Table of Contents

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 March 31, 2020

OR

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

For the transition period from to

Commission file number: 001-37372

Collegium Pharmaceutical, Inc.

(Exact name of registrant as specified in its charter)

Virginia (State or other jurisdiction of incorporation or organization)	**03-0416362** (I.R.S. Employer Identification Number)
100 Technology Center Drive **Stoughton, MA** (Address of principal executive offices)	**02072** (Zip Code)

(781) 713-3699
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	COLL	The NASDAQ Global Select Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See 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 ☐ (Do not check if smaller reporting company)	Smaller reporting company ☐	Emerging growth company ☐

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

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

As of April 30, 2020, there were 34,336,032 shares of Common Stock, $0.001 par value per share, outstanding.

TABLE OF CONTENTS

FORWARD-LOOKING STATEMENTS

Statements made in this Quarterly Report on Form 10-Q that are not statements of historical or current facts, such as those under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations," are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements discuss our current expectations and projections relating to our financial condition, results of operations, plans, objectives, future performance and business. These statements may be preceded by, followed by or include the words "aim," "anticipate," "believe," "estimate," "expect," "forecast," "intend," "outlook," "plan," "potential," "project," "projection," "seek," "may," "could," "would," "should," "can," "can have," "likely," the negatives thereof and other words and terms of similar meaning.

Forward-looking statements are inherently subject to risks, uncertainties and assumptions; they are not guarantees of performance. You should not place undue reliance on these statements. We have based these forward-looking statements on our current expectations and projections about future events. Although we believe that our assumptions made in connection with the forward-looking statements are reasonable, we cannot assure you that the assumptions and expectations will prove to be correct.

You should understand that the following important factors could affect our future results and could cause those results or other outcomes to differ materially from those expressed or implied in our forward-looking statements:

- our ability to commercialize and grow sales of our products, particularly in light of current global challenges stemming from the COVID-19 pandemic;
- our ability to obtain and maintain regulatory approval of our products and any product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product;
- the size of the markets for our products and any product candidates, and our ability to service those markets;
- the success of competing products that are or become available;
- our ability to obtain and maintain reimbursement and third-party payor contracts for our products;
- the costs of commercialization activities, including marketing, sales and distribution;
- the rate and degree of market acceptance of our products;
- changing market conditions for our products;
- the outcome of any patent infringement, opioid-related or other litigation that may be brought by or against us, including litigation with Purdue Pharma, L.P. and Teva Pharmaceuticals USA, Inc.;
- the outcome of any governmental investigation related to the manufacture, marketing and sale of opioid medications;
- the performance of our third-party suppliers and manufacturers;
- our ability to secure adequate supplies of active pharmaceutical ingredient for each of our products and to manufacture adequate quantities of commercially salable inventory and to maintain our supply chain in the face of global challenges, such as the COVID-19 pandemic;
- our ability to effectively manage our relationships with licensors and to commercialize products that we may in-license from third parties;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our ability to obtain funding for our operations and business development;
- our ability to comply with the terms of our outstanding indebtedness;
- regulatory developments in the United States;
- our ability to obtain and maintain sufficient intellectual property protection for our products and any product candidates;
- our ability to comply with stringent government regulations relating to the manufacturing and marketing of pharmaceutical products, including U.S. Drug Enforcement Agency ("DEA") compliance;
- the loss of key commercial, scientific or management personnel;
- our customer concentration, which may adversely affect our financial condition and results of operations;
- the accuracy of our estimates regarding expenses, revenue, capital requirements and need for additional financing; and
- the other risks, uncertainties and factors discussed under the heading "Risk Factors" in this Quarterly Report on Form 10-Q.

In light of these risks and uncertainties, expected results or other anticipated events or circumstances discussed in this Quarterly Report on Form 10-Q (including the exhibits hereto) might not occur. We undertake no obligation, and specifically decline any obligation, to publicly update or revise any forward-looking statements, even if experience or future developments make it clear that projected results expressed or implied in such statements will not be realized, except as may be required by law.

These and other risks are described under the heading "Risk Factors" in this Quarterly Report on Form 10-Q. Those factors and the other risk factors described therein are not necessarily all of the important factors that could cause actual results or developments to differ materially from those expressed in any of our forward-looking statements. Other unknown or unpredictable factors also could harm our results. Consequently, there can be no assurance that actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us. Given these uncertainties, prospective investors are cautioned not to place undue reliance on such forward-looking statements.

PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited).

Collegium Pharmaceutical, Inc.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)

	March 31, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 116,178	$ 170,019
Accounts receivable	85,427	72,953
Inventory	15,963	9,643
Prepaid expenses and other current assets	6,107	3,105
Total current assets	223,675	255,720
Property and equipment, net	13,145	11,854
Operating lease assets	8,873	9,047
Intangible asset, net	386,289	29,503
Restricted cash	2,645	—
Other noncurrent assets	166	178
Total assets	$ 634,793	$ 306,302
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	$ 6,139	$ 6,247
Accrued expenses	18,814	33,480
Accrued rebates, returns and discounts	171,886	157,549
Current portion of term notes payable	46,859	3,833
Current portion of operating lease liabilities	676	656
Total current liabilities	244,374	201,765
Term notes payable, net of current portion	145,711	7,667
Convertible senior notes	94,383	—
Operating lease liabilities, net of current portion	9,262	9,438
Total liabilities	493,730	218,870
Commitments and contingencies (see Note 14)		
Shareholders’ equity:		
Preferred stock, $0.001 par value; authorized shares - 5,000,000 at March 31, 2020 and December 31, 2019; issued and outstanding shares - none at March 31, 2020 and December 31, 2019	—	—
Common stock, $0.001 par value; authorized shares - 100,000,000 at March 31, 2020 and December 31, 2019; issued and outstanding shares - 34,306,040 at March 31, 2020 and 33,678,840 at December 31, 2019	34	34
Additional paid-in capital	500,478	447,297
Accumulated deficit	(359,449)	(359,899)
Total shareholders’ equity	141,063	87,432
Total liabilities and shareholders’ equity	$ 634,793	$ 306,302

See accompanying notes to the Condensed Consolidated Financial Statements.

Collegium Pharmaceutical, Inc.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

	Three months ended March 31,	
	2020	**2019**
Product revenues, net	$ 76,511	$ 74,516
Cost of product revenues		
Cost of product revenues (excluding intangible asset amortization)	27,229	45,476
Intangible asset amortization	10,295	3,688
Total cost of products revenues	37,524	49,164
Gross profit	38,987	25,352
Operating expenses		
Research and development	2,666	2,992
Selling, general and administrative	31,260	32,352
Total operating expenses	33,926	35,344
Income (loss) from operations	5,061	(9,992)
Interest expense	(4,823)	(234)
Interest income	212	526
Net income (loss)	$ 450	$ (9,700)
Earnings (loss) per share — basic	$ 0.01	$ (0.29)
Weighted-average shares — basic	34,100,688	33,331,917
Earnings (loss) per share — diluted	$ 0.01	$ (0.29)
Weighted-average shares — diluted	35,069,693	33,331,917

See accompanying notes to the Condensed Consolidated Financial Statements.

Collegium Pharmaceutical, Inc.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Three months ended March 31,	
	2020	**2019**
Operating activities		
Net income (loss)	$ 450	$ (9,700)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Amortization expense	10,295	3,688
Depreciation expense	198	184
Stock-based compensation expense	4,951	4,263
Non-cash lease expense	18	114
Non-cash interest expense for amortization of debt discount and issuance costs	1,336	—
Changes in operating assets and liabilities:		
Accounts receivable	(12,474)	(7,193)
Inventory	(6,714)	(924)
Prepaid expenses and other assets	(2,990)	76
Accounts payable	(108)	1,583
Accrued expenses	(15,968)	(8,263)
Accrued rebates, returns and discounts	14,337	7,545
Operating lease assets and liabilities	—	734
Other long-term liabilities	—	(676)
Net cash used in operating activities	(6,669)	(8,569)
Investing activities		
Purchase of intangible asset	(366,811)	—
Purchases of property and equipment	(836)	(3,323)
Net cash used in investing activities	(367,647)	(3,323)
Financing activities		
Proceeds from issuances of common stock from employee stock purchase plans	357	444
Proceeds from the exercise of stock options	4,454	213
Payments made for employee restricted stock tax withholdings	(1,358)	(488)
Proceeds from issuance of term note, net of issuance costs of $2,200	192,373	—
Proceeds from convertible senior notes, net of issuance costs of $4,956	138,794	—
Repayment of term loan	(11,500)	—
Net cash provided by financing activities	323,120	169
Net decrease in cash, cash equivalents and restricted cash	(51,196)	(11,723)
Cash, cash equivalents and restricted cash at beginning of period	170,019	146,633
Cash, cash equivalents and restricted cash at end of period	$ 118,823	$ 134,910
Reconciliation of cash, cash equivalents and restricted cash to the condensed consolidated balance sheets:		
Cash and cash equivalents	$ 116,178	$ 134,910
Restricted cash	2,645	—
Total cash, cash equivalents and restricted cash	$ 118,823	$ 134,910
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 3,456	$ 178
Supplemental disclosure of non-cash activities		
Acquisition of property and equipment in accounts payable and accrued expenses	$ 392	$ 810
Asset acquisition transaction costs in accounts payable and accrued expenses	$ 1,415	$ —
Accrued royalties discharged upon closing of asset acquisition	$ 1,145	$ —
Inventory used in the construction and installation of property and equipment	$ 394	$ —
Term notes issuance costs in accounts payable and accrued expenses	$ 256	$ —
Convertible senior notes issuance costs in accounts payable and accrued expenses	$ 517	$ —
Receivable from stock option exercises in other current assets	$ —	$ 33
Operating lease assets assumed	$ —	$ 9,957
Operating lease liabilities assumed	$ —	$ 10,691

See accompanying notes to the Condensed Consolidated Financial Statements.

Collegium Pharmaceutical, Inc.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited, in thousands, except share and per share amounts)

1. Nature of Business

Collegium Pharmaceutical, Inc. (the "Company") was incorporated in Delaware in April 2002 and then reincorporated in Virginia in July 2014. The Company has its principal operations in Stoughton, Massachusetts. The Company is a specialty pharmaceutical company committed to being the leader in responsible pain management. The Company's first product, Xtampza ER, is an abuse-deterrent, extended-release, oral formulation of oxycodone. In April 2016, the United States Food and Drug Administration (the "FDA") approved the Company's new drug application ("NDA") for Xtampza ER for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. In June 2016, the Company announced the commercial launch of Xtampza ER.

The Company's product portfolio also includes Nucynta ER and Nucynta IR (the "Nucynta Products"). In December 2017, the Company entered into a Commercialization Agreement (the "Nucynta Commercialization Agreement") with Assertio Therapeutics, Inc. (formerly known as Depomed) ("Assertio"), pursuant to which the Company acquired the right to commercialize the Nucynta Products in the United States. The Company began shipping and recognizing product sales on the Nucynta Products on January 9, 2018 and began marketing the Nucynta Products in February 2018. Nucynta ER is an extended-release formulation of tapentadol that is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment, including neuropathic pain associated with diabetic peripheral neuropathy in adults, and for which alternate treatment options are inadequate. Nucynta IR is an immediate-release formulation of tapentadol that is indicated for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults.

On February 6, 2020, the Company entered into an Asset Purchase Agreement with Assertio (the "Nucynta Purchase Agreement"), pursuant to which the Company agreed to acquire from Assertio certain assets related to the Nucynta Products (the "Nucynta Acquisition"), including the rights to the license from Grünenthal GmbH ("Grünenthal"), for an aggregate purchase price of $375,000, subject to certain closing and post-closing adjustments as described in the Nucynta Purchase Agreement. On February 13, 2020, the Company closed the Nucynta Acquisition in accordance with the Nucynta Purchase Agreement. Upon closing, the Nucynta Commercialization Agreement was terminated, with the exception of certain provisions thereof which survived pursuant to the terms of the Nucynta Purchase Agreement, and the Company's royalty payment obligations to Assertio thereunder ceased. Following the closing, the Company will pay royalties directly to Grünenthal at a rate of 14% of net sales of the Nucynta Products.

In March 2020, the World Health Organization declared the continued spread of a novel coronavirus ("COVID-19") a pandemic. The pandemic has severely impacted global economic activity, and many countries and many states in the United States have reacted to the outbreak by instituting quarantines, mandating business and school closures and restricting travel. The Company periodically reviews its accounting estimates in light of changes in circumstances, facts and experience. As of the date of the filing of this Quarterly Report on Form 10-Q, the Company expects the COVID-19 pandemic and actions taken to contain it to impact revenue (due to fewer new patients beginning therapy with the Company's products) and decrease certain operating expenses, including travel and regulatory expenses associated with post-marketing trials that are delayed for 2020. The Company believes that the disruptions caused by COVID-19 will be temporary, but there remains substantial uncertainty as to when such disruptions will cease (or ease).

The Company's operations are subject to certain risks and uncertainties. The principal risks include inability to successfully commercialize products, changing market conditions for products and development of competing products, changing regulatory environment and reimbursement landscape, litigation related to opioid marketing and distribution practices, manufacture of adequate commercial inventory, inability to secure adequate supplies of active pharmaceutical ingredients, key personnel retention, protection of intellectual property, patent infringement litigation and the availability of additional capital financing on terms acceptable to the Company.

The Company believes that its cash and cash equivalents at March 31, 2020, together with expected cash inflows from the commercialization of its products, will enable the Company to fund its operating expenses, debt service and capital expenditure requirements under its current business plan for the foreseeable future.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited Condensed Consolidated Financial Statements include the accounts of Collegium Pharmaceutical, Inc. (a Virginia corporation) as well as the accounts of Collegium Securities Corp. (a Massachusetts corporation), incorporated in December 2015, and Collegium NF, LLC (a Delaware limited liability company), organized in December 2017, both wholly owned subsidiaries requiring consolidation. The consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial reporting and as required by Regulation S-X, Rule 10-01. Accordingly, they do not include all of the information and footnotes required by GAAP for complete consolidated financial statements.

In the opinion of the Company's management, the accompanying unaudited Condensed Consolidated Financial Statements contain all adjustments (consisting of items of a normal and recurring nature) necessary to fairly present the financial position of the Company as of March 31, 2020, the results of operations for the three months ended March 31, 2020 and 2019, and cash flows for the three months ended March 31, 2020 and 2019. The results of operations for the three months ended March 31, 2020 are not necessarily indicative of the results to be expected for the full year.

The preparation of the condensed consolidated financial statements in accordance with GAAP requires the Company to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues, costs and expenses and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements and accompanying notes. Estimates in the Company's consolidated financial statements include revenue recognition, including the estimates of product returns, units prescribed, discounts and allowances related to commercial sales of products, estimates of useful lives with respect to intangible assets, accounting for stock based compensation, contingencies, impairment of intangible assets, and tax valuation reserves. The Company bases estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis. The Company's actual results may differ from these estimates under different assumptions or conditions. The consolidated interim financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 (the "Annual Report").

Significant Accounting Policies

The Company's significant accounting policies are described in Note 2, "Summary of Significant Accounting Policies," in the Company's Annual Report. During the current interim period covered by this report, the Company assumed certain material assets and liabilities in connection with consummating the Nucynta Acquisition, in addition to the issuance of convertible notes and term notes that required a review for embedded derivatives. As a result, the Company adopted the following accounting policy:

Embedded Derivatives

The Company accounts for derivative financial instruments as either equity or liabilities in accordance with Accounting Standards Codification Topic 815, *Derivatives and Hedging*, based on the characteristics and provisions based of each instrument. Embedded derivatives are required to be bifurcated from the host instruments and recorded at fair value if the derivatives are not clearly and closely related to the host instruments on the date of issuance. The Company's term notes (see Note 10) and convertible notes (see Note 11) contain certain features that, in accordance with ASC 815, are not clearly and closely related to the host instrument and represent derivatives that are required to be re-measured at fair value each reporting period. The Company determined that the estimated fair value of the derivatives at issuance and as of March 31, 2020 were not material based on a scenario-based cash flow model that uses unobservable inputs that reflect the Company's own assumptions. Should the Company's assessment of the probabilities around these scenarios change, including for changes in market conditions, there could be a change to the fair value.

Other than the aforementioned changes, there have been no material changes in the Company's significant accounting policies, other than the adoption of accounting pronouncements below, as compared to the significant accounting policies described in the Annual Report.

Reclassifications

The Company has reclassified certain amounts in its condensed consolidated statements of operations for the three months ended March 31, 2019 to conform to the 2020 presentation. Specifically, the Company disaggregated previously reported cost of product revenue of $49,164 into the captions Cost of product revenues (excluding intangible asset amortization) $45,476 and Intangible asset amortization $3,688. The reclassifications relate to the presentation of the Company's gross profit and amortization expense and were made to provide the readers of the Company's consolidated financial statements with additional insight into how the Company and its management view and evaluate its performance and profitability. This reclassification within the consolidated statements of operations for the three months ended March 31, 2019 had no impact on previously reported total consolidated revenues or consolidated results of operations.

Recently Adopted Accounting Pronouncements

New accounting pronouncements are issued periodically by the Financial Accounting Standards Board ("FASB") and are adopted by the Company as of the specified effective dates.

The Company adopted Accounting Standard Updated ("ASU") 2016-13, *Financial Instruments – Credit Losses (ASC Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires companies to measure credit losses utilizing a methodology that reflects expected credit losses and requires a consideration of a broader range of reasonable and supportable information to inform credit loss estimates. Subsequent to issuance, the FASB issued ASUs 2019-04, 2019-05, 2019-10, 2019-11 and 2020-03 to provide additional guidance on the adoption of ASU 2016-13. The Company adopted ASU 2016-13 on January 1, 2020 and the adoption did not have a material impact on the Company's consolidated financial position, results of operations, equity or cash flows.

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*, to ease the potential burden in accounting for reference rate reform. The amendments in ASU 2020-04 are elective and apply to all entities that have contracts, hedging relationships, and other transactions that reference LIBOR or another reference rate expected to be discontinued due to reference rate reform. The new standard is effective from the beginning of the current interim period and may be prospectively applied to transactions through December 31, 2022. Upon the transition of the Company's contracts and transactions to new

reference rates in connection with reference rate reform, the Company will prospectively apply the amendments of ASU 2020-04 and disclose the effect on its consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. The amendments in ASU 2019-12 affect a wide variety of income tax accounting standards with the objective of reducing their complexity. The new standard is effective for annual and interim periods beginning after December 15, 2020, with early adoption permitted. The Company is currently evaluating the standard's effect on the Company's consolidated financial statements.

3. Revenue from Contracts with Customers

The Company's revenue to date is from sales of the Company's products, which are primarily sold to distributors ("customers"), which in turn sell the product to pharmacies for the treatment of patients ("end users").

Revenue Recognition

In accordance with Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* ("ASC Topic 606"), the Company recognizes revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Performance Obligations

The Company determined that performance obligations are satisfied and revenue is recognized when a customer takes control of the Company's product, which occurs at a point in time. This generally occurs upon delivery of the products to customers, at which point the Company recognizes revenue and records accounts receivable, which represents the Company's only contract asset. Payment is typically received 30 to 90 days after satisfaction of the Company's performance obligations and generally does not have an effect on contract asset and contract liability balances. Under the practical expedients permitted by the rules of the adoption, the Company will expense incremental costs of obtaining a contract as and when incurred if the expected amortization period of the assets is one year or less.

Transaction Price and Variable Consideration

Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer ("transaction price"). The transaction price for product sales includes variable consideration related to sales deductions, including (1) rebates and incentives, including managed care rebates, government rebates, co-pay program incentives, and sales incentives and allowances; (2) product returns, including return estimates for both the Nucynta Products and Xtampza ER; and, (3) trade allowances and chargebacks, including fees for distribution service fees, prompt pay discounts, and chargebacks. The Company will estimate the amount of variable consideration that should be included in the transaction price under the expected value method for all sales deductions other than trade allowances, which are estimated under the most likely amount method. These provisions reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the contract. In addition, the Company made a policy election to exclude from the measurement of the transaction price all taxes that are assessed by a governmental authority that are imposed on revenue-producing transactions.

Provisions for rebates and incentives are based on the estimated amount of rebates and incentives to be claimed on the related sales from the period. As the Company's rebates and incentives are based on products dispensed to patients, the Company is required to estimate the expected value of claims at the time of product delivery to distributors. Given that distributors sell the product to pharmacies, which in turn dispense the product to patients, claims can be submitted significantly after the related sales are recognized. The Company's estimates of these claims are based on the historical experience of existing or similar programs, including current contractual and statutory requirements, specific known market events and trends, industry data, and estimated distribution channel inventory levels. Accruals and related reserves required for rebates and incentives are adjusted as new information becomes available, including actual claims. If actual results vary, the Company may need to adjust these estimates, which could have an effect on earnings in the period of the adjustment.

