildings and the Project; provided, however, that (a) all such costs shall be subject to the limitations set forth in Article 4 of the Original Lease with respect to Operating expenses, (b) Tenant shall not be responsible for payment of such Operating Expenses attributable to the Common Amenity Space until the later to occur of (x) such Common Amenity Space being available for use by Tenant, and (y) the Tranche Lease Commencement Date for the KM Tranche, and (c) such costs shall not include the cost of constructing the Common Amenity Space, the cost of acquiring furniture, fixtures and equipment for the Common Amenity Space, any Capital Expense incurred in connection with the Common Amenity Space, or any expense resulting from amenities or services provided solely for the benefit of tenants of the One Paseo Office Buildings (including, without limitation, shuttle services). Landlord shall use commercially reasonable and diligent efforts to complete construction of the Common Amenity Space (including the fitness center) by January 1, 2022.

5. **Right of First Offer**. Landlord and Tenant (i) hereby acknowledge that the 12790 Premises constitutes the entirety of the "First Offer Space" identified in Section 5 of the First Amendment, (ii) hereby amend such "First Offer Space" to mean all of the rentable space located in the building commonly known as 12770 El Camino Real, and (iii) further acknowledge that the right of offer shall otherwise apply pursuant to Section 5 of the First Amendment, except (A) that the same shall be applicable to the 12770 Building (as opposed to the 12790 Building), (B) to the extent any particular First Offer Space is leased by Tenant in accordance with such right of first offer during the first thirty-six (36) months of the Expansion Term, then the term of such First Offer Space shall expire on the Expansion Term Expiration Date, and (C) the Superior Rights and Superior Right Holders are, as of the date of this Third Amendment, as set forth on **Exhibit D** attached hereto.

6. **Right of First Refusal**. Landlord hereby grants to the Original Tenant and its Permitted Assignee (as opposed to any other assignee, Sublessee, licensee or transferee), a one-time right of first refusal with respect to the space located on the third (3rd) floor of the 12770 Building (the "**First Refusal Space**"). Notwithstanding the foregoing, Landlord's obligation to offer the First Refusal Space shall commence only following the expiration or earlier termination of the existing leases of the First Refusal 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 with such existing tenant), the Superior Right Holder for which is identified on **Exhibit D** attached hereto. Tenant's right of first offer shall be on the terms and conditions set forth in this Section 6.

6.1 **Procedure for Refusal Offer**. Landlord shall notify Tenant (the "**First Refusal Notice**") from time-to-time when and if Landlord receives a "bona-fide third-party offer" for the First Refusal Space. Pursuant to such First Refusal Notice, Landlord shall offer to lease to Tenant the applicable First Refusal Space. The First Refusal Notice shall describe the First Refusal Space, and the lease term, rent and other fundamental economic terms and conditions upon which Landlord proposes to lease such First Refusal Space pursuant to the bona-fide third-party offer. For purposes of this Section 6.1, a "**bona-fide third-party offer**" shall mean an offer or a counter-offer received by Landlord to lease First Refusal Space from an unaffiliated and qualified third party which Landlord would otherwise be willing to accept (but for Tenant's superior rights hereunder). For purposes of example only, the following would each constitute a bona-fide third-party offer:

6.1.1 Landlord receives a request for proposal from an unaffiliated and qualified third party. Landlord responds to the request for proposal with a lease proposal and subsequently receives a written bona-fide counter proposal from the unaffiliated and qualified third party.

6.1.2 Landlord receives a written offer to lease from an unaffiliated and qualified third party. Landlord responds to the offer with a written counter offer and subsequently receives a bona-fide counter to Landlord's counter offer from the unaffiliated and qualified third party.