Provisions for product returns are based on product-level historical trends, as well as relevant market events and other factors. For the Nucynta Products, estimates of product returns are primarily based on historical trends as the Nucynta Products have been commercially sold for a number of years. For Xtampza ER, since the product has only been commercially sold since June 2016, estimates of product returns are based on a combination of historical returns processed to date, taking into consideration the expiration date of the product upon delivery to customers, as well as forecasted customer buying patterns, shipment and prescription trends, channel inventory levels, and other specifically known market events and trends.

Provisions for trade allowances and chargebacks are primarily based on customer-level contractual terms. Accruals and related reserves are adjusted as new information becomes available, which generally consists of actual trade allowances and chargebacks processed relating to sales recognized in the period.

The amount of variable consideration that is included in the transaction price may be constrained and is included in net sales only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. In general, performance obligations do not include any estimated amounts of variable consideration that are constrained. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

The following tables summarize activity in each of the Company's product revenue provision and allowance categories for the three months ended March 31, 2020 and 2019:

Three months ended March 31, 2020	Rebates and Incentives (1)	Product Returns (2)	Trade Allowances and Chargebacks (3)
Balance at December 31, 2019	$ 129,901	$ 27,648	$ 14,020
Provision related to current period sales	83,573	3,406	18,770
Changes in estimate related to prior period sales	1,131	—	49
Credits/payments made	(73,075)	(698)	(18,625)
Balance at March 31, 2020	$ 141,530	$ 30,356	$ 14,214

Three months ended March 31, 2019	Rebates and Incentives (1)	Product Returns (2)	Trade Allowances and Chargebacks (3)
Balance at December 31, 2018	$ 129,318	$ 15,465	$ 14,841
Provision related to current period sales	65,881	4,992	15,658
Changes in estimate related to prior period sales	(3,017)	—	—
Credits/payments made	(59,295)	(1,016)	(15,728)
Balance at March 31, 2019	$ 132,887	$ 19,441	$ 14,771

(1) Provisions for rebates and incentives includes managed care rebates, government rebates and co-pay program incentives. Provisions for rebates and incentives are deducted from gross revenues at the time revenues are recognized and are included in accrued rebates, returns and discounts in the Company's Consolidated Condensed Balance Sheets.

(2) Provisions for product returns are deducted from gross revenues at the time revenues are recognized and are included in accrued rebates, returns and discounts in the Company's Condensed Consolidated Balance Sheets.

(3) Provisions for trade allowances and chargebacks include fees for distribution service fees, prompt pay discounts, and chargebacks. Trade allowances and chargebacks are deducted from gross revenue at the time revenues are recognized and are recorded as a reduction to accounts receivable in the Company's Condensed Consolidated Balance Sheets.

As of March 31, 2020, the Company did not have any transaction price allocated to remaining performance obligations and any costs to obtain contracts with customers, including pre-contract costs and set up costs, were immaterial.

Disaggregation of Revenue

The Company disaggregates its product revenue, net from contracts with customers, into the categories included in the table below. These categories depict how the nature, timing and uncertainty of revenue and cash flows are affected by economic factors:

	Three months ended March 31,	
	2020	**2019**
Xtampza ER	$ 31,507	$ 25,134
Nucynta Products	45,004	49,382
Total product revenues, net	$ 76,511	$ 74,516

For the three months ended March 31, 2020, the Company recognized Nucynta IR and Nucynta ER product revenues, net of $27,970 and $17,034, respectively. For the three months ended March 31, 2019, the Company recognized Nucynta IR and Nucynta ER product revenues, net of $29,861 and $19,521, respectively.

4. License Agreements

The Company periodically enters into license agreements to develop and commercialize products. During the three months ended March 31, 2020 and 2019, the only products sold by the Company under a license agreement were the Nucynta Products. Prior to February 13, 2020, the Company sold the Nucynta Products pursuant to the rights licensed to it under the Nucynta Commercialization Agreement. Effective February 13, 2020, the Company sold the Nucynta Products pursuant to the rights licensed and acquired under the Nucynta Purchase Agreement, including certain intellectual property and manufacturing rights that it did not previously own under the Commercialization Agreement (see Note 8).

Nucynta Commercialization Agreement

On January 9, 2018 (the "Nucynta Commercialization Closing Date"), the Company consummated the transactions contemplated by the Nucynta Commercialization Agreement, pursuant to which Assertio agreed to grant a sublicense of certain of its intellectual property related to the Nucynta Products for commercialization in the United States. The Company began recording revenues from sales of the Nucynta Products on the Nucynta Commercialization Closing Date and began commercial promotion of the Nucynta Products in February 2018. Pursuant to the Nucynta Commercialization Agreement, the Company paid a one-time, non-refundable license fee of $10,000 to Assertio on the Nucynta Commercialization Closing Date, $6,223 for transferred inventory and $1,987 as reimbursement for prepaid expenses. The Company also assumed the existing liabilities of the Nucynta Products, including $22,660 related to sales of Nucynta Products that occurred prior to the Nucynta Commercialization Closing Date. The Nucynta Commercialization Agreement initially required the Company to pay a guaranteed minimum royalty of $135,000 per year through December 2021, payable in quarterly payments of $33,750, prorated in 2018 for the Nucynta Commercialization Closing Date, as well as a variable royalty based on annual net sales over $233,000. Beginning January 2022 and for each year of the Nucynta Commercialization Agreement term thereafter, the Company was required to pay a variable royalty on annual net sales of the Nucynta Products, but without a guaranteed minimum.

Effective August 2018, the Company entered into a Second Amendment to the Nucynta Commercialization Agreement to clarify the mechanism for transferring title of products to be sold by the Company pursuant to the agreement and various related matters. The Second Amendment did not have an impact on the Company's financial statements.

Effective November 2018, the Company entered into the Third Amendment to the Nucynta Commercialization Agreement to adjust the royalty structure and termination clauses. Pursuant to the amended Nucynta Commercialization Agreement, the $135,000 guaranteed minimum annual royalties were eliminated, and the Company was no longer required to secure its royalty payment obligations with a standby letter of credit. Beginning on January 1, 2019 and

thereafter, the Company was obligated to make royalty payments to Assertio conditional upon net sales and based on the following royalty structure for the period between January 1, 2019 and December 31, 2021:

(i) 65% of annual net sales of the Nucynta Products up to $180,000, plus
(ii) 14% of annual net sales of the Nucynta Products between $180,000 and $210,000, plus
(iii) 58% of annual net sales of the Nucynta Products between $210,000 and $233,000, plus
(iv) 20% of annual net sales of the Nucynta Products between $233,000 and $258,000, plus
(v) 15% of annual net sales of the Nucynta Products in excess of $258,000.

The Amendment did not modify the royalties payable on sales of the Nucynta Products on and after January 1, 2022, which remained as contemplated by the Nucynta Commercialization Agreement as in effect on January 9, 2018. In addition, prior to January 1, 2022, the Company was obligated to make royalty payments to Assertio, for ultimate payment to Grünenthal, at a rate of 14% of net sales of the Nucynta Products, subject to a guaranteed royalty of $34,000 when net sales were between $180,000 and $243,000. The Amendment further provided that if annual net sales of the Nucynta Products were less than $180,000 in any 12-month period through January 1, 2022, or if they are less than $170,000 in any 12-month period commencing on January 1, 2022, Assertio had the right to terminate the Nucynta Commercialization Agreement without penalty. The Amendment further provides that the Company did not have a right to terminate the Nucynta Commercialization Agreement prior to December 31, 2021.

In connection with execution of the Third Amendment to the Nucynta Commercialization Agreement, the Company issued a warrant to Assertio to purchase 1,041,667 shares of common stock of the Company (the “Warrant”) at an exercise price of $19.20 per share. The Warrant will expire in November 2022 and includes customary adjustments for changes in the Company’s capitalization.

Nucynta Purchase Agreement

On February 6, 2020, the Company entered into the Nucynta Purchase Agreement with Assertio, pursuant to which the Company agreed to acquire from Assertio certain intellectual property and manufacturing rights related to the Nucynta Products for an aggregate purchase price of $375,000, subject to certain closing and post-closing adjustments as described in the Nucynta Purchase Agreement. In connection with the Nucynta Purchase Agreement, the Company also agreed to assume certain regulatory and supply chain contracts and obligations related to Nucynta Products. The Nucynta Purchase Agreement contains customary representations, warranties and covenants, and indemnification provisions subject to specified limitations. After the closing of the Nucynta Purchase Agreement, for the years 2020 and 2021, the Company will pay conditional royalties directly to Grünenthal at a rate of 14% of net sales of the Nucynta Products. This royalty payment obligation will replace the Company’s previous obligation to pay a royalty rate of 14% of net sales of the Nucynta Products to Grünenthal, subject to a guaranteed royalty of $34,000 when net sales are between $180,000 and $243,000.

On February 13, 2020, the Company closed the Nucynta Acquisition in accordance with the Nucynta Purchase Agreement. Upon the closing, the Nucynta Commercialization Agreement was terminated, with the exception of certain provisions thereof which survived pursuant to the terms of the Nucynta Purchase Agreement, and the Company’s royalty payment obligations to Assertio thereunder ceased.

The assets acquired, liabilities assumed, and equity interests issued by the Company in connection with the Nucynta Commercialization Agreement and Nucynta Purchase Agreement are further described in Note 8.

5. Earnings Per Share

Basic net earnings per share is calculated by dividing the net income (loss) by the weighted average number of shares of common stock outstanding during the period. Diluted earnings per share is computed by dividing the net income (loss) by the weighted average number of shares of common stock, plus potentially dilutive securities outstanding for the period, as determined in accordance with the treasury stock accounting method. Potentially dilutive securities outstanding include stock options, unvested restricted stock units, performance share units and warrants, but are only included to the extent that their addition is dilutive.

The following table presents the computations of basic and dilutive earnings (loss) per common share:

	Three months ended March 31,	
	2020	**2019 (1)**
Numerator:		
Net income (loss)	$ 450	$ (9,700)
Denominator:		
Weighted-average shares outstanding - basic	34,100,688	33,331,917
Effect of dilutive securities:		
Stock options	553,197	—
Restricted stock units	305,341	—
Performance share units	8,141	—
Employee Stock Purchase Program	29,681	
Warrants	72,645	—
Weighted average shares outstanding - diluted	35,069,693	33,331,917
Earnings (loss) per share — basic	$ 0.01	$ (0.29)
Earnings (loss) per share — diluted	$ 0.01	$ (0.29)

(1) The Company incurred a net loss for the three months ended March 31, 2019, causing inclusion of any potentially dilutive securities to have an anti-dilutive effect, which resulted in basic loss per share and dilutive loss per share being equivalent.

The Company has the option to settle the conversion obligation for its convertible senior notes due in 2026 in cash, shares or any combination of the two. Since the Company's intends to settle the principal amount of the convertible senior notes in cash, the Company used the treasury stock method for determining the potential dilution in the diluted earnings per share computation. For the three months ended March 31, 2020, the Company excluded 4,925,134 shares related to the convertible senior notes because their effect is anti-dilutive.

The following table presents dilutive securities excluded from the calculation of diluted earnings per share due to their anti-dilutive effect:

	Three months ended March 31,	
	2020	**2019**
Stock options	2,262,400	4,156,580
Warrants	—	1,041,667
Restricted stock units	57,834	893,462
Performance share units	267,498	99,400
Convertible senior notes	4,925,134	—

6. Fair Value of Financial Instruments

Disclosures of fair value information about financial instruments are required for financial instruments with respect to which it is practicable to estimate that value. Fair value measurements and disclosures describe the fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value, as follows:

Level 1 inputs:	Quoted prices (unadjusted) in active markets for identical assets or liabilities
Level 2 inputs:	Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly
Level 3 inputs:	Unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability

Transfers are calculated on values as of the transfer date. There were no transfers between Levels 1, 2 and 3 during the three months ended March 31, 2020 and 2019.

The following tables present the Company's financial instruments carried at fair value using the lowest level input applicable to each financial instrument at March 31, 2020 and December 31, 2019:

	Total	Quoted Prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
March 31, 2020				
Money market funds, included in cash equivalents	$ 45,052	$ 45,052	$ —	$ —
December 31, 2019				
Money market funds, included in cash equivalents	$ 94,841	$ 94,841	$ —	$ —

The Company's convertible senior notes fall into the Level 2 category within the fair value level hierarchy. The fair value was determined using broker quotes in a non-active market for valuation. As of March 31, 2020, the convertible senior notes had a fair value of approximately $126,500 and a net carrying value of $94,383.

The Company's term notes fall into the Level 2 category within the fair value level hierarchy and the fair value was determined using quoted prices for similar liabilities in active markets, as well as inputs that are observable for the liability (other than quoted prices), such as interest rates that are observable at commonly quoted intervals.

As of March 31, 2020, the carrying amounts of the cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses, accrued rebates, returns and discounts and operating lease liabilities approximated their estimated fair values.

7. Inventory

Inventory as of March 31, 2020 and December 31, 2019 consisted of the following:

	As of March 31, 2020	As of December 31, 2019
Raw materials	$ 5,626	$ 795
Work in process	1,685	1,427
Finished goods	8,652	7,421
Total inventory	$ 15,963	$ 9,643

The aggregate charges related to excess inventory for the three months ended March 31, 2020 and 2019 were immaterial. These expenses were recorded as a component of cost of product revenues. During the three months ended March 31, 2020 and 2019, inventory used in the construction and installation of property and equipment was $394 and $0, respectively.

8. Intangible Asset

As of March 31, 2020 and December 31, 2019, the Company's only intangible asset (the "Nucynta Intangible Asset") is related to the Nucynta Acquisition and Nucynta Commercialization Agreement. The gross carrying amount and accumulated amortization of the Nucynta Intangible Asset were as follows:

	As of March 31, 2020	As of December 31, 2019
Gross carrying amount	$ 521,170	$ 154,089
Accumulated amortization	(134,881)	(124,586)
Intangible asset, net	$ 386,289	$ 29,503

Nucynta Acquisition

In February 2020, the Company entered into the Nucynta Purchase Agreement with Assertio, pursuant to which the Company acquired certain intellectual property and manufacturing rights related to the Nucynta Products, including U.S. commercialization rights, U.S. manufacturing rights, and inventory, for an aggregate purchase price of $375,000, subject to certain closing and post-closing adjustments. The Company also agreed to assume certain regulatory and supply chain contracts, and obligations related to Nucynta Products (see Note 4). In February 2020, the Company entered into a loan agreement (see Note 10) and issued convertible senior notes (see Note 11) to finance a portion of the purchase price paid pursuant to the Nucynta Purchase Agreement.

The Company determined that the Nucynta Acquisition, closed in February 2020, should be accounted for as an asset acquisition in accordance with ASC Topic 805-50 because substantially all of the fair value of the gross assets acquired are concentrated in the right to commercialize the Nucynta Products in the U.S. The Company concluded that the fair value estimates of the assets surrendered was more clearly evident than the fair value of the assets received, and therefore followed a cost accumulation model to determine the consideration transferred in the asset acquisition.

The consideration transferred in the asset acquisition was measured at cost, including transaction costs, assets transferred by the Company, and royalty obligations discharged by the seller. The table below represents the costs accumulated to acquire the commercial rights for the Nucynta Products based on the terms of the Nucynta Purchase Agreement, as amended:

Acquisition consideration:		
Base purchase price	$	375,000
Cash paid for inventory		6,030
Transaction costs		6,297
Reduction for 2020 cash transferred to Assertio under the prior Nucynta Commercialization Agreement[(1)]		(13,071)
Reduction for accrued royalty obligation discharged upon closing[(1)]		(1,145)
Total acquisition consideration:	$	373,111

(1) Represents $14,216 total reduction to the base purchase price comprising of $13,071 of cash payments transferred to Assertio under the prior Nucynta Commercialization Agreement as well as a reduction for discharged pre-acquisition accrued royalties based on sales from January 1, 2020 through closing.

The Company then allocated the consideration transferred to the individual assets acquired on a relative fair value basis as summarized in the table below:

Assets acquired:		
Nucynta Intangible Asset	$	367,081
Inventory		6,030
Total consideration allocated to assets acquired:	$	373,111

The Company concluded that the consideration allocable to the Nucynta Intangible Asset for the additional intellectual property and manufacturing rights it acquired as part of the Nucynta Acquisition were incremental costs associated with the pre-existing intangible asset from the former Nucynta Commercialization Agreement, as such costs result in probable future economic benefits. Specifically, the additional intellectual property rights acquired in the Nucynta Acquisition enable the Company to eliminate royalty obligations otherwise payable to Assertio under the former Nucynta Commercialization Agreement.

Nucynta Commercialization Agreement

The Company determined that the Nucynta Commercialization Agreement, which closed in January 2018, should be accounted for as an asset acquisition in accordance with ASC Topic 805-50, as substantially all of the fair value of the gross assets acquired was concentrated in the sublicense of the Nucynta Products, which is a single identifiable asset. The Company concluded that the fair value estimates of the assets surrendered, liabilities incurred, and equity interests issued were more clearly evident than the fair value of the assets received, and therefore followed a cost accumulation model to determine the consideration transferred in the asset acquisition.

Under the original terms of the Nucynta Commercialization Agreement, the Company was obligated to make guaranteed annual minimum royalty payments of $537,000 to Assertio, which consisted of scheduled payments of $132,000 in 2018, $135,000 in 2019, $135,000 in 2020, and $135,000 in 2021. Due to the nature of the guaranteed minimum royalty payment obligation and the fact that it was required to be settled in cash, the Company determined that the future minimum royalty payments represented a liability that should be recorded at its fair value as of the Nucynta Commercialization Closing Date. The Company calculated the fair value of the future minimum royalty payments to be $482,300 using a discount rate of 5.7%. The discount rate was determined based on a review of observable market data relating to similar liabilities. The Company determined the $54,700 discount should be recognized as interest expense in the Statement of Operations using the effective interest method and over the repayment period from January 9, 2018 through December 2021. Prior to the Third Amendment to the Nucynta Commercialization Agreement in November 2018, the Company recognized interest expense of $19,281 relating to the minimum royalty payments and amortization expense of $107,662 related to the intangible asset

Effective November 8, 2018 (the "Third Amendment Date"), the Company entered into the Third Amendment to the Nucynta Commercialization Agreement, which eliminated the guaranteed minimum royalty payment obligations for years 2019, 2020 and 2021. As a result, the Company remeasured the remaining contractual obligation as of the Third Amendment Date and recorded a reduction of the acquired intangible asset and obligation. As of December 31, 2018, the Company had paid all of the $132,000 of minimum royalty payment obligation owed under the Nucynta Commercialization Agreement for 2018. In connection with the Third Amendment to the Nucynta Commercialization Agreement, the Company issued a warrant to Assertio to purchase 1,041,667 shares of common stock of the Company at an exercise price of $19.20 per share. The Company estimated the fair value of the warrant on the date of issuance to be approximately $8,043 using the Black-Scholes option-pricing model. See Note 12 for further detail regarding the warrant issued to Assertio.

A summary of the gross carrying amount, accumulated amortization, and net book value of the Nucynta Intangible Asset from the execution of the Nucynta Commercialization Agreement through period end are as follows:

	Gross Carrying Value	Accumulated Amortization	Net Book Value
Intangible Asset, net			
Cost basis as of acquisition date	$ 515,627	$ —	$ 515,627
Amortization expense from acquisition date through Third Amendment Date	—	(107,662)	(107,662)
Adjustment due to the remeasurement of liability as of Third Amendment Date	(369,581)	—	(369,581)
Additional costs incurred as of Third Amendment Date[(1)]	8,043	—	8,043
Amortization expense from Amendment Date through fiscal year end	—	(2,172)	(2,172)
Balance as of December 31, 2018	$ 154,089	$ (109,834)	$ 44,255
Amortization expense	—	(14,752)	(14,752)
Balance as of December 31, 2019	$ 154,089	$ (124,586)	$ 29,503
Amortization expense through Nucynta Acquisition	—	(1,754)	(1,754)
Additional cost incurred from Nucynta Acquisition	367,081	—	367,081
Amortization expense from Nucynta Acquisition through period end	—	(8,541)	(8,541)
Balance as of March 31, 2020:	$ 521,170	$ (134,881)	$ 386,289

(1) Represents fair value of warrant issued in connection with the Amendment to the Nucynta Commercialization Agreement.

Amortization

The Company has been amortizing the Nucynta Intangible Asset over its useful life, which is the period over which the asset is expected to contribute directly or indirectly to the future cash flows of the Company. The Company had initially determined that the useful life for the intangible asset was approximately 4.0 years from the closing date of the Nucynta Commercialization Agreement, January 9, 2018 on the basis of the majority of the cash flows expected to be realized for future product sales under the Nucynta Commercialization Agreement. The Nucynta Acquisition significantly impacted the timing and amount of future cash inflows from the sales of the Nucynta Products, and, therefore, the Company considered it to be a triggering event to remeasure the expected useful life of the Nucynta Intangible Asset. The Company determined that the useful life for the Nucynta Intangible Asset was approximately 5.9 years from the Closing Date of the Nucynta Acquisition and accordingly, the intangible asset will be amortized prospectively over its revised useful life. The Company will recognize amortization expense as a component of cost of product revenues in the Condensed Consolidated Statement of Operations on a straight-line basis over its useful life as it approximates the period of economic benefits expected to be realized from future cash inflows from sales of the Nucynta Products. Prior to the Nucynta Acquisition, the Company had recognized $126,340 of amortization expense related to the Nucynta Intangible Asset. As the accumulated cost basis of the Nucynta Intangible Asset was increased with the Nucynta Acquisition, the Company will continue to prospectively amortize the resulting net intangible asset on a straight-line basis over the remaining useful life.

The following table presents amortization expense recognized for the three months ended March 31, 2020 and 2019:

	Three months ended March 31,	
	2020	2019
Nucynta amortization expense included in cost of product revenues	$ 10,295	$ 3,688

As of March 31, 2020, the remaining amortization period is approximately 5.8 years and the remaining estimated amortization for 2020, 2021, 2022, 2023, 2024 and 2025 is expected to be $50,385, $67,181, $67,181, $67,181, $67,181 and $67,180, respectively.

9. Accrued Expenses

Accrued expenses as of March 31, 2020 and December 31, 2019 consisted of the following:

	As of March 31,	As of December 31,
	2020	2019
Accrued royalties	$ 6,301	$ 21,893
Accrued product taxes and fees	3,541	—
Accrued bonuses	1,198	4,047
Accrued incentive compensation	1,522	1,650
Accrued payroll and related benefits	2,260	1,154
Accrued sales and marketing	805	775
Accrued interest	503	473
Accrued audit and legal	823	308
Accrued inventory	267	—
Accrued other operating costs	1,594	3,180
Total accrued expenses	$ 18,814	$ 33,480

10. Term Notes Payable

Pharmakon Term Notes

On February 6, 2020, in connection with the execution of the Nucynta Purchase Agreement, the Company, together with its subsidiary, Collegium Securities Corporation, entered into a Loan Agreement (the "Loan Agreement") with BioPharma Credit PLC, as collateral agent and lender, and BioPharma Credit Investments V (Master) LP, as lender (collectively "Pharmakon"). The Loan Agreement provides for a $200,000 secured term loan (the "term notes"), the proceeds of which were used to finance a portion of the purchase price paid pursuant to the Nucynta Purchase Agreement. On February 13, 2020 (the "Closing Date"), the Company received the net proceeds.

The term notes bear interest at a rate based upon the three-month LIBOR rate, subject to a LIBOR floor of 2.0%, plus a margin of 7.5% per annum, payable quarterly in arrears. The Company is required to repay the term notes by making equal quarterly payments of principal beginning in the first quarter immediately following the third month anniversary of the Closing Date. The term notes will mature on the calendar quarter end immediately following the 48-month anniversary of the Closing Date and is guaranteed by the Company's material domestic subsidiaries and also secured by substantially all of the Company's material assets. On the Closing Date, the Company paid to Pharmakon a facility fee equal to 2.50% of the aggregate principal amount of the term notes, or $5,000, in addition to $427 of other expenses incurred by Pharmakon and reimbursed by the Company (together, the "discount"). Net proceeds of $194,573 were transferred to Assertio by Collegium as agent in partial satisfaction of the Nucynta Purchase Agreement. In addition, the Company capitalized $2,456 of term notes issuance costs, related to legal and advisory fees.

The Loan Agreement permits voluntary prepayment at any time in whole or in part, subject to a prepayment premium. Except with respect to certain prepayments made with the proceeds from new equity issuances as described below, the prepayment premium is equal to 3.00% of the principal amount being prepaid prior to the second-year anniversary of the Closing Date, 2.00% of the principal amount being prepaid on or after the second-year anniversary, but on or prior to the

third-year anniversary, of the Closing Date, and 1.00% of the principal amount being prepaid on or after the third-year anniversary of the Closing Date, but prior to the fourth-year anniversary of the Closing Date. The Loan Agreement also includes a make-whole premium if there is a voluntary prepayment, a prepayment due to a change in control or acceleration following an Event of Default on or prior to the second-year anniversary of the Closing Date in an amount equal to foregone interest from the date of prepayment through the second-year anniversary of the Closing Date. A change of control triggers a mandatory prepayment of the term notes.

If any single voluntary prepayment of the Loan Agreement of less than or equal to $50,000 is made solely from the proceeds of an equity issuance by the Company prior to the second-year anniversary of the Closing Date a prepayment premium of 5.00% would apply, with no make-whole.

The Loan Agreement contains certain covenants and obligations of the parties, including, without limitation, covenants that require the Company to maintain $200,000 in annual net sales and covenants that limit the Company's ability to incur additional indebtedness or liens, make acquisitions or other investments or dispose of assets outside the ordinary course of business, restrictions which limit the Company's ability pay dividends and restrictions of net assets of subsidiaries. The Loan Agreement also contains customary events of default, including payment defaults, breaches of covenants, change of control and a material adverse change default. Failure to comply with these covenants would constitute an event of default under the Loan Agreement, notwithstanding the Company's ability to meet its debt service obligations. The Loan Agreement also includes various customary remedies for Pharmakon following an event of default, including the acceleration of repayment of outstanding amounts under the Loan Agreement and execution upon the collateral securing obligations under the Loan Agreement. Under certain circumstances, a default interest rate will apply on outstanding obligations during the occurrence and continuance of an event of default. As of March 31, 2020, the Company was in compliance with all of its covenants.

In March 2020, the Company amended the term notes with Pharmakon to clarify the timing of the quarterly payments of principal. The amendment did not modify the Company's borrowings, interest rates, or covenants.

During the three months ended March 31, 2020, the Company recognized approximately $2,986 of interest expense related to the term notes.

As of March 31, 2020, scheduled principal repayments under the term notes are as follows:

Years ended December 31,	**Principal Payments**
2020	$ 37,500
2021	50,000
2022	37,500
2023	50,000
2024	25,000
Total before unamortized discount and issuance costs	$ 200,000
Less: unamortized discount and issuance costs	(7,430)
Total term notes	$ 192,570

Silicon Valley Bank Term Loan Facility

From August 2012 until January 2020, the Company maintained a term loan facility with Silicon Valley Bank ("SVB"), which was amended in connection with, and as a condition to, consummation of the transactions contemplated by the Nucynta Commercialization Agreement. Under the amended term loan ("Consent and Amendment"), the Company had a term loan facility in an amount of $11.5 million, which replaced the Company's previously existing term loan facility. The proceeds of the Consent and Amendment were used to finance certain payment obligations under the Nucynta Commercialization Agreement and to repay the balance of the previously existing term loan.

The Consent and Amendment bore interest at a rate per annum of 0.75% above the prime rate (as defined in the Consent and Amendment). The Company was eligible to repay the Consent and Amendment in equal consecutive monthly installments of principal plus monthly payments of accrued interest, commencing in January 2020.

In January 2020, the Company prepaid the outstanding principal and accrued interest on the Consent and Amendment along with the required prepayment fees. The loss on extinguishment of the term loan was immaterial and was recorded as a component of interest expense.

11. Convertible Senior Notes

On February 13, 2020, the Company issued 2.625% convertible senior notes due in 2026 (the "convertible notes") in the aggregate principal amount of $143,750, in a public offering registered under the Securities Act of 1933, as amended. The convertible notes were issued in connection with funding the Nucynta Acquisition, and the proceeds of the convertible notes were used to finance a portion of the purchase price payable pursuant to the Nucynta Purchase Agreement. Some of the Company's existing investors participated in the convertible notes offering.

The Company may, at its option, settle the convertible notes in cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock. Accordingly, the Company separately accounted for the liability component (the "Liability Component") and the embedded derivative conversion option (the "Equity Component") of the convertible notes by allocating the proceeds between the Liability Component and the Equity Component. In connection with the issuance of the convertible notes, the Company incurred approximately $5,473 of debt issuance costs, which primarily consisted of underwriting, legal and other professional fees, and allocated these costs between the Liability Component and the Equity Component based on the allocation of the proceeds. Of the total debt issuance costs, $1,773 was allocated to the Equity Component and recorded as a reduction to additional paid-in capital and $3,700 was allocated to the Liability Component and recorded as a debt discount of the convertible notes. The portion allocated to the Liability Component is amortized to interest expense using the effective interest method over six years.

The convertible notes are the Company's senior unsecured obligations and bear interest at a rate of 2.625% per year payable semi-annually in arrears on February 15 and August 15 of each year, beginning on August 15, 2020. Before August 15, 2025, noteholders will have the right to convert their notes only upon the occurrence of certain events. From and after August 15, 2025, noteholders may convert their notes at any time at their election until the close of business on the scheduled trading day immediately before the maturity date. The Company will settle conversions by paying or delivering, as applicable, cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's election. The notes will mature on February 15, 2026, unless earlier repurchased, redeemed or converted. The initial conversion rate is 34.2618 shares of common stock per $1 principal amount of notes, which represents an initial conversion price of approximately $29.19 per share of common stock. The conversion rate and conversion price are subject to adjustment upon the occurrence of certain events.

Holders of the convertible notes may convert all or any portion of their convertible notes, in multiples of $1 principal amount, at their option only under the following circumstances:

(1) during any calendar quarter commencing after the calendar quarter ending on March 31, 2020, if the last reported sale price per share of the Company's common stock exceeds 130% of the conversion price for at least 20 trading days during the 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter;
(2) during the five consecutive business days immediately after any 10 consecutive trading day period (such 10 consecutive trading day period, the ''measurement period'') in which the "trading price" per $1 principal amount of the Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price per share of the Company's common stock on such trading day and the conversion rate on such trading day;
(3) upon the occurrence of certain corporate events or distributions on the Company's common stock;
(4) if the Company calls the convertible notes for redemption; or
(5) at any time from, and including, August 15, 2025 until the close of business on the scheduled trading day immediately before the maturity date.

As of March 31, 2020, none of the above circumstances had occurred and as such, the convertible notes could not have been converted.

The Company may not redeem the convertible notes prior to February 15, 2023. On or after February 15, 2023, the Company may redeem the convertible notes, in whole and not in part, at a cash redemption price equal to the principal

amount of the Notes to be redeemed, plus accrued and unpaid interest, if any, only if the last reported sale price per share of the Company's common stock exceeds 130% of the conversion price on:

(1) each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the trading day immediately before the date the Company sends the related redemption notice; and
(2) the trading day immediately before the date the Company sends such notice.

Calling any convertible note for redemption will constitute a make-whole fundamental change with respect to that convertible note, in which case the conversion rate applicable to the conversion of that convertible note, if it is converted in connection with the redemption, will be increased in certain circumstances for a specified period of time.

The convertible notes have customary default provisions, including (i) a default in the payment when due (whether at maturity, upon redemption or repurchase upon fundamental change or otherwise) of the principal of, or the redemption price or fundamental change repurchase price for, any note; (ii) a default for 30 days in the payment when due of interest on any note; (iii) a default in the Company's obligation to convert a note in accordance with the indenture; (iv) a default with respect to the Company's obligations under the indenture related to consolidations, mergers and asset sales; (v) certain payment or other defaults by the Company or certain subsidiaries with respect to mortgages, agreements or other instruments for indebtedness for money borrowed of at least $20,000; and (vi) certain events of bankruptcy, insolvency and reorganization with respect to the Company or any of its significant subsidiaries.

The initial carrying amount of the Liability Component of $97,200 was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The allocation was performed in a manner that reflected the Company's non-convertible borrowing rate for similar debt. The Equity Component of the Notes of $46,550 was recognized as a debt discount. The excess of the principal amount of the Liability Component over its carrying amount is amortized to interest expense using the effective interest method over six years. The Equity Component, which is included in the additional paid in capital portion of stockholders' equity on the Company's consolidated balance sheet, is not remeasured as long as it continues to meet the conditions for equity classification.

As of March 31, 2020, the convertible notes outstanding consisted of the following:

Liability component:		
Principal	$	143,750
Less: unamortized debt discount and issuance costs		(49,367)
Net carrying amount	$	94,383
Equity component, net of issuance costs of $1,773	$	44,777

The Company determined the expected life of the convertible notes was equal to its six-year term. The effective interest rate on the Liability Component of the convertible notes was 10.31%. As of March 31, 2020, the "if-converted value" did not exceed the remaining principal amount of the convertible notes. The fair value of the convertible notes was determined based on data points other than quoted prices that are observable, either directly or indirectly, and has been classified as Level 2 within the fair value hierarchy. The fair value of the convertible notes, which differs from their carrying value, is influenced by market interest rates, the Company's stock price and stock price volatility.

The following table presents the total interest expense recognized related to the convertible notes during the three months ended March 31, 2020:

	Three months ended March 31, 2020
Contractual interest expense	$ 503
Amortization of debt discount	818
Amortization of debt issuance costs	65
Total interest expense	$ 1,386

As of March 31, 2020, the future minimum payments on the convertible notes were as follows:

Years ended December 31,	Future Minimum Payments
2020	$ 1,939
2021	3,826
2022	3,826
2023	3,826
2024	3,836
Thereafter	149,504
Total minimum payments	$ 166,757
Less: interest	(23,007)
Less: unamortized debt discount and issuance costs	(49,367)
Convertible senior notes	$ 94,383

12. Equity

The changes in shareholders' equity for three months ended March 31, 2020 were as follows:

	Common Stock		Additional Paid- In Capital	Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Shares	Amount			
Balance, December 31, 2019	33,678,840	$ 34	$ 447,297	$ (359,899)	$ 87,432
Exercise of common stock options	455,573	—	4,454	—	4,454
Issuance for employee stock purchase plan	39,411	—	357	—	357
Vesting of restricted stock units ("RSUs")	195,280	—	—	—	—
Shares withheld for employee taxes upon vesting of RSUs	(63,064)	—	(1,358)	—	(1,358)
Stock-based compensation	—	—	4,951	—	4,951
Equity component of 2020 Convertible Notes, net of issuance costs of $1,773	—	—	44,777	—	44,777
Net income	—	—	—	450	450
Balance, March 31, 2020	34,306,040	$ 34	$ 500,478	$ (359,449)	$ 141,063

The changes in shareholders' equity for three months ended March 31, 2019 were as follows:

	Common Stock		Additional Paid- In Capital	Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Shares	Amount			
Balance, December 31, 2018	33,265,629	$ 33	$ 428,729	$ (337,177)	$ 91,585
Exercise of common stock options	18,693	—	246	—	246
Issuance for employee stock purchase plan	32,826	—	444	—	444
Vesting of RSUs	101,483	—	—	—	—
Shares withheld for employee taxes upon vesting of RSUs	(33,503)	—	(488)	—	(488)
Stock-based compensation	—	—	4,263	—	4,263
Net loss	—	—	—	(9,700)	(9,700)
Balance, March 31, 2019	33,385,128	$ 33	$ 433,194	$ (346,877)	$ 86,350

Warrants

As of March 31, 2020, the warrant issued to Assertio in November 2018 was the Company's only outstanding warrant. In connection with the Third Amendment to the Nucynta Commercialization Agreement, the Company issued a warrant to Assertio to purchase 1,041,667 shares of common stock of the Company at an exercise price of $19.20 per share. The terms of the warrant are fixed, with the exception of customary adjustments for changes in the Company's capitalization. The warrant may only be settled with the issuance of shares of common stock upon exercise and will expire in November 2022. The Company has recorded the relative fair value of the warrant as a component of equity interest issued by the Company as consideration transferred in the cost accumulation model for the asset acquisition. The Company estimated the fair value of the warrant on the date of issuance to be approximately $8,043 using the Black-Scholes option-pricing model. The Company concluded that the warrant met the definition of an equity instrument and was recorded as a component of additional paid-in capital in the Company's Condensed Consolidated Balance Sheet as of the issuance date.

13. Stock-based Compensation

A summary of the Company's stock-based compensation expense included in the Condensed Consolidated Statements of Operations are as follows:

	Three months ended March 31,	
	2020	**2019**
Research and development expenses	$ 770	$ 567
Selling, general and administrative expenses	4,181	3,696
Total stock-based compensation expense	$ 4,951	$ 4,263

At March 31, 2020, there was approximately $48,713 of unrecognized compensation expense related to unvested options, restricted stock units and performance stock units, which is expected to be recognized as expense over a weighted average period of approximately 3.0 years.

Performance Share Units, Restricted Stock Units and Stock Options

In May 2015, the Company adopted the Amended and Restated 2014 Stock Incentive Plan (the "Plan"), under which an aggregate of 2,700,000 shares of common stock were authorized for issuance to employees, officers, directors, consultants and advisors of the Company, plus an annual increase on the first day of each fiscal year until the expiration of the Plan equal to 4% of the total number of outstanding shares of common stock on December 31st of the immediately preceding calendar year (or a lower amount as otherwise determined by the Company's board of directors ("Board of Directors") prior to January 1st). As of March 31, 2020, there were 946,952 shares of common stock available for issuance pursuant to the Plan. The Plan provides for granting of both Internal Revenue Service qualified incentive stock options and non-qualified options, restricted stock awards, restricted stock units and performance stock units.

Performance Share Units

The Company periodically grants performance share units ("PSUs") to certain members of the Company's senior management team. PSUs vest subject to the satisfaction of annual and cumulative performance and/or market conditions established by the Compensation Committee.

In January 2019, the Company granted PSUs with performance conditions related to 2019, 2020, 2021 and three-year cumulative revenue goals for Xtampza ER. The PSUs will vest following a three-year performance period, subject to the satisfaction of the performance criteria and the executive's continued employment through the performance period. PSUs may vest in a range between 0% and 200%, based on the satisfaction of performance criteria, and no shares will be issued if the minimum applicable performance metric is not achieved. The Company recognizes compensation expense ratably over the required service period based on its estimate of the number of shares that will vest based upon the probability of achieving the performance metrics. If there is a change in the estimate of the number of shares that are likely to vest, the Company will cumulatively adjust compensation expense in the period that the change in estimate is made.

In February 2020, the Company additionally granted PSUs with performance criteria related to the relative ranking of the total stockholder return ("TSR") of the Company's common stock in 2020, 2021, 2022 and the cumulative three-year performance period return relative to the TSR of certain peer companies within the S&P Pharmaceutical Select Industry Index. TSR will be measured based on the 30-day average stock price on the first day of each period compared to the 30-day average stock price on the last day of each period. The 2020, 2021, and 2022 PSUs will vest annually, subject to the satisfaction of the performance criteria and the executive's continued employment through the performance period. The cumulative PSUs will vest following the three-year performance period, subject to the satisfaction of the performance criteria and the executive's continued employment through the performance period. PSUs may vest in a range between 0% and 200%, based on the satisfaction of performance, and no shares will be issued if the minimum applicable performance metric is not achieved. As these PSUs vest based on the achievement of market conditions, the grant date fair values were determined using a Monte-Carlo valuation model. The Monte-Carlo valuation model considered a variety of potential future share prices for the Company as well as its peer companies in the selected market index. The weighted-average grant date fair value of 2020 PSUs granted with market-based vesting conditions was $28.81 based on the valuation model.

A summary of the Company's PSUs activity for the three months ended March 31, 2020 and related information is as follows:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2019	99,400	$ 15.90
Granted	187,978	28.49
Vested	—	—
Forfeited	—	—
Performance adjustment	(4,155)	15.90
Outstanding at March 31, 2020	283,223	$ 24.26

The number of PSUs awarded represents the target number of shares of common stock that may be earned; however, the actual number of shares earned may vary based on the satisfaction of performance criteria. For the three months ended March 31, 2020 and 2019, the stock-based compensation expense for PSUs was $397 and $15, respectively.