6.2 **Procedure for Acceptance**. If Tenant wishes to exercise Tenant's right of first refusal with respect to the First Refusal Space described in the First Refusal Notice, then within ten (10) business days of delivery of the First Refusal Notice to Tenant (the "**Election Period**"), Tenant shall deliver to Landlord written notice (an "**Election Notice**") of Tenant's exercise of its right of first refusal with respect to all of the First Refusal Space described in the First Refusal Notice at the rent, for the term and upon the other fundamental economic terms and conditions contained in such First Refusal Notice, including, but not limited to rental concessions and improvement allowances. If Tenant does not so notify Landlord within such Election Period of Tenant's exercise of its first refusal right, or Tenant affirmatively elects not to exercise such first refusal right (either of the foregoing being referred to herein as a "**First Refusal Rejection**"), then Landlord shall be free to negotiate and enter into a lease for the First Refusal Space to anyone whom it desires on any terms it desires; provided, however, to the extent such third party lease of First Refusal Space would be on "Economic Terms," as that term is defined hereinbelow, which on a per rentable square foot basis are (in the aggregate) less than ninety-five percent (95%) of the Economic Terms (in the aggregate) on a per rentable square foot basis offered to Tenant in the applicable First Refusal Notice, then Landlord shall deliver another First Refusal Notice (the "**Additional Notice**") to Tenant offering such more favorable terms to Tenant (provided that such terms and conditions shall be adjusted to account for the difference, if any, in the lease term offered to Tenant and the lease term offered to such third party). If Tenant thereafter wishes to exercise its right of first refusal with respect to the Additional Notice, Tenant shall deliver the Election Notice to Landlord within ten (10) business days of delivery of such Additional Notice to Tenant (which procedure shall be repeated until Landlord enters into a lease or lease amendment with respect to such First Refusal Space which does not require Landlord to deliver another Additional Notice to Tenant pursuant to the terms hereof or Tenant timely exercises such right of first refusal, as applicable). The term "**Economic Terms**" for purposes of this Section 6.2 shall mean only the annual base rent, tenant improvement allowance, if any, moving allowance, if any, free parking, if any, and abated base rent, if any.

6.3 **Amendment to Lease**. If Tenant timely exercises Tenant's right of first refusal to lease First Refusal Space as set forth herein, Landlord and Tenant shall within sixty (60) days thereafter execute an amendment to the Lease (the "**First Refusal Space Amendment**") for such First Refusal Space upon the terms set forth in the First Refusal Notice, including, but not limited to rent (the "**First Refusal Space Rent**"), but otherwise upon the terms, covenants and conditions set forth in the Lease and this Section 6. Notwithstanding the foregoing, Landlord may, at its sole option, require that a separate lease be executed by Landlord and Tenant in connection with Tenant's lease of the First Refusal Space, in which event such lease (the "**First Refusal Space Lease**") shall be on the same TCCs as the Lease, except as provided in this Section 6 and specifically in the Lease to the contrary. The First Refusal Space Lease, if applicable, shall be executed by Landlord and Tenant within sixty (60) days following Tenant's exercise of its right to lease the First Refusal Space. Notwithstanding the foregoing documentation obligations, Landlord and Tenant hereby acknowledge and agree that Tenant's timely delivery of the Election Notice shall, in and of itself, conclusively establish Tenant's obligation to lease the subject First Refusal Space on the express TCCs set forth in the corresponding First Refusal Notice.

6.4 **No Defaults; Required Financial Condition of Tenant**. The rights contained in this Section 6 shall be personal to the Original Tenant and its Permitted Assignees and may only be exercised by the Original Tenant or a Permitted Assignee (and not any other assignee, sublessee or other transferee of the Original Tenant's interest in the Lease) if the Original Tenant and/or a Permitted Assignee occupies not less than the entire then-existing Premises. The right to lease the First Refusal Space as provided in this Section 6 may not be exercised if, as of the date Tenant attempts to exercise its right of first refusal with respect to the First Refusal Space described in the First Refusal Notice, or as of the scheduled date of delivery of such First Refusal Space to Tenant, (A) Tenant is in economic or material non-economic default pursuant to the terms of the Lease (beyond any applicable notice and cure periods), and (B) Tenant has previously been in default under the Lease (beyond the applicable notice and cure periods) more than once during the previous twenty-four (24) month period.

6.5 **First Refusal Space Commencement Date; Construction in First Refusal Space**. The commencement date for the First Refusal Space shall be the applicable date specified in the applicable First Refusal Notice (the "**First Refusal Space Commencement Date**") (provided that such First Refusal Space Commencement Date shall not be earlier than one hundred fifty (150) days following the date of delivery of such First Refusal Space to Tenant) and the term of Tenant's lease of such First Refusal Space shall expire on the applicable date set forth in the First Refusal Notice (the "**First Refusal Space Expiration Date**") (provided that the First Refusal Space Expiration Date shall be coterminous with the Premises on the Expansion Term Expiration Date (as the same may be subsequently extended pursuant to Section 2.2 of the Original Lease) to the extent that as of the First Refusal Space Commencement Date more than five (5) years remain in the Expansion Term (as the same may be subsequently extended pursuant to Section 2.2 of the Original Lease)). The term of Tenant's occupancy of the First Refusal Space shall be referred to herein as a "**First Refusal Space Lease Term**." Except as otherwise expressly identified in the First Refusal Notice, Tenant shall take the First Refusal Space in its "as is" condition, and the construction of improvements in the First Refusal Space shall comply with the terms of Section 8.4 of the Lease.