Restricted Stock Units

A summary of the Company's restricted stock units activity for the three months ended March 31, 2020 and related information is as follows:

	Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2019	849,679	$ 17.10
Granted	725,422	21.34
Vested	(195,280)	17.83
Forfeited	(7,263)	17.63
Outstanding at March 31, 2020	1,372,558	$ 19.23

The Company's restricted stock units generally vest ratably over a four-year period of service.

Stock Options

A summary of the Company's stock option activity for the three months ended March 31, 2020 and related information is as follows:

	Shares	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2019	3,955,887	$ 16.00	7.5	$ 21,257
Granted	574,783	21.39		
Exercised	(455,573)	9.78		
Cancelled	(40,883)	19.36		
Outstanding at March 31, 2020	4,034,214	$ 17.44	7.8	$ 5,904
Exercisable at March 31, 2020	1,916,510	$ 16.55	6.7	$ 3,550

The Company's stock options generally vest ratably over a four-year period of service and have a ten-year contractual life. Upon termination, vested stock options are generally exercisable between one and three months following the termination date, while unvested options are forfeited immediately upon termination. The fair value of each stock option is estimated on the grant date using the Black-Scholes option-pricing model using the following assumptions:

	Three months ended March 31,	
	2020	2019
Risk-free interest rate	1.5 %	2.6 %
Volatility	65.5 %	63.3 %
Expected term (years)	6.1	6.1
Expected dividend yield	— %	— %

Employee Stock Purchase Plan

The Company's 2015 Employee Stock Purchase Plan allows employees to purchase shares of the Company's common stock. The purchase price is equal to 85% of the lower of the closing price of the Company's common stock on (1) the first day of the purchase period or (2) the last day of the purchase period. During the three months ended March 31, 2020, 39,411 shares of common stock were purchased for total proceeds of $357. During the three months ended March 31, 2019, 32,826 shares of common stock were purchased for total proceeds of $444. The expense for the three months ended March 31, 2020 and 2019 was $79 and $100, respectively.

14. Commitments and Contingencies

Legal Proceedings

From time to time, the Company may face legal claims or actions in the normal course of business. Except as disclosed below, the Company is not currently a party to any litigation and, accordingly, does not have any amounts recorded for any litigation related matters.

Xtampza ER Litigation

The Company filed the NDA for Xtampza ER as a 505(b)(2) application, which allows the Company to reference data from an approved drug listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book), in this case Oxycontin. The 505(b)(2) process requires that the Company certifies to the FDA and notify Purdue Pharma, L.P ("Purdue"), as the holder of the NDA and any other Orange Book-listed patent owners, that the Company does not infringe any of the patents listed for Oxycontin in the Orange Book, or that the patents are invalid. The Company made such certification and provided such notice on February 11, 2015 and such certification documented why Xtampza ER does not infringe any of the 11 Orange Book listed patents for Oxycontin, five of which have been invalidated in court proceedings. Under the Hatch-Waxman Act of 1984, Purdue had

the option to sue the Company for infringement and receive a stay of up to 30 months before the FDA could issue a final approval for Xtampza ER, unless the stay was earlier terminated.

Purdue exercised its option and elected to sue the Company for infringement in the District of Delaware on March 24, 2015 asserting infringement of three of Purdue's Orange Book-listed patents (Patent Nos. 7,674,799, 7,674,800, and 7,683,072) and a non-Orange Book-listed patent (Patent No. 8,652,497), and accordingly, received a 30-month stay of FDA approval.

The Delaware court transferred the case to the District of Massachusetts. After the Company filed a partial motion for judgment on the pleadings relating to the Orange Book-listed patents, the District Court of Massachusetts ordered judgment in the Company's favor on those three patents, and dismissed the claims asserting infringement of those patents with prejudice. Upon dismissal of those claims, the 30-month stay of FDA approval was lifted. As a result, the Company was able to obtain final approval for Xtampza ER and launch the product commercially.

In November 2015, Purdue filed a follow-on suit asserting infringement of another patent, Patent No. 9,073,933, which was late-listed in the Orange Book and therefore could not trigger any stay of FDA approval. In June 2016, Purdue filed another follow-on suit asserting infringement of another non-Orange Book listed patent, Patent No. 9,155,717. In April 2017, Purdue filed another follow-on suit asserting infringement of another patent, Patent No. 9,522,919, which was late-listed in the Orange Book and therefore could not trigger any stay of FDA approval. Then, in September 2017, Purdue filed another follow-on suit asserting infringement of another non-Orange Book listed patent, Patent No. 9,693,961.

On March 13, 2018, the Company filed a Petition for Post-Grant Review ("PGR") of the ′961 patent with the Patent Trial and Appeal Board ("PTAB"). The PGR argues that the ′961 patent is invalid for lack of a written description, for lack of enablement, for indefiniteness, and as being anticipated by prior art. Purdue filed its Patent Owner Preliminary Response on July 10, 2018. The PTAB entered an order to institute post-grant review of all claims of the ′961 patent on October 4, 2018, upon a finding that it is more likely than not that the claims of the ′961 patent are unpatentable. Purdue filed its Patent Owner Response on January 30, 2019. The Company filed its reply on April 12, 2019, and Purdue filed a sur-reply on May 10, 2019. The PTAB held oral argument on the proceedings on July 10, 2019 and was scheduled to issue a decision on the patentability of the ′961 patent by no later than October 4, 2019. On September 15, 2019, Purdue commenced a voluntary case under chapter 11 of title 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the Southern District of New York. On September 24, 2019, Purdue gave the PTAB notice of its bankruptcy filing and sought the imposition of an automatic stay of the PGR proceedings. On October 2, 2019, the PTAB extended the one-year period for issuing its decision by up to six months.

In October 2017, and in response to the filing of the Company's Supplemental NDA ("sNDA") seeking to update the drug abuse and dependence section of the Xtampza ER label, Purdue filed another suit asserting infringement of the ′933 and ′919 patents. The Company filed a motion to dismiss that action, and the Court granted its motion on January 16, 2018.

The current suits have been consolidated by the District of Massachusetts, where Purdue asserted infringement of five patents: the ′497 patent, the ′933 patent, the ′717 patent, the ′919 patent, and the ′961 patent. The Court issued an order on September 28, 2018 in which it granted in part a motion for summary judgment filed by the Company, and in which the Court ruled that the ′497 and ′717 patents are not infringed by the Company. As a result, only the ′933, the ′919, and the ′961 patents remain in dispute. On October 16, 2018, the Company filed a motion to stay proceedings in the district court on the '961 patent pending the PGR. None of these suits are associated with any stay of FDA approval for Xtampza ER. Purdue has made a demand for monetary relief but has not quantified its alleged damages. Purdue has also requested a judgment of infringement, an adjustment of the effective date of FDA approval, and an injunction on the sale of the Company's products accused of infringement. The Company has denied all claims and seeks a judgment that the patents are invalid and/or not infringed by the Company; the Company is also seeking a judgment that the case is exceptional, with an award to the Company of its attorneys' fees for defending the case.

A claim construction hearing was held on June 1, 2017. On November 21, 2017, the Court issued its claim construction ruling, construing certain claims of the ′933, ′497, and ′717 patents. No trial date has been scheduled. On September 18, 2019, Purdue gave the Court notice of its bankruptcy filing and sought the imposition of an automatic stay of the proceedings. On September 20, 2019, the matter was stayed pending further order of the Court.

Once the stay is lifted, the Company plans to defend this case vigorously. At this stage, the Company is unable to evaluate the likelihood of an unfavorable outcome or estimate the amount or range of potential loss, if any.

Nucynta Litigation

On February 7, 2018, Purdue filed a patent infringement suit against the Company in the District of Delaware. Specifically, Purdue argues that the Company's sale of immediate-release and extended-release Nucynta infringes U.S. Patent Nos. 9,861,583, 9,867,784, and 9,872,836. Purdue has made a demand for monetary relief in its complaint but has not quantified its alleged damages.

On December 6, 2018, the Company filed an Amended Answer asserting an affirmative defense for patent exhaustion. On December 10, 2018, the Court granted the parties' stipulation for resolution of the Company's affirmative defense of patent exhaustion and stayed the action, with the exception of briefing on and resolution of the Company's Motion for Judgment on the Pleadings related to patent exhaustion and any discovery related to that Motion. Also, on December 10, 2018, the Company filed a Rule 12(c) Motion for Judgment on the Pleadings, arguing that the Purdue's claims were barred by the doctrine of patent exhaustion. Purdue filed its response on January 11, 2019 and the Company filed a reply on January 25, 2019. On June 18, 2019, the court heard oral argument on the Company's Rule 12(c) Motion for Judgment on the Pleadings. On June 19, 2019, the court issued an order stating that "judgment in Collegium's favor is warranted under the doctrine of patent exhaustion to the extent Collegium's alleged infringing activities resulted from sales that fall within the scope of that covenant." The court explained, however, that based on the current record, it was not possible "to determine whether title of the Nucynta Products was transferred to Collegium" from sales authorized by Purdue's covenant not to sue. The court ordered discovery on this issue and the case remained "stayed with the exception of discovery and briefing on and resolution of the Company's anticipated motion for summary judgment based on patent exhaustion."

On September 19, 2019, Purdue gave the court notice of its bankruptcy filing and sought the imposition of an automatic stay of the proceedings. The Nucynta litigation is subject to the automatic bankruptcy stay.

Pending resolution of the bankruptcy action, the Company plans to defend this case vigorously. At this stage, the Company is unable to evaluate the likelihood of an unfavorable outcome or estimate the amount or range of potential loss, if any.

Teva Litigation

The Company has fifteen patents listed in the FDA Orange Book as covering the Company's abuse-deterrent product and methods of using it to treat patients: Patents Nos. 7,399,488; 7,771,707; 8,449,909; 8,557,291; 8,758,813; 8,840,928; 9,044,398; 9,248,195; 9,592,200; 9,682,075; 9,737,530, 9,763,883; 9,968,598; 10,004,729; and 10,188,644 (the "Orange Book Patents").

Teva Pharmaceuticals USA, Inc. ("Teva") filed Notice Letters of Patent Certification against all of the fifteen listed Orange Book Patents alleging that they were invalid and/or not infringed by the proposed oxycodone products that are the subject of Teva's Abbreviated New Drug Application ("ANDA"). On February 22, 2018—within the 45-day period that gives the Company a 30-month stay of FDA approval of Teva's ANDA while the parties have an opportunity to litigate—the Company sued Teva in the District of Delaware on eleven of the Orange Book Patents. Teva responded to the Company's complaint on May 14, 2018, alleging that the Orange Book Patents are invalid and are not infringed by Teva's proposed ANDA products and asserting counterclaims of non-infringement and invalidity of the Orange Book Patents. The Company answered Teva's counterclaims on June 4, 2018. The parties briefed claim construction and the court heard argument on April 12, 2019. On September 11, 2019, the Court issued a Report and Recommendation construing two of the six terms or sets of terms that are in dispute. The remaining terms will be addressed in one or more forthcoming Report and Recommendations. Fact discovery was scheduled to close on September 20, 2019 and expert discovery was scheduled to close on January 24, 2020.

The Company filed a second lawsuit in the District of Delaware, asserting two additional Orange Book Patents, on November 30, 2018. Teva responded to the Company's complaint on January 11, 2019, alleging that the asserted patents are invalid and are not infringed by Teva's proposed ANDA products, and asserting counterclaims of non-infringement and invalidity of the asserted patents. The Company answered Teva's counterclaims on February 1, 2019. The court consolidated the second suit with the first suit, and thus both suits are proceeding on the same schedule.

The Company filed a third lawsuit in the District of Delaware, asserting one additional Orange Book Patent, on May 9, 2019. Teva responded to the Company's complaint on June 6, 2019, alleging that the asserted patent is invalid and is not infringed by Teva's proposed ANDA products, and asserting counterclaims of non-infringement and invalidity of the asserted patent. The Company answered Teva's counterclaims on June 27, 2019. The parties filed a proposed Scheduling Order, which the Court entered on September 4, 2019. The parties have exchanged initial disclosures pursuant to that Order.

On September 20, 2019, the parties jointly agreed to stay both litigations, which the Court so ordered. Once the stay is lifted, the Company plans to continue defending this case vigorously.

Opioid Litigation

On March 19, 2018, a lawsuit was filed by multiple local governments in the Circuit Court of Crittenden County, Arkansas, against the Company and other pharmaceutical manufacturers and distributors alleging a variety of claims related to opioid marketing and distribution practices. On January 29, 2019, the Company was dismissed from this litigation without prejudice.

On March 21, 2018, the Company, along with other pharmaceutical manufacturers and distributors, was named in a class-action lawsuit filed in the Eastern District of Kentucky by a family practice clinic, on behalf of other similarly-situated healthcare providers. The action alleges violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO") relating to opioid marketing and distribution practices. On April 14, 2018, the lawsuit was conditionally transferred by the Judicial Panel on Multi-District Litigation to the federal Prescription Opiate Multi District Litigation (the "MDL") in the Southern District of Ohio. On April 10, 2018, the conditional transfer was finalized and the lawsuit was docketed in the MDL on April 11, 2018. On May 4, 2018, the Company, along with other pharmaceutical manufacturers and distributors, were named in two lawsuits filed in the MDL by the Fiscal Court of Bourbon County, Kentucky and the Fiscal Court of Owen County, Kentucky, relating to opioid marketing and distribution practices. On July 11 and 12, 2018, the Company was named in four lawsuits filed in the MDL by a health system and various member hospitals. On September 26, 2018, the Company was named in two lawsuits filed in the MDL by the Fiscal Court of Lee County, Kentucky and the Fiscal Court of Wolfe County, Kentucky. On March 15, 2019, the plaintiffs in these MDL cases filed amended complaints which no longer name the Company as a defendant, effectively terminating these lawsuits as to the Company.

On September 6, 2019, Triad Health Systems filed a class action lawsuit in the MDL on behalf of itself and similarly situated health care systems, generally alleging negligence, fraud, and violations of the RICO Act relating to opioid marketing and distribution practices, naming the Company and other pharmaceutical distributors and manufacturers. On October 18, 2019, three counties in Kentucky filed lawsuits in the MDL, naming the Company: the Fiscal Court of Casey County Kentucky; the Fiscal Court of Gallatin County Kentucky; and the Fiscal Court of Lewis County Kentucky. These three lawsuits generally allege negligence, fraud, and violations of the RICO Act relating to opioid marketing and distribution practices. The Company was dismissed from these four lawsuits on November 6, 2019.

On January 11, 2019, the City of Portsmouth filed a lawsuit in Virginia Circuit Court against the Company and other pharmaceutical manufacturers and distributors. The lawsuit alleges a variety of claims related to opioid marketing and distribution practices including public nuisance, common law fraud, negligent misrepresentation, negligence, and violations of state consumer protection laws. On October 3, 2019, the City of Portsmouth case was transferred to the MDL.

On March 15, 2019, the Company was named in a lawsuit in the MDL by the City of Paterson, New Jersey. The lawsuit alleges violations of fraud, public nuisance, negligent misrepresentation, and violations of state consumer protection laws, and seeks, generally, penalties and/or injunctive relief. In April 2019, the City of Norwich, Connecticut and the Town of Enfield, Connecticut filed lawsuits in Connecticut Superior Court. The lawsuits allege violations of fraud, public nuisance, negligent misrepresentation, and violations of state consumer protection laws. On June 28, 2019, both cases were transferred to the MDL. In October 2019, the Company was named in two additional Connecticut lawsuits: the City of Middletown and the Town of Wethersfield. These cases were both also transferred to the MDL in July 2019. On January 15, 2020, the Company was named in a new lawsuit in Connecticut Superior Court, filed by the Town of Windham. This case was removed and transferred to the MDL in March 2020.

On June 14, 2019, the City of Trenton filed a lawsuit in New Jersey Superior Court against the Company and other pharmaceutical manufacturers and distributors. The lawsuit alleges a variety of claims related to opioid marketing and distribution practices including public nuisance, common law fraud, negligent misrepresentation, negligence, and violations of state consumer protection laws and the New Jersey Drug Dealer Liability Act. On August 23, 2019, the case was removed to the District Court of New Jersey. The plaintiff filed an opposition to coordination and requested remand, but on December 18, 2019, the case was transferred to the MDL. Each of the lawsuits in the MDL naming the Company seeks, generally, penalties and injunctive relief. None of the lawsuits naming the Company are designated as representative cases in the MDL, and therefore, are effectively currently stayed.

On May 29, 2018, a lawsuit was filed by Bucks County, Pennsylvania against the Company and other pharmaceutical manufacturers and on June 12, 2018, a lawsuit was filed by Clinton County, Pennsylvania, against the Company and other pharmaceutical manufacturers and distributors. On June 6, 2018, a lawsuit was filed by Mercer County, Pennsylvania, against the Company and other pharmaceutical manufacturers and distributors. These lawsuits allege claims related to opioid marketing and distribution, including negligence, fraud, unjust enrichment, public nuisance, and violations of state consumer protections laws. These cases have been consolidated for discovery purposes in the Delaware County Court of Common Pleas as part of a consolidated proceeding of similar lawsuits brought by numerous Pennsylvania counties against other pharmaceutical manufacturers and distributors. In March 2019, three additional cases were filed in Pennsylvania by two payor groups and Warminster Township. The Company has been dismissed from both of the payor group cases. In July 2019, the Company learned of additional lawsuits alleging similar claims which were filed by Warrington Township in the Bucks County Court of Common Pleas, and filed by the City of Lock Haven in the Clinton County Court of Common Pleas. The City of Lock Haven and the Warrington Township cases have been coordinated into the consolidated proceeding before the Delaware County Court of Common Pleas. None of these cases have been designated a Track One case in which discovery would commence, and therefore are effectively stayed at present.

On July 30, 2018, a lawsuit was filed by the City of Worcester, Massachusetts against the Company and other pharmaceutical manufacturers and distributors. The action alleges a variety of claims related to opioid marketing and distribution practices including public nuisance, common law fraud, negligent misrepresentation, negligence, violations of Mass Gen. Laws ch. 93A, Section 11, unjust enrichment and civil conspiracy. In February 2019, the City of Worcester case was transferred to the Business Litigation Session of the Superior Court. Additional lawsuits brought by the following cities and counties Massachusetts were filed between October 2018 and April 2019: City of Salem, City of Framingham, Town of Lynnfield, City of Springfield, City of Haverhill, City of Gloucester, Town of Canton, Town of Wakefield, City of Chicopee; Town of Natick; City of Cambridge, and Town of Randolph. Each of these additional lawsuits has been coordinated before the Business Litigation Session. The case brought by the City of Springfield was selected to advance for the purpose of motion practice, and defendants' motions to dismiss were denied on January 3, 2020. The Company has answered the City of Cambridge complaint, and discovery in these coordinated cases is stayed, pending a May 28, 2020 case management conference where further scheduling and discovery will be addressed.

The Company disputes the allegations in these lawsuits and intends to vigorously defend these actions. At this stage, the Company is unable to evaluate the likelihood of an unfavorable outcome or estimate the amount or range of potential loss, if any.

Opioid-Related Request and Subpoenas

The Company, like a number of other pharmaceutical companies, has received subpoenas or civil investigative demands related to opioid sales and marketing. The Company has received such subpoenas or civil investigative demands from the Offices of the Attorney General of each of Washington, New Hampshire, Massachusetts, and Maryland. The Company is currently cooperating with each of the foregoing states in their respective investigations.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q. The following discussion contains forward-looking statements that involve risks uncertainties and assumptions. Our actual results and the timing of certain events could differ materially from those anticipated in these forward-looking statements as a result of many factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this Quarterly Report on Form 10-Q, including those set forth under "Forward-looking Statements" and "Risk Factors", as revised and supplemented by those risks described from time to time in other reports which we file with the SEC.

OVERVIEW

We are a specialty pharmaceutical company committed to being the leader in responsible pain management. Our first product, Xtampza ER, is an abuse-deterrent, extended-release, oral formulation of oxycodone. In April 2016, the FDA approved our NDA for Xtampza ER for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. In June 2016, we announced the commercial launch of Xtampza ER.

Our product portfolio also includes Nucynta IR and Nucynta ER (collectively, the "Nucynta Products"). In December 2017, we entered into a Commercialization Agreement (the "Nucynta Commercialization Agreement") with Assertio Therapeutics, Inc. ("Assertio"), pursuant to which we licensed the right to commercialize the Nucynta Products in the United States. Nucynta ER is an extended-release formulation of tapentadol that is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment, including neuropathic pain associated with diabetic peripheral neuropathy in adults, and for which alternate treatment options are inadequate. Nucynta IR is an immediate-release formulation of tapentadol that is indicated for the management of acute adult pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

We began shipping and recognizing product sales on the Nucynta Products on January 9, 2018 and began marketing the Nucynta Products in February 2018. On February 6, 2020, we entered into an Asset Purchase Agreement with Assertio (the "Nucynta Purchase Agreement"), pursuant to which the Company agreed to acquire from Assertio certain assets related to the Nucynta Products (the "Nucynta Acquisition"), including the rights to the license from Grünenthal GmbH ("Grünenthal"), for an aggregate purchase price of $375.0 million. On February 13, 2020, we closed the Nucynta Acquisition in accordance with the Nucynta Purchase Agreement. Upon closing, the Nucynta Commercialization Agreement was terminated, with the exception of certain provisions thereof which survived pursuant to the terms of the Nucynta Purchase Agreement, and our royalty payment obligations to Assertio thereunder ceased. Following the closing, the Company will pay royalties directly to Grünenthal at a rate of 14% of net sales of the Nucynta Products.

Outlook

We expect to continue to incur significant commercialization expenses related to marketing, manufacturing, distribution, selling and reimbursement activities. We are promoting Xtampza ER to approximately 11,000 health care professionals who write approximately 65% of the branded extended-release oral opioid prescriptions in the United States with a sales team of approximately 150 sales representatives and managers. We are promoting the Nucynta Products to the same health care professionals to whom we promote Xtampza ER, leveraging our existing sales organization.

Net income for the three months ended March 31, 2020 was $450,000. In every annual reporting period since inception, we have incurred net losses. As of March 31, 2020, we had an accumulated deficit of $359.4 million. Substantially all of our prior net losses resulted from costs incurred in connection with selling, general and administrative costs associated with our operations and research and development programs. We have historically paid royalties to Assertio on all revenues from the sale of Nucynta Products based on certain net sales thresholds, which ceased upon closing of the Nucynta Acquisition. Our net income (loss) may fluctuate significantly from quarter to quarter and year to year.

We believe that our cash and cash equivalents at March 31, 2020, together with expected cash inflows from the commercialization of our products, will enable us to fund our operating expenses, debt service and capital expenditure requirements under our current business plan for the foreseeable future.

In December 2019, a novel strain of coronavirus began infecting people in China; since then, the disease caused by that virus, COVID-19, has sickened millions of people across the world and in March 2020, the World Health organization declared COVID-19 a pandemic. The pandemic has severely impacted global economic activity, and many countries and many states in the United States have reacted to the outbreak by instituting quarantines, mandating business and school closures and restricting travel. As of the date of the filing of this Quarterly Report on Form 10-Q, we expect the COVID-19 pandemic and actions taken to contain it to impact our revenue (due to fewer new patients beginning therapy with our products) and decrease certain operating expenses, including travel and regulatory expenses associated with post-marketing trials that are delayed for 2020. We believe that the disruptions caused by COVID-19 will be temporary, but there remains substantial uncertainty as to when such disruptions will cease (or ease).

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as “critical” because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates—which also would have been reasonable—could have been used, which would have resulted in different financial results.

The critical accounting policies we identified in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019 (“Annual Report”), relate to revenue recognition and impairment of intangible assets. Estimates include revenue recognition, including the estimates of product returns, units prescribed, discounts and allowances related to commercial sales of our products, estimates utilized in the valuation of inventory, estimates of useful lives with respect to intangible assets, accounting for stock-based compensation, contingencies, intangible assets, and tax valuation reserves. We base our estimates and assumptions on historical experience when available and on various factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Actual results may differ from these estimates under different assumptions or conditions. It is important that the discussion of our operating results that follows be read in conjunction with the critical accounting policies disclosed in our Annual Report.

RESULTS OF OPERATIONS
(in thousands)

	Three months ended March 31,	
	2020	2019
	(in thousands)	
Product revenues, net	$ 76,511	$ 74,516
Cost of product revenues		
Cost of product revenues (excluding intangible asset amortization)	27,229	45,476
Intangible asset amortization	10,295	3,688
Total cost of products revenues	37,524	49,164
Gross profit	38,987	25,352
Operating expenses		
Research and development	2,666	2,992
Selling, general and administrative	31,260	32,352
Total operating expenses	33,926	35,344
Income (loss) from operations	5,061	(9,992)
Interest expense	(4,823)	(234)
Interest income	212	526
Net income (loss)	$ 450	$ (9,700)

Comparison of the three months ended March 31, 2020 and March 31, 2019

Product revenues, net were $76.5 million for the three months ended March 31, 2020 (the "2020 Quarter"), compared to $74.5 million for the three months ended March 31, 2019 (the "2019 Quarter"). The $2.0 million increase was related to an increase in revenue for Xtampza ER of $6.4 million, offset by a decrease in revenue for the Nucynta Products of $4.4 million. For the 2020 Quarter, Xtampza ER product revenues, net were $31.5 million, compared to $25.1 million for the 2019 Quarter. The increase in revenue for Xtampza ER was primarily related to an increase in sales volume due to increased demand and an increase in price. For the 2020 Quarter, Nucynta IR and ER product revenues, net were $28.0 million and $17.0 million, respectively, compared to $29.9 million and $19.5 million, respectively, for the 2019 Quarter. The decrease in revenue for the Nucynta Products was primarily related to lower sales volume, partially offset by an increase in price.

Cost of product revenues was $27.2 million for the 2020 Quarter, compared to $45.5 million for the 2019 Quarter. The $18.3 million decrease was primarily related to a decrease in royalty expense for the Nucynta Products. In the 2019 Quarter, we recognized $32.1 million in sales-based royalty expense due to Assertio under the terms of the Nucynta Commercialization Agreement. Our sales-based royalty obligations to Assertio ceased upon closing of the Nucynta Acquisition on February 13, 2020. Prior to the closing, the Company recognized $14.2 million of non-cash royalty expense in the 2020 Quarter.

Intangible asset amortization was $10.3 million for the 2020 Quarter, compared to $3.7 million for the 2019 Quarter. The $6.6 million increase was primarily related to the Nucynta Acquisition, in which $367.1 million of consideration was allocated to the existing intangible asset as incremental cost. The intangible asset is being amortized on a straight-line basis over its estimated useful life of approximately six years.

Research and development expenses were $2.7 million for the 2020 Quarter, compared to $3.0 million for the 2019 Quarter. The $326,000 decrease was primarily related to a decrease in trials costs and supplies offset by an increase in salaries, wages and benefits, including stock-based compensation expense.

Selling, general and administrative expenses were $31.3 million for the 2020 Quarter, compared to $32.4 million for the 2019 Quarter. The $1.1 million decrease was primarily related to:

- a decrease in audit, legal, and other professional fees of $2.3 million;
- a decrease in sales, marketing and consulting costs of $941,000, primarily due to higher costs incurred in the 2019 Quarter to commercialize the Nucynta Products;
- a decrease in trainings, conferences and meetings of $898,000, primarily due to timing of events; offset by

- an increase in product taxes and fees of $1.6 million, primarily due to certain states recently enacting excise taxes on the sale of opioids; and
- an increase in salaries, wages and benefits of $1.1 million, primarily due to stock-based compensation expense, wage increases and incentive compensation expense.

Interest expense was $4.8 million for the 2020 Quarter, compared to $234,000 in the 2019 Quarter. The increase was primarily due to $4.4 million of interest expense recognized in the 2020 Quarter associated with the term notes and convertible notes issues in connection with the Nucynta Acquisition.

Interest income was $212,000 for the 2020 Quarter, compared to $526,000 in the 2019 Quarter. The $314,000 decrease was primarily due to a lower balance invested in money market funds in the 2020 Quarter.

LIQUIDITY AND CAPITAL RESOURCES

Sources of Liquidity

Since inception, we have funded our operations primarily through the private placements of our preferred stock and convertible notes, public offerings of common stock, and commercial bank debt. As of March 31, 2020, we had $116.2 million in cash and cash equivalents.

Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents at March 31, 2020, together with expected cash inflows from the commercialization of our products, will enable us to fund our operating expenses, debt service and capital expenditure requirements under our current business plan for the foreseeable future.

Borrowing Arrangements and Equity Offerings

The following transactions represent the material changes in borrowing arrangements and equity offerings that were previously disclosed in our most recent Annual Report.

Pharmakon Term Notes

On February 6, 2020, in connection with the execution of the Nucynta Purchase Agreement, we, together with our subsidiary, Collegium Securities Corporation, entered into the Loan Agreement with BioPharma Credit PLC, as collateral agent and lender; and BioPharma Credit Investments V (Master) LP, as lender. The Loan Agreement provides for a $200.0 million secured term loan (the “term notes”), the proceeds of which were used to finance a portion of the purchase price paid pursuant to the Nucynta Purchase Agreement.

The term notes will mature on the calendar quarter end immediately following the 48-month anniversary of the closing of the Nucynta Acquisition, and is guaranteed by our material domestic subsidiaries and is also secured by substantially all of our material domestic assets. The term notes will bear interest at a rate based upon LIBOR (subject to a LIBOR floor of 2.0%), plus a margin of 7.5% per annum. We are required to repay the term notes by making equal quarterly payments.

The Loan Agreement contains certain covenants and obligations of the parties, including, without limitation, covenants that require us to maintain $200.0 million in annual net sales and covenants that limit our ability to incur additional indebtedness or liens, make acquisitions or other investments or dispose of assets outside the ordinary course of business. Failure to comply with these covenants would constitute an event of default under the Loan Agreement, notwithstanding our ability to meet its debt service obligations. The Loan Agreement also includes various customary remedies for the lenders following an event of default, including the acceleration of repayment of outstanding amounts under the Loan Agreement and execution upon the collateral securing obligations under the Loan Agreement.

2026 Convertible Notes

On February 13, 2020, in connection with the execution of the Nucynta Purchase Agreement, we issued 2.625% convertible senior notes due 2026 (the "convertible notes"), in the aggregate principal amount of $143.8 million, in a public offering registered under the Securities Act of 1933, as amended. The proceeds were used to finance a portion of the purchase price paid pursuant to the Nucynta Purchase Agreement.

The convertible notes are senior, unsecured obligations and will accrue interest at a rate of 2.625% per annum, payable semi-annually in arrears on February 15 and August 15 of each year, beginning on August 15, 2020. The notes will mature on February 15, 2026, unless earlier repurchased, redeemed or converted. Before August 15, 2025, noteholders will have the right to convert their notes only upon the occurrence of certain events. From and after August 15, 2025, noteholders may convert their notes at any time at their election until the close of business on the scheduled trading day immediately before the maturity date. We will settle conversions by paying or delivering, as applicable, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election. The initial conversion rate is 34.2618 shares of common stock per $1,000 principal amount of notes, which represents an initial conversion price of approximately $29.19 per share of common stock. The conversion rate and conversion price will be subject to adjustment upon the occurrence of certain events.

Silicon Valley Bank Term Loan Facility

From August 2012 until January 2020, we maintained a term loan facility with Silicon Valley Bank, which was amended in connection with, and as a condition to, consummation of the transactions contemplated by the Nucynta Commercialization Agreement. Under the amended term loan, we had a term loan facility in an amount of $11.5 million, which replaced our previously existing term loan facility. The proceeds were used to finance certain payment obligations under the Nucynta Commercialization Agreement and to repay the balance of the previously existing term loan. In January 2020, in anticipation of consummation of the Nucynta Acquisition and related financing activities, we repaid all of our outstanding indebtedness under the amended term loan.

Cash Flows

	Three months ended March 31,	
	2020	2019
Net cash used in operating activities	$ (6,669)	$ (8,569)
Net cash used in investing activities	(367,647)	(3,323)
Net cash provided by financing activities	323,120	169
Net decrease in cash, cash equivalents and restricted cash	$ (51,196)	$ (11,723)

Operating activities. Cash used in operating activities was $6.7 million in the three months ended March 31, 2020 (the "2020 Quarter"), compared to cash used in operating activities of $8.6 million in the three months ended March 31, 2019 (the "2019 Quarter"). The $1.9 million decrease in cash used in operating activities was primarily due to higher net income and non-cash adjustments related to the Nucynta Acquisition, which resulted in higher intangible asset amortization and higher non-cash interest expense from the term notes and convertible notes. These increases were partially offset by decreases in the working capital accounts.

Investing activities. Cash used in investing activities was $367.6 million in the 2020 Quarter, compared to cash used in investing activities of $3.3 million in the 2019 Quarter. The $364.3 million increase in cash used in investing activities was primarily related to the Nucynta Acquisition. The remaining change is primarily related to purchases of property, plant, and equipment primarily for the dedicated production suite at our contract manufacturing organization.

Financing activities. Cash provided by financing activities was $323.1 million for the 2020 Quarter, compared to cash provided by financing activities of $169,000 in the 2019 Quarter. The $322.9 million increase in cash provided by financing activities was primarily related to net proceeds from the term notes of $192.4 million and issuance the convertible notes of $138.8 million issued in the 2020 Quarter. This increase was partially offset by the term loan repayment of $11.5 million. The remaining change is primarily related to changes in proceeds from the issuance of shares under our employee stock purchase plan and proceeds from exercises of stock options, offset by payments made for employee restricted stock tax withholdings.

Funding Requirements

We believe that our cash and cash equivalents at March 31, 2020 together with expected cash inflows from the commercialization of our products, will enable us to fund our operating expenses, debt service and capital expenditure requirements under our current business plan for the foreseeable future. However, we are subject to all the risks common to the commercialization and development of new pharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

Certain economic or strategic considerations may cause us to seek additional cash through private or public debt or equity offerings. Such funds may not be available when needed, or, we may not be able to obtain funding on favorable terms, or at all. The continued spread of COVID-19 has led to severe disruption and volatility in the global capital markets, which could increase our cost of capital and adversely affect our ability to access the capital markets. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing shareholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Our forecast that our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. The amount and timing of future funding requirements, both near- and long-term, will depend on many factors, including:

- the generation of reasonable levels of revenue from products sales and the impact of the COVID-19 pandemic on our business and results of operations;
- the cost of growing and maintaining sales, marketing and distribution capabilities for our products;
- the cost of patent infringement litigation, including our litigation with each of Purdue and Teva, relating to Xtampza ER and the Nucynta Products, which may be expensive to defend;
- the cost of litigation related to opioid marketing and distribution practices;
- the timing and costs associated with manufacturing our products, for commercial sale and clinical trials; and
- the effect of competing technological and market developments

If we cannot capitalize on our business opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected.

ADDITIONAL INFORMATION

To supplement our financial results presented on a GAAP basis, we have included information about non-GAAP adjusted income (loss). We use this non-GAAP financial measure to understand, manage and evaluate the Company as we believe it represents the performance of our core business. Because this non-GAAP financial measure is an important internal measure for the Company, we believe that the presentation of the non-GAAP financial measure provides analysts, investors and lenders insight into management's view and assessment of the Company's ongoing operating performance. In addition, we believe that the presentation of this non-GAAP financial measure, when viewed with our results under GAAP and the accompanying reconciliation, provides supplementary information that may be useful to analysts, investors, lenders, and other third parties in assessing the Company's performance and results from period to period. We report this non-GAAP financial measure in order to portray the results of our major operations prior to considering certain income statement elements. This non-GAAP financial measure should be considered in addition to, and not a substitute for, or superior to, net income or other financial measures calculated in accordance with GAAP.

Non-GAAP adjusted income (loss) is not based on any standardized methodology prescribed by GAAP and represents GAAP net income (loss) adjusted to exclude stock-based compensation expense, amortization expense, non-cash interest expense, and certain royalty costs recognized in connection with the Nucynta Commercialization Agreement. Any non-GAAP financial measures used by us may be calculated differently from, and therefore may not be comparable to, a non-GAAP measure used by other companies.

	Three months ended March 31,	
	2020	**2019**
GAAP net income (loss)	$ 450	$ (9,700)
Non-GAAP adjustments:		
Stock-based compensation expense(1)	4,951	4,263
Intangible asset amortization(2)	10,295	3,688
Non-cash interest expense(3)	1,336	—
Nucynta royalty adjustment (4)	14,216	—
Total non-GAAP adjustments	$ 30,798	$ 7,951
Non-GAAP adjusted income (loss)	$ 31,248	$ (1,749)

(1) Represents stock-based compensation expense associated with our stock option, restricted stock unit and performance stock unit grants and our employee share purchase plan.
(2) Represents amortization expense from the Nucynta Intangible Asset.
(3) Represents non-cash interest expense recognized related to the accretion of debt discount and amortization of debt issuance costs.
(4) Represents adjustment for royalty expense recognized in 2020 prior to the closing of the Nucynta Asset Purchase Agreement in February 2020. The royalty expense was included as a reduction to the base purchase price for the Nucynta Asset Purchase Ag

CONTRACTUAL OBLIGATIONS

With the exception of the Loan Agreement with Pharmakon and issuance of convertible notes previously discussed, there have been no material changes to the contractual obligations and commitments described under Management's Discussion and Analysis of Financial Condition and Results of Operations in our most recent Annual Report.

OFF-BALANCE SHEET ARRANGEMENTS

We did not have during the periods presented any off-balance sheet arrangements, as defined under SEC rules.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

For information regarding our exposure to certain market risks, see Item 7A, Quantitative and Qualitative Disclosures About Market Risk, in our Annual Report. There have been no significant changes in our financial instrument portfolio or market risk exposures since our fiscal year ended December 31, 2019.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2020. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of March 31, 2020, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

During the current interim period covered by this Quarterly Report on Form 10-Q, we assumed certain material assets and liabilities in connection with the Nucynta Acquisition. In response, we added and modified certain processes that are part of our internal control over financial reporting to monitor the resulting intangible asset, term notes and convertible senior notes. Other than the aforementioned changes, there has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. As a result of the COVID-19 pandemic, in March certain employees of the Company began working remotely. As a result of these changes to the working environment the Company has not identified any material changes in the Company's internal control over financial reporting. The Company is continually monitoring and assessing the COVID-19 situation to determine any potential impacts on the design and operating effectiveness of our internal controls over financial reporting

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

Except as set forth in Note 14 to our financial statements, which is incorporated herein by reference to the extent applicable, there are no material changes from the legal proceedings previously disclosed in our Annual Report.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. Investors should carefully consider the risks described below, as well as all other information included in this Quarterly Report on Form 10-Q, including our financial statements, the notes thereto and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations." If any of the following risks actually occurs, our business, financial condition, operating results, prospects and ability to accomplish our strategic objectives could be materially harmed. As a result, the trading price of our common stock could decline and investors could lose all or part of their investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and the market price of our common stock.

Risks Related to Our Financial Position and Capital Needs

Our ability to generate sufficient revenue to become profitable is dependent upon our ability to successfully commercialize our products and any products and product candidates that we may develop or acquire in the future on a timely basis, and to address all regulatory requirements applicable to the development and commercialization of our products and any product candidates. Our failure to do so successfully could impair our growth strategy and plans and could have a material adverse effect on our business, financial position, and operating results.

We began the commercial sale of our first product, Xtampza ER, in June 2016 and assumed responsibility for the sales and marketing of the Nucynta Products in January 2018. Our ability to generate sufficient revenue to become profitable depends upon our ability to successfully commercialize our products and any other products and product candidates that we may develop, in-license or acquire in the future. Our ability to generate revenue from our current or future products depends on a number of factors, including our ability to:

- successfully commercialize our products;
- successfully satisfy FDA post-marketing requirements for our products, including studies and clinical trials that have been required for other extended-release/long acting opioid analgesics and individual studies and clinical trials of our products;
- set a commercially viable price for our products;
- manufacture commercial quantities of our products at acceptable cost levels;
- grow and sustain a commercial organization capable of sales, marketing and distribution for the products we sell;
- obtain coverage and adequate reimbursement from third parties, including government payors;
- complete and submit regulatory submissions to the FDA; and
- comply with existing and changing laws and regulations that apply to the pharmaceutical industry, including opioid manufacturers.

In addition, because of the numerous risks and uncertainties associated with product development and commercialization, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability.

If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

If we require additional capital to fund our operations and we fail to obtain necessary financing, we may be unable to complete the commercialization of our products or the development and commercialization of our future product candidates.

Our operations have consumed substantial amounts of cash. We believe that our cash and cash equivalents at December 31, 2019, together with expected cash inflows from the commercialization of our products, will enable us to fund our operating expenses, debt service and capital expenditure requirements under our current business plan for the foreseeable future. However, certain economic or strategic factors may require us to seek additional cash through private or public debt or equity offerings.