7. **Letter of Credit; Tolling of Decrease Determination Date**. Landlord and Tenant hereby acknowledge that the "Amended Letter of Credit" defined in Section 4.7 of the Original Lease is currently held by Landlord in the "New L-C Amount" of $3,000,000 in accordance with Section 6 of the First Amendment. Landlord and Tenant herby amend Section 6.2 of the First Amendment, such that the reduction date of any reduction of such Amended Letter of Credit to the "50% L-C Amount" (i.e., $1,500,000) in accordance with the terms thereof shall be tolled until December 31, 2025 (as opposed to after the fifth (5th) full year of the 12780 Extended Term).

8. **Landlord Contribution Amount for Building Lobby Work**. Landlord and Tenant hereby acknowledge that pursuant to the terms of Section 1.2 of the Work Letter (" **First Amendment Work Letter**") attached to and incorporated in the First Amendment by reference, Landlord previously agreed to contribute up to $1,410,910.00 in the aggregate (as defined in such Section 1.2 of the First Amendment Work Letter, the "**Landlord Contribution Amount**") towards the Building Lobby Work (as that term is defined in Section 1.2 of the First Amendment Work Letter). Landlord and Tenant desire to increase such Landlord Contribution Amount, and accordingly, effective as of the date of this Third Amendment, (i) Landlord and Tenant hereby increase the Landlord Contribution Amount by $50,000.00 to a new total of $1,460,910.00, and (ii) the term "**Landlord Contribution Amount**" shall hereafter refer to such amount.

9. **Improvement Allowance**. Landlord and Tenant hereby acknowledge that pursuant to the terms of Section 2.5 of the First Amendment Work Letter and Section 2 of the Second Amendment, Tenant is entitled to a one-time Improvement Allowance in the amount of $12,698,190.00 (the "**12780 Improvement Allowance**") for the costs relating to the initial design and construction of the improvements which are permanently affixed to the Premises. In connection with the increase of the Landlord Contribution Amount set forth in Section 8 above, Landlord and Tenant hereby desire to decrease such 12780 Improvement Allowance, and accordingly, effective as of the date of this Third Amendment, (i) Landlord and Tenant hereby decrease the 12780 Improvement Allowance by $50,000.00 to a new total of $12,648,190.00, and (ii) the term "**12780 Improvement Allowance**" shall hereafter refer to such amount.

10. **Parking**. Effective as of the final Tranche Lease Commencement Date and continuing throughout the Expansion Term, Tenant shall be entitled to utilize up to 593 unreserved parking passes in connection with Tenant's lease of the 12780 Premises and the 12790 Premises (the "**Parking Passes**"), the exact locations of which are more particularly indicated on **Exhibit E** attached hereto. Up to ten (10) of the Parking Passes shall be selected by Tenant and converted to visitor parking for Tenant's exclusive use at a location near the entrances to the 12780 Building and the 12790 Building (the "**Visitor Parking Spaces**"). With regard to the portion of the Expansion Term preceding the final Tranche Lease Commencement Date, Tenant shall be entitled to a pro-rata share of such Parking Passes, including the entirety of the Parking Passes in the 12780 Building's parking garage, and a pro-rata share of Parking Passes within the 12790 Building's parking garage, based upon the then-applicable rentable square footage of the 12790 Premises from time-to-time existing during such period. Landlord, at its sole cost and expense (but subject to inclusion in Operating Expenses in accordance with Article 4 of the Original Lease), shall use commercially reasonable efforts to establish and thereafter enforce a parking management program in order to preserve Tenant's parking rights set forth herein (specifically including the exclusive right to the Visitor Parking Spaces), which program may include (a) the issuance of physical parking cards, decals or hanging tags for use by Tenant, its employees and invitees (the "**Parking Identification**"), and (b) the periodic monitoring of the parking areas by Landlord in a commercially reasonable manner to enforce restrictions limiting use of the parking areas to only those holding such Parking Identification. Except as set forth in this Section 10, Tenant shall lease the Parking Passes in accordance with the provisions of the Lease. There shall be no charge for Tenant's access to and use of the Parking Passes throughout the Expansion Term. Tenant shall have access to and use of such Parking Passes twenty-four (24) hours per day, seven (7) days per week.

11. **Signage**. Provided that Original Tenant or a Permitted Assignee leases the entirety of, and is in occupancy of not less than seventy percent (70%) of the 12790 Premises, then Tenant shall be entitled to install (i) one (1) exclusive Building top signage consisting identifying Tenant's name and/or logo in each of two (2) locations to be reasonably and mutually agreed upon by Landlord and Tenant (and subject to the receipt of all necessary approvals), and (ii) two (2) slots identifying Tenant's name and/or logo on each side of the north monument sign serving the Project in the position to be determined by Landlord (the "**Tenant's Signage**"). Landlord hereby approves Tenant's Signage depicted on **Exhibit F** attached hereto. Landlord shall retain the rights to the eyebrow signage pertaining to the Project rotunda. Tenant may, at its sole cost and expense and subject to all applicable laws, the CC&Rs, and Tenant's receipt of all applicable governmental approvals, cause the road leading from El Camino Real to the 12780 and 12790 Buildings to be renamed "Neurocrine Place" (with appropriate and customary corresponding street identification signage), provided that prior to Tenant's vacation and surrender of the Premises, Tenant shall cause the name of such road to revert to Townsgate Dr., or shall otherwise cooperate with Landlord to cause such road to be renamed as designated by Landlord.

11.1 **Tenant's Signage Specifications and Permits**. Tenant's Signage shall set forth Tenant's name or logo as determined by Tenant; provided, however, in no event shall Tenant's Signage include an "Objectionable Name or Logo," as that term is defined in Section 11.2, of this Third Amendment. The graphics, materials, color, design, lettering, lighting, size, illumination, specifications and exact location of Tenant's Signage shall be subject to the prior written approval of Landlord, which approval shall not be unreasonably withheld, conditioned or delayed, and shall be consistent and compatible with the quality and nature of the Project and the exterior Building signage of other tenants of the Building. In addition, Tenant's Signage shall be subject to Tenant's receipt of all required governmental permits and approvals and shall be subject to all Applicable Laws and the CC&Rs. Landlord shall use commercially reasonable efforts to assist Tenant in obtaining all necessary governmental permits and approvals for Tenant's Signage. Tenant hereby acknowledges that, notwithstanding Landlord's approval of Tenant's Signage, Landlord has made no representation or warranty to Tenant with respect to the probability of obtaining all necessary governmental approvals and permits for Tenant's Signage. In the event Tenant does not receive the necessary governmental approvals and permits for Tenant's Signage, Tenant's and Landlord's rights and obligations under the remaining terms and conditions of this Third Amendment shall be unaffected.

11.2 **Objectionable Name or Logo**. In no event shall Tenant's Signage include, identify or otherwise refer to a name and/or logo which relates to an entity which is of a character or reputation, or is associated with a political faction or orientation, which is inconsistent with the quality of the Project, or which would otherwise reasonably offend a landlord of a Comparable Building (an "**Objectionable Name or Logo**"). The parties hereby agree that the name "Neurocrine Biosciences, Inc." or any reasonable derivation thereof, shall not be deemed an Objectionable Name or Logo.

11.3 **Termination of Right to Tenant's Signage**. The rights to the Tenant's Signage contained in this Section 11 may only be exercised by Original Tenant or a Permitted Assignee (and not any other assignee or any sublessee or other transferee of the Original Tenant's interest in the Lease).