We cannot be certain that additional funding will be available on acceptable terms, or at all. As of May 7, 2020, the continued spread of a novel coronavirus ("COVID-19") has led to severe disruption and volatility in the global capital markets, which could increase our cost of capital and adversely affect our ability to access the capital markets. It is likely that the continued spread of COVID-19 could cause an economic slowdown or recession or cause other unpredictable events, each of which could adversely affect our ability to raise additional capital to fund our operations.

If we are unable to raise additional capital in sufficient amounts, when required or on acceptable terms, we also could be required to:

- significantly delay, scale back or discontinue the development and/or the commercialization of our products or our other research and development initiatives;
- seek collaborators for our products and/or one or more of our future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- relinquish or license on unfavorable terms our rights to technologies, products or future product candidates that we otherwise would seek to develop or commercialize ourselves; or
- significantly curtail operations.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the generation of sufficient levels of revenue from the sale of our products;
- the cost of growing and maintaining sales, marketing and distribution capabilities for our products and any other products we may acquire or develop;
- the outcome, timing and cost of regulatory approvals by the FDA, including the potential for the FDA to require that we perform more studies than, or evaluate clinical endpoints other than those that we currently expect;
- the timing and costs associated with manufacturing (1) our products, for commercial sale and clinical trials, and (2) our future product candidates for preclinical studies, clinical trials and, if approved, for commercial sale;
- the cost of litigation relating to our products or future product candidates, including our patent infringement litigation with each of Purdue and Teva, and ongoing litigation related to opioid marketing and distribution practices, which may be expensive to defend;

- the cost of implementing additional infrastructure and internal systems and hiring additional employees as our organization grows;
- our need to expand our regulatory and compliance functions; and
- the effect of competing technological and market developments.

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

We may seek additional capital through a combination of private and public equity offerings, debt financings, receivables or royalty financings, strategic collaborations and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing shareholders' ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of existing shareholders. Debt, receivables and royalty financings may be coupled with an equity component, such as warrants to purchase stock, which could also result in dilution of our existing shareholders' ownership. The incurrence of additional indebtedness could result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur further debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could have a material adverse effect on our ability to conduct our business and may result in additional liens being placed on our assets and intellectual property. If we were to default on any of our indebtedness, we could lose such assets and intellectual property. If we raise additional funds through strategic collaborations and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our products, technologies or revenue streams or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our commercialization or product development efforts or grant rights to develop and market our technologies that we would otherwise prefer to develop and market ourselves.

We have a limited operating history, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Our predecessor was originally incorporated in Delaware in April 2002 under the name Collegium Pharmaceuticals, Inc. and in October 2003, our predecessor changed its name to Collegium Pharmaceutical, Inc. In July 2014, we reincorporated in the Commonwealth of Virginia pursuant to a merger whereby Collegium Pharmaceutical, Inc., a Delaware corporation, merged with and into Collegium Pharmaceutical, Inc., a Virginia corporation, with the Virginia corporation surviving the merger. From 2002 until 2010, our operations focused primarily on marketing proprietary therapies to the wound care and dermatology industry through our former subsidiary, Onset Therapeutics, LLC, which was spun off and became a part of PreCision Dermatology, Inc. in 2010. Since 2010, our operations have focused primarily on developing the DETERx technology platform and identifying and developing product candidates that utilize the DETERx technology, including our first product, Xtampza ER. Although we began the commercial sale of Xtampza ER in June 2016 and acquired the right to commercialize the Nucynta Products in the United States in January 2018, we have a limited track record of successful commercialization of these products. Consequently, any predictions about our future success, performance or viability may not be as accurate as they could be if we had a longer operating history.

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

As of December 31, 2019, we had a federal net operating loss ("NOL"), carryforward of approximately $292.3 million and state NOL carryovers of approximately $222.6 million, which are available to offset future taxable income. The U.S. federal NOL carryforwards begin to expire in 2022, and the state NOL carryforwards begin to expire in 2030. We also had U.S. federal tax credits of approximately $4.0 million, and state tax credits of approximately $1.1 million. These tax attributes are generally subject to a limited carryover/carryback period and are also subject to the annual limitations that may be imposed under Section 382 of the Internal Revenue Code of 1986, as amended ("IRC 382").

The federal R&D credit generally has a twenty-year carryover term, and our state R&D credit is generally available for a fifteen-year carryover.

Under IRC 382, if a corporation undergoes an "ownership change," 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-ownership change NOLs and other pre-ownership change tax attributes (such as research and development tax credits) to offset its post-change income may be limited. We may experience ownership changes in the future as a result of shifts in our stock ownership some of which are outside our control.

During 2019, we completed a study to assess the impact of ownership changes, if any, on our ability to use our NOL and tax credit carryovers. As a result of the study, we concluded that there were ownership changes that occurred in the years 2006, 2012 and 2015 that could be subject to IRC 382 limitations. Of our total federal NOL carryovers of $292.3 million at December 31, 2019, approximately $29.0 million are estimated to expire unbenefited due to IRC 382 annual limitations, and approximately $0.1 million of state NOL carryovers are estimated to expire unbenefited due to IRC 382 limitations. In addition, of our federal R&D credit carryovers of $4.0 million at December 31, 2019, approximately $1.2 million are estimated to expire unbenefited due to IRC 382 limitations. These IRC 382 annual limitations may limit our ability to use these pre-ownership change federal and state NOL carryovers and pre-ownership change federal tax credit carryovers, which may potentially increase our future federal and state income tax liability.

As of December 31, 2019, and December 31, 2018, we have provided a full valuation allowance for deferred tax assets including NOL and tax credit carryovers.

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 and impair our ability to satisfy our obligations to our debtholders.

In February 2020, in connection with the Nucynta Acquisition, we incurred (i) $143.8 million in principal amount of indebtedness in the form of convertible notes; and (ii) $200.0 million in secured indebtedness pursuant to our
Loan Agreement with BioPharma Credit PLC, as collateral agent and lender, and BioPharma Credit Investments V (Master) LP, as lender (the "Loan Agreement"). In January 2020, we paid off the outstanding principal and accrued interest under our term loan facility with Silicon Valley Bank with cash on hand. 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 shareholders as a result of issuing shares of our common stock upon conversion of the convertible 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 our indebtedness, including the convertible notes, and our cash needs may increase in the future. In addition, our Loan Agreement contains, and 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.

We may be unable to raise the funds necessary to repurchase our convertible notes for cash following a fundamental change, or to pay any cash amounts due upon conversion, and our other indebtedness limits our ability to repurchase the notes or pay cash upon their conversion. Noteholders, subject to a limited exception described in the notes, may require us to repurchase their notes following a fundamental change at a cash repurchase price generally equal to the principal amount of the notes to be repurchased, plus accrued and unpaid interest, if any. In addition, upon conversion, we will satisfy part or all of our conversion obligation in cash unless we elect to settle conversions solely in shares of our common stock. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the notes or pay the cash amounts due upon conversion. In addition, applicable law, regulatory authorities and the agreements governing our other indebtedness may restrict our ability to repurchase the notes or pay the cash amounts due upon conversion. Our failure to repurchase notes or to pay the cash amounts due upon conversion when required will constitute a default under the indenture. A default under the indenture or the fundamental change itself could also lead to a default under agreements governing our other indebtedness, which may result in that other indebtedness becoming immediately payable in full. Concurrently with the closing of the Nucynta Acquisition, we incurred approximately $200.0 million of term notes under our Loan Agreement. Such indebtedness will amortize on a quarterly basis, and is due to fully mature in 2024. We may not have sufficient funds to satisfy all amounts due under our other indebtedness (including the Loan Agreement) and the notes.

Risks Related to our Products

If we are unable to successfully commercialize Xtampza ER or the Nucynta Products, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

To date, we have invested substantial resources in the development of Xtampza ER, which has been approved by the FDA. In February 2018, we began marketing the Nucynta Products. Our business and future success are substantially dependent on our ability to successfully and timely commercialize these products. We may never be able to successfully commercialize our products.

Our ability to successfully commercialize Xtampza ER will depend on many factors, including but not limited to:

- our ability to successfully satisfy FDA post-marketing requirements, including studies and clinical trials that have been required for other extended-release/long acting opioid analgesics and individual studies of Xtampza ER and its components;
- our ability to manufacture commercial quantities of Xtampza ER at reasonable cost and with sufficient speed to meet commercial demand;
- our ability to continue to build and retain a sales and marketing organization to market Xtampza ER;
- our success in educating physicians, patients and caregivers about the benefits, administration, use and coverage of Xtampza ER;
- the perceived availability and advantages, relative cost, relative safety and relative efficacy of other abuse-deterrent products and treatments with similar indications;
- our ability to successfully defend any challenges to our intellectual property or suits asserting patent infringement relating to Xtampza ER;
- the availability of coverage and adequate reimbursement for Xtampza ER;
- a continued acceptable safety profile of Xtampza ER; and

- our ability to comply with applicable legal and regulatory requirements, including any additional manufacturing or packaging requirements that may become applicable to certain opioid products.

Our ability to successfully commercialize the Nucynta Products will depend on many factors including, but not limited to, our ability to:

- develop and execute our sales and marketing strategies for the Nucynta Products;
- obtain and maintain adequate coverage, reimbursement and pricing from managed care, government and other third-party payers;
- maintain and manage the necessary sales, marketing, supply chain, managed markets and other capabilities and infrastructure that are required to successfully commercialize the Nucynta Products;
- successfully defend any challenges to intellectual property or suits asserting patent infringement relating to the Nucynta Products;
- our ability to manufacture commercial quantities of Nucynta ER and Nucynta IR at reasonable cost and with sufficient speed to meet commercial demand; and
- comply with applicable legal and regulatory requirements.

Many of these matters are beyond our control and are subject to other risks described elsewhere in this "Risk Factors" section. Accordingly, we cannot assure you that we will be able to successfully commercialize or generate sufficient revenue from our products. If we cannot do so, or are significantly delayed in doing so, our business will be materially harmed.

Despite receiving approval by the FDA, additional data may emerge that could change the FDA's position on the product labeling of Xtampza ER and our ability to successfully market Xtampza ER may be adversely affected.

Xtampza ER was approved with label language describing abuse-deterrent properties of the formulation with respect to the nasal and IV routes of abuse, consistent with Guidance for Industry, "Abuse-Deterrent Opioids- Evaluation and Labeling". In November 2017, the FDA approved an sNDA for Xtampza ER to include comparative oral pharmacokinetic data from a clinical study evaluating the effect of physical manipulation by crushing Xtampza ER compared with OxyContin and a control (oxycodone hydrochloride immediate-release), results from an oral human abuse potential study and the addition of an oral abuse deterrent claim. Per FDA guidance, data that emerges from post-marketing studies or other sources could prompt the FDA to withdraw or amend its approval of the product labeling describing the abuse deterrent properties of the formulation, which withdrawal or amendment could adversely impact our ability to successfully commercialize Xtampza ER.

The FDA can change the product labeling for Xtampza ER at any time. Per FDA guidance, data that emerges from post-marketing studies or other sources could prompt the FDA to withdraw or amend its approval of the product labeling describing the abuse deterrent properties of the formulation. If the product label for Xtampza ER is modified in the future so that the FDA requires us to have additional boxed warning language similar to competitor product labeling stating that "crushing, dissolving or chewing can cause rapid release and absorption of a potentially fatal dose of the active drug" or to exclude the flexible dose administration options, it will limit our ability to differentiate Xtampza ER from other abuse-deterrent opioid and this may have an adverse effect on our business and our prospects for future growth.

Xtampza ER and the Nucynta Products are subject to mandatory REMS programs, which could increase the cost, burden and liability associated with the commercialization of these products.

The FDA has approved REMS for extended-release and long acting ("LA"), opioid drugs formulated with the active pharmaceutical ingredients fentanyl, hydromorphone, methadone, morphine, oxycodone, oxymorphone, and others as part of a federal initiative to address prescription drug abuse and misuse, or the ER/LA opioid REMS. In September

2018, the FDA announced that immediate-release opioid drugs will be subject to the same REMS as ER/LA opioids (now called the Opioid Analgesic REMS). One of the primary goals of the REMS is to ensure that the benefits of these drugs continue to outweigh the risks.

The REMS introduces new safety measures designed to reduce risks and improve the safe use of opioids, while continuing to provide access to these medications for patients in pain. The REMS applies to more than 20 companies that manufacture opioid analgesics. Under the REMS, companies are required to make education programs available to prescribers based on the FDA's Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain. It is expected that companies will meet this obligation by providing educational grants to continuing education providers, who will develop and deliver the training. The REMS also requires companies to distribute FDA-approved educational materials to prescribers and patients on the safe use of these drugs. The companies must perform periodic assessments of the implementation of the REMS and the success of the program in meeting its goals. The FDA will review these assessments and may require additional elements to achieve the goals of the program. At present, a physician does not have to complete the training offered under REMS as a prerequisite for ability to prescribe opioids; however, the FDA is considering circumstances where it would require some type of mandatory training as a precondition. Congress has also considered legislation that would require prescribers to have continuing medical education on best practices in prescribing opioids. These requirements, if enacted, could impact the number of prescriptions written by physicians for our products.

Additionally, drug products that fall under the Opioid Analgesic REMS may be subject to class-wide safety labelling changes when FDA determines such changes are warranted. Such labeling has the potential to adversely impact prescribing or market acceptance of these products.

If the FDA determines that a REMS is necessary during review of an application, the drug sponsor must agree to the REMS plan at the time of approval. Xtampza ER and the Nucynta Products have been subject to the REMS requirement since their approval. REMS includes a Medication Guide that is dispensed with each prescription, physician training based on FDA-identified learning objectives, audits to ensure that the FDA's learning objectives are addressed in the physician trainings, letters to prescribing physicians, professional organizations and state licensing entities alerting each to the REMS, and the establishment of a call center to provide more information about the REMS. We anticipate that our future product candidates will also be subject to these REMS requirements. There may be increased cost, administrative burden and potential liability associated with the marketing and sale of these types of product candidates subject to the REMS requirements, which could reduce the commercial benefits to us from the sale of these product candidates.

Although Xtampza ER has been approved with abuse deterrent labeling, the FDA could require changes to such labeling or we could fail to promote such abuse deterrent labeling in compliance with FDA regulations.

Xtampza ER was developed in compliance with the FDA's April 2015 guidance regarding opioid abuse deterrence and has received FDA-approved product labeling that describes its abuse deterrent features, which allows us to promote those features and differentiate Xtampza ER from other opioid products containing the same active pharmaceutical ingredients. Because the FDA closely regulates promotional materials and other promotional activities, even though the FDA approved product labeling that includes a description of the abuse deterrent characteristics of Xtampza ER, the FDA may object to our marketing claims and product advertising campaigns. This could lead to the issuance of warning letters or untitled letters, suspension or withdrawal of our products from the market, recalls, fines, disgorgement of money, operating restrictions, injunctions, and civil or criminal prosecution. Any of these consequences would harm the commercial success of Xtampza ER. In addition, the April 2015 final FDA guidance on abuse-deterrent opioids is not binding law and may be superseded or modified at any time. Also, if the FDA determines that our post-marketing data do not demonstrate that the abuse-deterrent properties result in reduction of abuse, or demonstrate a shift to routes of abuse that present a greater risk, the FDA may find that product labeling revisions are needed, and potentially require the removal of our abuse-deterrence claims, which would have a material adverse effect on our ability to successfully commercialize Xtampza ER.

Failure to comply with ongoing governmental regulations for marketing any product, including Xtampza ER and the Nucynta Products, could delay or inhibit our ability to generate revenues from their sale and could also expose us to claims or other sanctions.

Advertising and promotion of any product that has obtained approval in the United States, including Xtampza ER and the Nucynta Products, is heavily scrutinized by, among others, the FDA, the Department of Justice, the Office of Inspector General for the U.S. Department of Health and Human Services ("HHS"), state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or other government agencies.

In the United States, engaging in off-label promotion of our products, can also subject us to false claims litigation under federal and state statutes, and other litigation and/or investigation, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which we promote or distribute our drug products. These false claims statutes include the federal False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth in recent years, leading to several substantial civil and criminal settlements based on certain sales practices promoting off-label drug uses. This increased focus and scrutiny has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from the Medicare, Medicaid and other federal and state healthcare programs.

If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our products, we could become subject to significant liability, which could materially adversely affect our business and financial condition.

In addition, later discovery of previously unknown problems with a product, manufacturer or facility, or our failure to update regulatory files, may result in restrictions, including withdrawal of the product from the market. The failure to obtain or maintain requisite governmental approvals or FDA required product withdrawals or warnings arising from identification of serious and unanticipated adverse side effects, could delay or preclude us from further developing, marketing or realizing the full commercial potential of our products.

Risks Related to Intellectual Property

Unfavorable outcomes in intellectual property litigation could result in costly litigation and potentially limit our ability to commercialize our products.

Our commercial success depends upon our ability to commercialize products without infringing the intellectual property rights of others. Our current or future products, or any uses of them, may now or in the future infringe third-party patents or other intellectual property rights. This is due in part to the considerable uncertainty within the pharmaceutical industry about the validity, scope and enforceability of many issued patents in the United States and, to date, there is no consistency regarding the breadth of claims allowed in pharmaceutical patents. We cannot currently determine the ultimate scope and validity of patents which may be granted to third parties in the future or which patents might be asserted to be infringed by the manufacture, use and sale of our products. In part as a result of this uncertainty, there has been, and we expect that there will continue to be, significant litigation in the pharmaceutical industry regarding patents and other intellectual property rights.

Third parties may assert infringement claims against us, or other parties we have agreed to indemnify, based on existing patents or patents that may be granted in the future. We are aware of third-party patents and patent applications related to oxycodone formulations, including those listed in the FDA's Orange Book for oxycodone products. Because of the delay

between filing and publication of patent applications, and because applications can take several years to issue, there may be currently pending third-party patent applications that are unknown to us, which may later result in issued patents. Because of the uncertainty inherent in intellectual property litigation, we could lose, even if the case against us was weak or flawed.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing or commercializing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our products or force us to cease some of our business operations.

In connection with any NDA that we file under Section 505(b)(2), we are required to notify the patent holder of the reference listed drug that we identify in our NDA, that we have certified to the FDA that any patents listed for the listed drug in the FDA's Orange Book publication are invalid, unenforceable or will not be infringed by the manufacture, use or sale of our drug. If the patent holder files a patent infringement lawsuit against us within 45 days of its receipt of notice of our certification, the FDA is automatically prevented from approving our Section 505(b)(2) NDA until the earliest of 30 months after the lawsuit is filed, expiration of the patents, settlement of the lawsuit and a court decision in the infringement case that is favorable to us. Accordingly, we may invest significant time and expense in the development of our products only to be subject to significant delay and patent litigation before our products may be commercialized.

If we are found by the court to have infringed a valid patent claim, we could be prevented from using the patented technology or be required to pay the patent holder for the right to license the patented technology. If we decide to pursue a license to use one or more of these patents, we may not be able to obtain a license on commercially reasonable terms, if at all, or the license we obtain may require us to pay substantial royalties or grant cross licenses to our patent rights. For example, if the relevant patent is owned by a competitor, such as Purdue, that competitor may choose not to license patent rights to us. If we decide to develop alternative technology, we may not be able to do so in a timely or cost-effective manner, if at all.

Even if we are found not to infringe or patent claims are found invalid or unenforceable, defending any such infringement claim would be expensive and time consuming, and could delay the commercialization of our products and distract management from their normal responsibilities.

Competitors may sue us as a way of delaying the introduction of our products. Any litigation, including any interference or derivation proceedings to determine priority of inventions, oppositions or other post-grant review proceedings to patents in the United States, or litigation against our collaborators may be costly and time consuming and 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 expect that litigation may be necessary in some instances to determine the validity and scope of our proprietary rights. Litigation may be necessary in other instances to determine the validity, scope or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. Ultimately, the outcome of such litigation, including our pending litigation with Purdue, could compromise the validity and scope of our patents or other proprietary rights or hinder our ability to manufacture and market our products.

If we are unable to obtain or maintain intellectual property rights for our technologies, products or any future product candidates which we may develop, we may lose valuable assets or be unable to compete effectively in our market.

We depend on our ability to protect our proprietary technology. We rely on patent and trademark laws, unpatented trade secrets and know-how, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our success depends in large part on our ability to obtain and maintain patent protection in the United States with respect to our proprietary technology and products.

The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights in the United States. The rights already granted under any of our currently issued patents and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking.

The patent prosecution process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them.

Given the amount of time required for the development, testing and regulatory review of product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products identical, similar or superior to ours, and our ability to successfully commercialize our technology and products may be adversely affected.

With respect to patent rights, our patent applications may not issue into patents, and any issued patents may not provide protection against competitive technologies, may be held invalid or unenforceable if challenged or may be interpreted in a manner that does not adequately protect our technology or future product candidates. Even if our patent applications issue into patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. The examination process may require us to narrow the claims in our patents, which may limit the scope of patent protection that may be obtained. Our competitors may design around or otherwise circumvent patents issued to us or licensed by us.

The scope of patent protection in the United States is highly uncertain, and changes in U.S. patent law have increased that uncertainty and could diminish the value of patents in general, thereby impairing our ability to protect our products or future product candidates.

The patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. Changes in either the patent laws or interpretation of the patent laws in the United States may diminish the value of our patents or narrow the scope of our patent protection.

Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States typically are not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights, in the United States, are highly uncertain.

Patent reform legislation could increase the uncertainties and costs associated with the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith America Invents Act (the “Leahy-Smith Act”), which was signed into law on September 16, 2011, made significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted and litigated. Many of the substantive changes to patent law associated with the Leahy-Smith Act and, in particular, the “first to file” provisions described below, became effective in 2013. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Pursuant to the Leahy-Smith Act, the United States transitioned to a “first to file” system in which the first inventor to file a patent application will be entitled to the patent. In addition, third parties are allowed to submit prior art before the issuance of a patent by the U.S. Patent and Trademark Office (the “USPTO”) and may become involved in opposition, derivation, reexamination, or inter partes review challenging our patent rights or the patent rights of others. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including novelty, non-obviousness and enablement. It is possible that prior art of which both we and the patent examiner were unaware during prosecution exists, which could render our patents invalid. Moreover, there may exist prior art of which we were or are

aware, and which we did not or do not consider relevant to our patents, but which could nevertheless be determined to render our patents invalid. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, which could have a material adverse effect on our competitive position with respect to third parties.

Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or license from third parties may be challenged in the courts or patent offices in the United States. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents, or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our patented technology, trademarks and other intellectual property rights is expensive, difficult and, may in some cases not be possible. In some cases, it may be difficult or impossible to detect third party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

We may be forced to litigate to enforce or defend our intellectual property, which could be expensive, time consuming and unsuccessful, and result in the loss of valuable assets.

We may be forced to litigate to enforce or defend our intellectual property rights against infringement and unauthorized use by competitors, and to protect our trade secrets. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights. In so doing, we may place our intellectual property at risk of being invalidated, rendered unenforceable or limited or narrowed in scope.

Further, this can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can.

Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources, which could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. In addition, an adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

We may not be responsible for or have control over the prosecution or enforceability of our licensed technology and have to rely on the licensor to enforce or defend our intellectual property.

In some cases, patent prosecution of our licenses is controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;

- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we license prevent or impair our ability to maintain such licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected products.

We may be subject to claims by third parties of ownership of what we regard as our own intellectual property or obligations to make compensatory payments to employees or others.

While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing or obtaining such an agreement with each party who, in fact, develops intellectual property that we regard as our own. In addition, they may breach the assignment agreements or such agreements may not be self-executing, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

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

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

Many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including potential competitors. These employees typically executed proprietary rights, non-disclosure and non-competition agreements in connection with their previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any threatened or pending claims related to these matters, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs, damage our reputation and be a distraction to management.

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

The USPTO requires compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents are required to be paid to the USPTO in several stages over the lifetime of the patents. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products, our competitive position would be adversely affected.

Risks Related to the Commercialization of Our Products

If we are unable to successfully develop and utilize our own sales and marketing capabilities or enter into strategic alliances with marketing collaborators, we may not be successful in commercializing our products and may be unable to generate sufficient product revenue.

Our commercial organization continues to evolve, and in light of its short history and limited track record, we cannot guarantee that we will be successful in marketing our products that may be approved for marketing. In addition, we compete with other pharmaceutical and biotechnology companies with extensive and well-funded sales and marketing operations to recruit, hire, train and retain sales and marketing personnel. If we are unable to continue to grow and maintain adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. Factors that may inhibit our efforts to commercialize our products in the United States include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to reach adequate numbers of physicians who may prescribe our products; and
- unforeseen costs and expenses associated with creating and maintaining an independent sales and marketing organization.

If we are not successful in recruiting and retaining sales and marketing personnel or in maintaining our sales and marketing infrastructure or if we do not preserve strategic alliances with marketing collaborators, agreements with contract sales organizations or collaboration arrangements, we will have difficulty commercializing our products.

Additionally, our sales, marketing and distribution capabilities may be hindered as a result of the COVID-19 outbreak. In response to the outbreak and the resulting mandatory closure of non-essential businesses and “social distancing” measures recommended by U.S. public health officials, our sales personnel have transitioned to remote work. The safety and well-being of our employees is our highest priority and we expect to maintain such mitigating measures until such time as mandated closures are lifted and public health officials change their recommendations, and we are working to equip our personnel with the tools and resources needed to effectively continue their sales and marketing efforts in a manner that complies with all relevant regulations from a remote setting. We face the risk, however, that limitations on activities within the healthcare sector and on economic activity generally will impede our ability to successfully commercialize our products. The travel restrictions and “social distancing” recommendations resulting from the spread of COVID-19 have impacted our sales professionals’ ability to travel to and meet with customers in person. The outbreak has also prompted hospitals and other healthcare providers to limit our and our wholesalers’ and distributors’ access to physicians and other key healthcare personnel, which may inhibit our and our customers’ ability to meet existing, or generate new, demand for our products. Moreover, we face the risk that, despite social distancing and other mitigating measures, we could face a loss of productivity due to a number of our sales and marketing personnel

becoming infected with the virus. If we are unable to effectively commercialize our products during the COVID-19 outbreak, our ability to generate sufficient product revenue may be adversely affected

If physicians, patients, healthcare payors and the medical community do not accept and use our products, we will not achieve sufficient product revenues and our business will suffer.

Physicians, patients, healthcare payors and the medical community may not accept and use our products. Acceptance and use of our products will depend on a number of factors including:

- the timing of market introduction of our products as well as the availability of competitive products;
- approved indications, warnings and precautions language that may be less desirable than anticipated;
- perceptions by members of the healthcare community, including physicians, about the safety and efficacy of our products;
- perceptions by members of the healthcare community, including physicians, about the relevance and efficacy of our abuse deterrent technology;
- the pricing and cost-effectiveness of our products relative to competing products;
- the potential and perceived advantages of our products over alternative treatments;
- the convenience and ease of administration to patients of our products;
- actual and perceived availability of coverage and reimbursement for our products from government or other third-party payors;
- any negative publicity related to our or our competitors' products;
- the prevalence and severity of adverse side effects, including limitations or warnings contained in a product's FDA approved product labeling;
- FDA's and HHS's policy initiatives regarding opioids;
- our ability to implement a REMS; and
- effectiveness of marketing and distribution efforts by us and any licensees and distributors.

If our products fail to have an adequate level of acceptance by physicians, healthcare payors, patients or the medical community, we will not be able to generate sufficient revenue to become or remain profitable. Since we expect to rely on sales generated by Xtampza ER and the Nucynta Products for substantially all of our revenues for the foreseeable future, the failure of Xtampza ER or the Nucynta Products to maintain market acceptance would harm our business prospects.

Our products contain and our future product candidates may contain controlled substances, the manufacture, use, sale, importation, exportation and distribution of which are subject to regulation by state and federal law enforcement and other regulatory agencies.

Our products contain and our future product candidates may contain, controlled substances that are subject to state and federal laws and regulations regarding their manufacture, use, sale, importation, exportation and distribution. Xtampza ER's active ingredient, oxycodone, and the Nucynta Products' active ingredient, tapentadol, are both classified as

Schedule II controlled substances under the CSA and regulations of the DEA. A number of states also independently regulate these drugs, including oxycodone and tapentadol, as controlled substances.

We and our suppliers, manufacturers, contractors, customers and distributors are required to obtain and maintain applicable registrations from state and federal law enforcement and regulatory agencies and comply with state and federal laws and regulations regarding the manufacture, use, sale, importation, exportation and distribution of controlled substances. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription. In light of the COVID-19 public health emergency, the DEA now allows the issuance of a prescription for a controlled substance after examination of a patient through telemedicine technology as an in-person examination may not be possible

Furthermore, the amount of Schedule II substances that can be obtained for clinical trials and commercial distribution is limited by the CSA and DEA regulations. In July 2018, the DEA published final guidelines strengthening the process for setting controls over diversion of controlled substances and making other improvements in the quota management regulatory system. For 2019, the DEA has proposed decreased manufacturing quotas for the six most frequently misused opioids, including oxycodone, by an average of 10% as compared to the 2018 quotas. The DEA has proposed further decreasing manufacturing quotas in 2020 for five of the six opioids (fentanyl, hydrocodone, hydromorphone, oxycodone, oxymorphone), by an average of 28%. Together with reductions in morphine, this is a 53% decrease since 2016. In October 2019, the DEA proposed additional regulations to amend the manner in which the agency grants quotas to manufacturers. The proposed regulations will establish use-specific quotas, including commercial sales, product development, transfer, replacement, and packaging. To decrease the risk of diversion and increase accountability, inventory allowances will be reduced, and procurement quota certifications will be required. We may not be able to obtain sufficient quantities of these controlled substances in order to complete our clinical trials or meet commercial demand. If commercial demand for Xtampza ER, or any of our other approved products, increases and we cannot meet such demand in a timely fashion because of our limited supply of its active pharmaceutical ingredient (in the case of Xtampza ER, oxycodone) then physicians may perceive such product as unavailable and may be less likely to prescribe it in the future.

In addition, controlled substances are also subject to regulations governing manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, recordkeeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of our products that include controlled substances. The DEA and some states conduct periodic inspections of registered establishments that handle controlled substances.

Failure to obtain and maintain required registrations or to comply with any applicable regulations could delay or preclude us from developing and commercializing our products that contain controlled substances and subject us to enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In some circumstances, violations could lead to criminal proceedings. Because of their restrictive nature, these regulations could limit commercialization of our products containing controlled substances.

Recently enacted and future legislation may increase the difficulty and cost for us to commercialize our products and may reduce the prices we are able to obtain for our products.

In the United States, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system generally, and the manufacturing, distribution, and marketing of opioids in particular, that could prevent or delay marketing approval of future product candidates, restrict or regulate post-approval activities or affect our ability to profitably sell our products for which we obtain marketing approval.

Effective July 2019, New York imposed an excise tax on the first sale of an opioid unit by a registrant in New York based on morphine milligram equivalents. In addition, in 2019 several other states, including Delaware, Minnesota, and Rhode Island, enacted laws that imposed similar taxes or fees on the sale of opioids. Other states could impose similar taxes or fees, and such laws and proposals can vary in the tax and fee amounts imposed and the means of calculation. Liabilities for taxes or assessments under any such laws could have an adverse impact on our results of operations.

California and several other states have enacted legislation related to prescription drug pricing transparency and it is unclear the effect this legislation will have on our business. Laws intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms may continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

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

In October 2018, President Trump signed the Substance Use Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act. Among other things, this legislation provides funding for research and development of non-addictive painkillers that could potentially compete with our products. It also clarifies FDA's authority to require that certain opioids be dispensed in packaging that limits their abuse potential, makes changes to Medicare and Medicaid in an effort to limit over-prescription of opioid painkillers, and increases penalties against manufacturers and distributors related to the over-prescription of opioids, including the failure to report suspicious orders and keep accurate records. The ultimate effect of this legislation is currently not known, but could potentially have a material adverse effect on our business.

In addition, state pharmacy laws may permit pharmacists to substitute generic products for branded products if the products are therapeutic equivalents, or may permit pharmacists and pharmacy benefit managers to seek prescriber authorization to substitute generics in place of our products, which could significantly diminish demand for them and significantly impact our ability to successfully commercialize our products and generate revenues.

Our products may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could have a material adverse effect on our business. Such pricing regulations may address the rebates that manufacturers offer to pharmaceutical benefit managers, or the discounts that manufacturers provide others within the pharmaceutical distribution chain.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products can vary widely. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Pricing limitations may hinder our ability to recoup our investment in our products.

Our ability to commercialize any product successfully will also depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with discounts and rebates from list prices and are challenging the prices charged for medical products. We have agreed to provide such discounts and rebates to certain third-party payors. We expect increasing pressure to offer larger discounts and rebates. Additionally, a greater number of third-party payors may seek discounts and rebates in order to offer or maintain access for our products. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be and whether it will be satisfactory.

In January 2019, as part of its cost containment efforts for government-reimbursed prescription medications, HHS released a proposed rule that (1) eliminates federal anti-kickback statue safe harbor protection for rebates paid to prescription benefit managers; (2) creates a new safe harbor for discounts provided to beneficiaries at the point of sale;

and (3) creates a new safe harbor for administrative fees paid by manufacturers to prescription benefit managers. The goal of the proposed safe harbor changes is to eliminate rebates from manufacturers to prescription benefit managers and replace them with point-of-sale discounts to beneficiaries. The proposed new rule only applies to Medicare, Medicare Advantage and Medicaid plans, not to private commercial insurance plans. The proposed regulation faces opposition from pharmacy benefit managers and others who do not believe it will have its intended effect of reducing overall costs to government beneficiaries. We cannot be sure whether the proposed rule will be adopted either in its current form or in an amended form, and do not know what impact the uncertainty will have on our agreements and relationships with pharmacy benefit managers and other pertinent parties. If the rule is finalized, we will likely be required to alter our agreements with these parties to come into compliance with the new rule, and it is uncertain what financial impact these alterations will have on our list prices, discounts, and reimbursement levels for our products

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

Social issues around the abuse of opioids, including law enforcement concerns over diversion of opioids and regulatory efforts to combat abuse, could decrease the potential market for our products and may adversely impact external investor perceptions of our business.

Media stories regarding prescription drug abuse and the diversion of opioids and other controlled substances are commonplace. Law enforcement and regulatory agencies may apply policies and guidelines that seek to limit the availability or use of opioids. Such efforts may inhibit our ability to commercialize our products.

Aggressive enforcement and unfavorable publicity regarding, for example, the use or misuse of oxycodone or other opioid drugs; the limitations of abuse-resistant formulations; the ability of drug abusers to discover previously unknown ways to abuse opioid drugs, including Xtampza ER and the Nucynta Products; public inquiries and investigations into prescription drug abuse; litigation; or regulatory activity regarding sales, marketing, distribution or storage of opioid drugs could have a material adverse effect on our reputation. Such negative publicity could reduce the potential size of the market for our products, decrease the revenues we are able to generate from their sale and adversely impact external investor perceptions of our business. Similarly, to the extent opioid abuse becomes less prevalent or less urgent of a public health issue, regulators and third party payers may not be willing to pay a premium for abuse-deterrent formulations of opioid.

Many state legislatures have enacted legislation intended to reduce opioid abuse, for example by establishing prescription drug monitoring programs and mandating prescriber education. The SUPPORT Act allows for sharing of this type of data across state lines. Efforts by the FDA and other regulatory and legislative bodies to combat abuse of opioids may negatively impact the market for our products. In February 2016, the FDA released an action plan to address the opioid abuse epidemic and reassess the FDA's approach to opioid medications. The plan identifies the FDA's focus on implementing policies to reverse the opioid abuse epidemic, while maintaining access to effective treatments. The actions set forth in the FDA's plan include strengthening post marketing study requirements to evaluate the benefit of long-term opioid use, changing the REMS requirements to provide additional funding for physician education courses, releasing a draft guidance setting forth approval standards for generic-abuse deterrent opioid formulations, and seeking input from the FDA's Science Board to broaden the understanding of the public risks of opioid abuse. The FDA's Science Board met to address these issues on March 1, 2016. In November 2017, FDA issued a final guidance addressing approval standards for generic abuse-deterrent opioid formulations, which included recommendations about the types of studies that companies should conduct to demonstrate that the generic drug is no less abuse-deterrent than its

brand-name counterpart. In September 2018, the FDA announced that IR opioid drugs will be subject to the same REMS as ER/LA opioids (now called the Opioid Analgesic REMS). One of the primary goals of the REMS is to ensure that the benefits of these drugs continue to outweigh the risks The FDA's plan is part of a broader initiative led by the HHS to address opioid-related overdose, death and dependence. The HHS initiative's focus is on improving physician's use of opioids through education and resources to address opioid over-prescribing, increasing use and development of improved delivery systems for naloxone, which can reverse overdose from both prescription opioids and heroin, to reduce overdose-related deaths, and expanding the use of Medication-Assisted Treatment, which couples counseling and behavioral therapies with medication to address substance abuse. As part of this initiative, the CDC has launched a state grant program to offer state health departments resources to assist with abuse prevention efforts, including efforts to track opioid prescribing through state-run electronic databases. In March 2016, as part of the HHS initiative, the CDC released a Guideline for Prescribing Opioids for Chronic Pain. The guideline is intended to assist primary care providers treating adults for chronic pain in outpatient settings. The guideline provides recommendations to improve communications between doctors and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy. The guideline states that no treatment recommendations about the use of abuse-deterrent opioids can be made at this time. The SUPPORT Act, described above, also addresses opioid-related abuse by, among other things, seeking to increase access to and reimbursement for addiction treatment, advancing new initiatives to promote education and awareness of appropriate pain treatment among health care providers and improving coordination among federal agencies in relation to border checks.

The FDA continues to evaluate extended-release and abuse-deterrent opioids in the post-market setting. In March 2017, the FDA's Advisory Committee met to discuss OPANA ER (oxymorphone hydrochloride) extended-release tablets. A majority of the Advisory Committee voted that the benefits do not outweigh the risks of OPANA ER. Upon the FDA's subsequent request in June 2017, OPANA ER was removed from the market. Also, in July 2017, the FDA held a public workshop to discuss available data and methods to assess the impact of opioid formulations with abuse-deterrent properties on misuse, abuse, addiction, overdose, and death in the post-market context. The FDA will continue to scrutinize the impact of abuse-deterrent opioids and in the future could impose further restrictions to products currently on the market, which may include changing labeling, imposing additional prescribing restrictions, or seeking a product's removal from the market.

Recently, CVS Pharmacy announced it would only fill first-time opioid prescriptions for acute pain for a seven day supply. In July 2017, the Pharmaceutical Care Management Association, a trade association representing pharmacy benefit managers, wrote a letter to the commissioner of the FDA in which it expressed support for, among other things, the CDC guidelines and a seven-day limit on the supply of opioids for acute pain. In addition, states, including the Commonwealths of Massachusetts and Virginia and the States of New York, Ohio, Arizona, Maine, New Hampshire, Vermont, Rhode Island, Colorado, Wisconsin, Alabama, South Carolina, Washington and New Jersey, have either recently enacted, intend to enact, or have pending legislation or regulations designed to, among other things, limit the duration and quantity of initial prescriptions of immediate-release forms of opiates and mandate the use by prescribers of prescription drug databases and mandate prescriber education. FDA has announced that it will advance policies to require that immediate-release formulations of opioids be made available in fixed-quantity packaging- such as blister packs- to further encourage the writing of prescriptions for short durations for common acute pain conditions and procedures. Also, at the state and local level, a number of states and cities have brought separate lawsuits against various pharmaceutical companies marketing and selling opioid pain medications, alleging misleading or otherwise improper promotion of opioid drugs to physicians and consumers. In addition, the attorneys general from several states have announced the launch of a joint investigation into the marketing and sales practices of drug companies that market opioid pain medications. We are currently subject to such lawsuits and investigations, as discussed under the heading "Legal Proceedings" in this report. Many of these changes and others could cause us to expend additional resources in developing and commercializing our products to meet additional requirements. Advancements in development and approval of generic abuse-deterrent opioids could also compete with and potentially impact physician use of our products and cause our products to be less commercially successful.

If the FDA or other applicable regulatory authorities approve generic products with abuse deterrent claims that compete with our products, our sales could decline.

Once an NDA, including a Section 505(b)(2) application, is approved, the product covered thereby becomes a "listed

drug" which can, in turn, be cited by potential competitors in support of approval of an ANDA. The Federal Food, Drug, and Cosmetic Act, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active pharmaceutical ingredients, dosage form, strength, route of administration, and conditions of use, or product labeling, as our product and that the generic product is absorbed in the body at the same rate and to the same extent as, or is bioequivalent to, our product. These generic equivalents would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product are typically lost to the generic product. Accordingly, competition from generic equivalents to our products would substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our products. In November 2017, FDA issued a final guidance to assist industry in the development of generic versions of approved opioids with abuse-deterrent formulations, including recommendations about the types of studies that companies should conduct to demonstrate that the generic drug is no less abuse-deterrent than its brand-name counterpart. In the second half of 2018, the FDA posted three revised product-specific guidances related to generic abuse-deterrent opioid formulations, including one guidance specifically relating to Xtampza ER, which recommend specific in vivo studies and in vitro study considerations for abuse deterrence evaluations. These guidances are part of FDA's wider focus on assisting developers of generic abuse-deterrent formulations navigate the regulatory path to market more quickly. Earlier market entry of generic abuse-deterrent formulations could have a material adverse effect on our business.