11.4 **Cost and Maintenance of Tenant's Signage**. The costs of the actual sign(s) comprising Tenant's Signage and the installation, design, construction, and any and all other costs associated with Tenant's Signage, including, without limitation, utility charges and hook-up fees, permits, and maintenance and repairs, shall be the sole responsibility of Tenant, at Tenant's sole cost and expense, subject to application of the Improvement Allowance pursuant to the terms of the Work Letter. Should Tenant's Signage require repairs and/or maintenance, as determined in Landlord's reasonable judgment, Landlord shall cause such repairs and/or maintenance to be performed, and Tenant shall pay Landlord upon demand the cost of the same as Additional Rental. Upon the expiration or earlier termination of the Lease (or within five (5) business days following Tenant's receipt of written notice from Landlord that Tenant's rights to such Tenant's Signage have terminated as a result of a Tenant default under the Lease or Tenant's failure to satisfy the occupancy requirement, as set forth in Section 11 above), Tenant shall, at Tenant's sole cost and expense, cause Tenant's Signage to be removed and shall cause the area in which such Tenant's Signage was located to be restored to the condition existing immediately prior to the installation of such Tenant's Signage, reasonable wear and tear and damage by casualty excepted. If Tenant fails to timely remove such Tenant's Signage or to restore the areas in which such Tenant's Signage was located, as provided in the immediately preceding sentence, then Landlord may perform such work, and all costs incurred by Landlord in so performing shall be reimbursed by Tenant to Landlord within thirty (30) days after Tenant's receipt of an invoice therefor. The terms and conditions of this Section 11.4 shall survive the expiration or earlier termination of the Lease.

12. **California Accessibility Disclosure**. For purposes of Section 1938 of the California Civil Code, Landlord hereby discloses to Tenant, and Tenant hereby acknowledges that the Common Areas and the 12790 Premises have not undergone inspection by a Certified Access Specialist (CASp).

13. **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 First Amendment other than Tenant's use of Jones Lang LaSalle ("**Tenant's Broker**"), and Landlord's use of Cushman & Wakefield ("**Landlord's Broker**" and, collectively with Tenant's Broker, the "**Brokers**"), and that they know of no other real estate broker or agent who is entitled to a commission in connection with this Third Amendment. Landlord shall pay the fees of the Brokers pursuant to a separate agreement and Landlord shall indemnify Tenant for any claim made by the Brokers against either party; provided, however, in the event Tenant timely makes the "Additional Allowance Election" pursuant to Section 2.5 of the Work Letter, then (i) Landlord shall not be responsible for paying any commission to Tenant's Broker, (ii) Tenant shall receive from Landlord the "Additional Allowance" (as defined in Section 2.5 of the Work Letter) in an amount equal to the commission that would otherwise be payable to Tenant's Broker by Landlord, and (iii) Tenant shall indemnify Landlord for any claim made by Tenant's Broker against either party. 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 use or dealings with any other real estate broker or agent (i.e., other than the Brokers), occurring by, through, or under the indemnifying party. The terms of this Section 13 shall survive the expiration or earlier termination of the term of the Lease, as hereby amended.

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

[signatures contained on following page]

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

"LANDLORD":

KILROY REALTY, L.P.,
a Delaware limited partnership

By: Kilroy Realty Corporation,
a Maryland corporation

Its: General Partner

By: _____
Name: _____
Its: _____

By: _____
Name: _____
Its: _____

"TENANT":
NEUROCRINE BIOSCIENCES, INC.,
a Delaware corporation

By: _____
Name: _____
Its: _____

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kevin C. Gorman, Chief Executive Officer of Neurocrine Biosciences, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Neurocrine Biosciences, 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; and

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

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

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

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

Dated: November 4, 2019

/s/ Kevin C. Gorman
Kevin C. Gorman
Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Matthew C. Abernethy, Chief Financial Officer of Neurocrine Biosciences, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Neurocrine Biosciences, 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; and

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

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

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

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

Dated: November 4, 2019

/s/ Matthew C. Abernethy
Matthew C. Abernethy
Chief Financial Officer

Exhibit 32

CERTIFICATIONS OF
CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Neurocrine Biosciences, Inc. (Company) on Form 10-Q for the period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (Report), I, Kevin C. Gorman, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), of the Securities Exchange Act of 1934; and

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

November 4, 2019

By: /s/ Kevin C. Gorman
Name: Kevin C. Gorman
Title: Chief Executive Officer

In connection with the Quarterly Report of Neurocrine Biosciences, Inc. (Company) on Form 10-Q for the period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (Report), I, Matthew C. Abernethy, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), of the Securities Exchange Act of 1934; and

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

November 4, 2019

By: /s/ Matthew C. Abernethy
Name: Matthew C. Abernethy
Title: Chief Financial Officer