Guidelines and recommendations published by various organizations can reduce the use of our products.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the healthcare and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of our products or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of our products.

Risks Related to Our Dependence on Third Parties

If the third-party manufacturers of Xtampza ER or the Nucynta Products fail to devote sufficient time and resources to these products, or their performance is substandard, and/or we encounter challenges in completing our dedicated facility at our third-party manufacturer's site for the manufacturing of Xtampza ER, our costs may be higher than expected and could have a material adverse effect on our business.

We do not own any manufacturing facilities and have limited experience in drug development and commercial manufacturing. We currently have no plans to build our own clinical or commercial scale manufacturing facility. We lack the resources and expertise to manufacture and test, on a commercial scale, the technical performance of our products. We currently rely, and expect to continue to rely, on a limited number of experienced personnel and contract manufacturers for our products, as well as other vendors to formulate, test, supply, store and distribute our products and we control only certain aspects of their activities. In 2016, we began to construct a dedicated facility for a portion of the Xtampza ER manufacturing process, at a site operated by our contract manufacturing organization, Patheon, part of Thermo Fisher Scientific. This dedicated facility has required significant capital expenditures and, when operational, is likely to result in significantly increased fixed costs. This dedicated facility requires the maintenance of additional regulatory approvals and entails other costs, all of which we will need to absorb. We cannot guarantee that we will be able to successfully leverage the dedicated facility in a timely or profitable manner, or within the budget that we currently project. If the demand for Xtampza ER and any future related products never meets our expectations and forecasts, or if we do not produce the output we plan, we may not be able to realize the return on investment we anticipated, which would have a negative impact on our financial condition and results of operations.

Although we have identified alternate sources for these services, it would be time-consuming, and require us to incur additional cost, to qualify these sources.

Our reliance on a limited number of vendors and, in particular, Patheon as our single manufacturer for Xtampza ER and the future manufacturer of Nucynta ER, exposes us to the following risks, any of which could delay commercialization of our products, result in higher costs, or deprive us of potential product revenues:

- Our contract manufacturer, or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy commercial demand (even after accounting for the increased capacity to be provided by the dedicated facility), may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, may be affected by natural disasters that interrupt or prevent manufacturing of our products (including pandemics such as the COVID-19 outbreak whose impact on supply chains is discussed in more detail in the risk factors below), may experience shortages of qualified personnel to adequately staff production operations, may experience shortages of raw materials and may have difficulties finding replacement parts or equipment.

- Our contract manufacturer could default on their agreement with us to meet our requirements for commercial supplies of our products and/or deliver the dedicated facility according to the currently agreed timeline.

- The use of alternate manufacturers may be difficult because the number of potential manufacturers that have the necessary governmental licenses to produce narcotic products is limited. Additionally, the FDA and the DEA must approve any alternative manufacturer of our products, before we may use the alternative manufacturer to produce commercial supplies.

- It may be difficult or impossible for us to find a replacement manufacturer on acceptable terms quickly, or at all. Our contract manufacturer and vendors may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our products.

- If our contract manufacturer were to terminate our arrangement or fail to meet our commercial manufacturing demands, we may be forced to delay our development and commercial programs.

Failure to obtain the necessary active pharmaceutical ingredients, excipients or components necessary to manufacture our products could adversely affect our ability to commercialize the product, which could in turn adversely affect our results of operations and financial condition. Certain components of Xtampza ER are naturally derived products, for which we rely on sole suppliers. The inability of any of our raw material suppliers to provide components that meet our specifications and requirements could adversely impact our ability to manufacture our product. Furthermore, the quota procurement process limits the amount of DEA-controlled active pharmaceutical ingredient we have available for manufacture. Consequently, we are limited in our ability to execute a business strategy that builds appreciable safety stock of finished drug product.

Our reliance on third parties reduces our control over our development and commercialization activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards. The FDA and other regulatory authorities require that our products to be manufactured according to cGMP. Any failure by our third-party manufacturer to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of products in a timely manner, could lead to a shortage of commercial product. In addition, such failure could be the basis for the FDA to issue a warning or untitled letter, withdraw approvals for products previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction, imposing civil penalties or pursuing criminal prosecution.

Any stock out, or failure to obtain sufficient supplies of any of our products, or the necessary active pharmaceutical ingredients, excipients or components necessary to manufacture each of our products, could adversely affect our ability to commercialize such products, which could in turn adversely affect our results of operations and financial condition. Assertio, our previous commercialization partner with respect to the Nucynta Products, experienced delays in the manufacture, packaging and delivery of certain dosage strengths of Nucynta ER in the third and fourth quarters of 2017 and the first quarter of 2018 following Hurricanes Irma and Maria in Puerto Rico. We may experience further outages in the future.

Because we currently rely on a sole supplier to manufacture the active pharmaceutical ingredient of our products, any production problems with our supplier could have a material adverse effect on us.

We presently depend upon a single supplier for the active pharmaceutical ingredient for Xtampza ER (oxycodone base) and the Nucynta Products (tapentadol) and we contract with this supplier for commercial supply of our products. Although we have identified an alternate source for oxycodone base for Xtampza ER, it would be time-consuming and costly to qualify this source. Any changes executed by our supplier to the respective drug substance raw materials, intermediates, or manufacturing processes would introduce technical and regulatory risks to our downstream drug product supply. If our supplier were to terminate an arrangement for an active pharmaceutical ingredient, or fail to meet our supply needs (including as a result of disruptions in personnel or the global supply chain resulting from the COVID-19 outbreak), we might incur substantial costs and be forced to delay our development or commercialization programs. Any such delay could have a material adverse effect on our business.

Manufacturing issues may arise that could increase product and regulatory approval costs, delay commercialization or limit commercial supply.

In our current commercial manufacturing operations, and as we scale up manufacturing of our products and conduct required stability testing, we may encounter product, packaging, equipment and process-related issues that may require refinement or resolution in order to proceed with our planned clinical trials, obtain regulatory approval for commercial marketing and build commercial supplies. In the future, we may identify impurities, which could result in increased scrutiny by regulatory authorities, delays in our clinical programs and regulatory approval, increases in our operating expenses, failure to obtain or maintain approval or limitations in our commercial supply.

We depend on wholesale pharmaceutical distributors for retail distribution of our products; if we lose any of our significant wholesale pharmaceutical distributors, that loss may materially adversely affect our financial condition and results of operations.

A significant percentage of our product shipments are to a limited number of independent wholesale pharmaceutical distributors. Three of our wholesale pharmaceutical distributors represented 35%, 31% and 30% of our product shipments for the three months ended March 31, 2020. The loss by us of any of these wholesale pharmaceutical distributors' accounts, or a material reduction in their purchases, or a significant disruption to transportation infrastructure or other means of distribution of our products, including as a result of the ongoing COVID-19 outbreak, could have a material adverse effect on our business, results of operations, financial condition and prospects. The significance of each wholesale pharmaceutical distributor account to our business adversely impacts our ability to negotiate favorable commercial terms with each such distributor, and as a result, we may be forced to accept terms that adversely impact our results of operations.

In addition, these wholesale customers comprise a significant part of the distribution network for pharmaceutical products in the United States. This distribution network has undergone, and may continue to undergo, significant consolidation marked by mergers and acquisitions. As a result, a small number of large wholesale distributors control a significant share of the market. Consolidation of drug wholesalers has increased, and may continue to increase, competitive and pricing pressures on pharmaceutical products. We cannot guarantee that we can manage these pricing pressures or that wholesaler purchases will not fluctuate unexpectedly from period to period.

Our products could be subject to post-marketing requirements, which requirements may, in some cases, not be capable of timely or satisfactory completion without participation in consortia over which we have limited control.

Our products are subject to a comprehensive regulatory scheme, including post-marketing requirements ("PMRs") to conduct epidemiological studies and clinical trials. We intend to fulfill our PMRs by virtue of our participation in the Opioid PMR Consortium ("OPC"). Although we retain discretion in how to discharge such PMRs, the scale and scope of the studies required by the FDA make it cost prohibitive to discharge these requirements other than by joining the OPC that was formed to conduct them. We are a member of OPC and engage in decision-making as a member of that organization, but do not have a majority. If the OPC fails to conduct sufficiently rigorous studies or is unable to achieve the patient enrollment or other requirements established by the FDA, we may be unable to satisfy our PMRs and the FDA may choose to withdraw or otherwise restrict its approval of our products. Such withdrawal or restriction would have an adverse impact on our business and financial condition.

In the future, we may depend on collaborations with third parties for the development and commercialization of our products. If those collaborations are not successful, we may not be able to capitalize on the market potential of these products.

We may not be successful in establishing development and commercialization collaborations, which could adversely affect, and potentially prohibit, our ability to develop or commercialize our products. These collaborations pose the following risks to us:

- Collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations.
- Collaborators may not pursue development and commercialization of our product or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities.
- Collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon our product, repeat or conduct new clinical trials or require a new formulation of our product for clinical testing.
- Collaborators may fail to obtain necessary regulatory approval, conduct clinical trials inappropriately, or may obtain unfavorable results in their clinical trials, which may have an adverse effect on the development or commercialization of our product.
- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.
- A collaborator with marketing and distribution rights to our products may not commit sufficient resources to the marketing and distribution of such products.
- Collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation.
- Disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or that result in costly litigation or arbitration that diverts management attention and resources.
- We may lose certain valuable rights under circumstances specified in our collaborations.

- Collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable products.

- Collaboration agreements may not lead to development or commercialization of products in the most efficient manner or at all. If a future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

- Our ability to successfully commercialize products pursuant to collaboration agreements may be adversely affected by disputes or delays arising from supply and/or manufacturing agreements between such collaborators and third parties—agreements to which we may not be a party.

We rely on third parties to conduct our non-clinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or if they terminate their agreement with us, we may not be able to maintain regulatory approval for our products and our business could suffer a material adverse effect.

We have relied upon and plan to continue to rely upon contract research organizations ("CROs") to monitor and manage data for our ongoing non-clinical and clinical programs. We rely on these parties for execution of our non-clinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and clinical trials are conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with federal regulations and current good clinical practices ("GCP"), which are international standards meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, advisors and monitors, enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and foreign regulatory authorities in the form of International Conference on Harmonization guidelines for all of our products. We are also subject to GLP requirements for our non-clinical study programs. Regulatory authorities enforce GCP and GLP through periodic inspections of trial sponsors, principal investigators, trial sites and animal study sites. In addition, we and our CROs are required to comply with special regulations regarding the enrollment of recreational drug abusers in clinical trials. If we or any of our CROs fail to comply with applicable GCP and other regulations, including as a result of any recent changes in such regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. While we have agreements governing activities of our CROs, we have limited influence over their actual performance. Failure to comply with applicable regulations in the conduct of the clinical trials for our products may require us to repeat preclinical studies and clinical trials, which would have an adverse impact on our commercial efforts.

Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for our products. As a result, the commercial prospects for our products would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus, and there is a limited number of CROs that are equipped and willing to manage clinical trials that involve recreational drug abusers. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the patients participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. Identifying, qualifying and managing performance of third-party service providers can be difficult, time-consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. Though we carefully manage our relationships with our CROs,

there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. If any of our relationships with our CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines.

Our internal capacity to perform these functions is limited. Outsourcing these functions involves risks that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our ability to advance our products through clinical trials will be compromised. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

Risks Related to Our Business and Strategy

Our business may be adversely affected by the COVID-19 pandemic.

In December 2019, COVID-19 was reported to have surfaced in Wuhan, China. As of May 7, 2020, COVID-19 has spread to other countries, including the United States, and has been declared to be a pandemic by the World Health Organization. The United States has declared a national emergency and efforts to contain the spread of COVID-19 have intensified, including “shelter in place” or similar orders by state governments, the closing of non-essential businesses and severe travel restrictions imposed by the U.S. government related to China and Europe. The outbreak and any preventative or protective actions that we, our manufacturers, suppliers, licensors and other collaborators or governmental authorities may take with respect to the COVID-19 pandemic has disrupted and may continue to disrupt our business and the U.S. and global economies as a whole. We are diligently working to limit the disruption to our operations, and to mitigate the impact of the COVID-19 pandemic on our employees’ health and safety. However, the COVID-19 pandemic poses the risk that we or our employees, contractors, suppliers, and other partners may be prevented from conducting business activities for an indefinite period of time, including due to a substantial percentage of personnel contracting the virus or due to shutdowns that have been or may be requested or mandated by governmental authorities. Given the interconnectivity of the global economy and the possible rate of future global transmission, the full extent to which the COVID-19 pandemic could affect the U.S. and global economies is unknown and its impact may extend beyond the areas which are currently known to be impacted.

The COVID-19 pandemic has and will likely continue to have a substantial impact on the delivery of healthcare services in the United States. Hospitals have begun to reduce and divert staffing, divert resources to patients suffering from COVID-19 and limit hospital access for non-patients, including our sales professionals. In addition, as discussed above, travel restrictions due to COVID-19 have impacted our sales professionals’ ability to travel to customers, which will have a negative impact on our sales and the market penetration of our products. Moreover, the spread of COVID-19 has had, and may continue to have, an impact on the number of patients seeking and receiving treatment for conditions that might otherwise result in the prescription of our products, as patients increasingly make efforts to avoid or postpone seeking non-essential medical care and hospitals cancel elective surgeries due to the COVID-19 pandemic. These circumstances may result in reduced demand for our products and negatively impact our sales and results of operations.

The extent to which the COVID-19 pandemic impacts our results of operation will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19, the ultimate geographic spread of COVID-19, the duration of the pandemic, travel restrictions imposed by the United States and other countries, business closures or business disruption in the United States and other countries, a reduction in time spent out of home and the actions taken throughout the world, including in our markets, to contain COVID-19 or treat its impact. We do not yet know the full extent of potential delays or impacts on our business, our commercialization efforts, healthcare systems or the global economy as a whole. However, these effects could have a material adverse impact on our business, financial condition and results of operations, and we will continue to monitor the effects of the COVID-19 pandemic closely.

Litigation or regulatory action regarding opioid medications could negatively affect our business.

Beginning in 2018, lawsuits alleging damages related to opioids have been filed naming us as a defendant along with other manufacturers of prescription opioid medications. These lawsuits, filed in multiple jurisdictions, are brought by various local governments as well as private claimants, against various manufacturers, distributors and retail pharmacies throughout the United States. These lawsuits generally contend that we have engaged in improper marketing practices related to Xtampza ER and the Nucynta Products. Plaintiffs seek a variety of remedies, including abatement, restitution, civil penalties, disgorgement of profits, treble damages, attorneys' fees and injunctive relief. In some of the lawsuits, the plaintiffs are seeking joint and several liability among the defendants. None of the complaints specify the exact amount of damages at issue. These cases are generally in early stages of litigation.

In addition, certain governmental and regulatory agencies are focused on the abuse of opioid medications, a concern we share, and we have received Civil Investigation Demands or subpoenas from four state attorneys general, investigating our sales and marketing of opioids and seeking documents relating to the manufacture, marketing and sale of opioid medications. We are cooperating fully in these investigations. Managing litigation and responding to governmental investigations is costly and may involve a significant diversion of management attention. Such proceedings are unpredictable and may develop over lengthy periods of time. An adverse resolution of any of these lawsuits or investigations may involve injunctive relief or substantial monetary penalties, either or both of which could have a material adverse effect on our reputation, business, results of operations and cash flows.

We face substantial competition from other biotechnology and pharmaceutical companies, which may result in others discovering, developing or commercializing products more successfully than we do.

The competition in the pain and opioid market is intense. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions.

Our products compete with oral opioids, transdermal opioids, local anesthetic patches, stimulants and implantable and external infusion pumps that can be used for infusion of opioids and local anesthetics. Products of these types are marketed by Actavis, BioDelivery Sciences, Endo, Mallinckrodt, Pfizer, Purdue, Teva, and others. Some of these current and potential future competitors may be addressing the same therapeutic areas or indications as we are. Many of our current and potential future competitors have significantly greater research and development capabilities than we do, have substantially more marketing, manufacturing, financial, technical, human and managerial resources than we do, and have more institutional experience than we do. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors.

Our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that allow them to develop and commercialize their products before us and limit our ability to develop or commercialize our products. Our competitors may also develop drugs that are safer, more effective, more widely used and less costly than ours, and they may also be more successful than us in manufacturing and marketing their products.

Our competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competitive products. Some of these products may have an entirely different approach or means of accomplishing similar therapeutic effects than our products. Our competitors may develop products that are safer, more effective or less costly than our products and, therefore, present a serious competitive threat to our product offerings.

The widespread acceptance of currently available therapies with which our products compete may limit market acceptance of our products. Oral medications, transdermal drug delivery systems, such as drug patches, injectable products and implantable drug delivery devices are currently available treatments for chronic pain, are widely accepted in the medical community and have a long history of use. These treatments will compete with our products and the established use of these competitive products may limit the potential for our products to receive widespread acceptance.

Our future success depends on our ability to retain our key personnel.

We are highly dependent upon the services of our key personnel, including our President and Chief Executive Officer, Joseph Ciaffoni, our Chief Technology Officer, Alison Fleming, PhD, our Chief Financial Officer, Paul Brannelly, our Chief Commercial Officer, Scott Dreyer, our General Counsel, Shirley Kuhlmann, and our Chief Medical Officer, Richard Malamut, M.D. Each employee is employed by us at will and is permitted to terminate his or her employment with us at any time pursuant to the terms of his or her employment agreement. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of Mr. Ciaffoni, Dr. Fleming, Mr. Brannelly, Mr. Dreyer, Ms. Kuhlmann or Dr. Malamut could impede the achievement of our development and commercialization objectives.

If we are unable to attract and retain highly qualified employees, we may not be able to achieve future success.

Our future growth and success depend on our ability to recruit, retain, manage and motivate our scientific, clinical, manufacturing and commercial employees. The loss of any member of our senior management team or the inability to hire or retain experienced management personnel could compromise our ability to execute our business plan and harm our operating results. Because of the specialized nature of our business, we rely heavily on our ability to attract and retain qualified personnel. The competition for qualified personnel in the pharmaceutical field is intense, and as a result, we may be unable to continue to attract and retain qualified personnel necessary to execute business or to recruit suitable replacement personnel.

We may acquire other assets or businesses, or form collaborations or make investments in other companies or technologies, which could have a material adverse effect on our operating results, dilute our shareholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of assets, including preclinical, clinical or commercial stage products or businesses, in-licensing or out-licensing of products or technologies, or other strategic alliances and collaborations, to expand our existing technologies and operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any such transaction, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. We have limited experience with acquiring other companies, products or product candidates, and limited experience with licensing and forming strategic alliances and collaborations. We may not find suitable acquisition candidates, and if we make an acquisition, we may not integrate the acquisition successfully into our existing business and we may incur additional debt or assume unknown or contingent liabilities in connection therewith. Integration of an acquired company or assets may also disrupt ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, especially the acquisition of commercial assets, and require management resources that would otherwise focus on developing our existing business. We may not be able to find suitable strategic alliances or collaborators or identify other investment opportunities, and we may experience losses related to any such investments.

To finance any acquisitions, licenses or collaborations, we may incur significant transaction expenses and we may choose to issue debt or shares of our common or preferred stock as consideration. Any such issuance of shares would dilute the ownership of our shareholders. If the price of our common stock is low or volatile, we may not be able to acquire, license, or otherwise obtain rights to other assets or companies or fund a transaction using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

Commercial sales of our products and clinical trials of our products and any future product candidates may expose us to expensive product liability claims, and we may not be able to maintain product liability insurance on reasonable terms or at all.

We currently carry product liability insurance. Product liability claims may be brought against us by patients, healthcare providers, others using, administering or selling our products or patients enrolled in our clinical trials. If we cannot successfully defend ourselves against claims that our products caused injuries, we could incur substantial liabilities. We

may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any products;
- injury to our reputation and significant negative media attention;
- significant costs to defend the related litigation;
- substantial monetary awards to patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations;
- termination of clinical trial sites or entire trial programs;
- withdrawal of clinical trial participants;
- regulatory or legislative actions that significantly impact the opioid market;
- the inability to commercialize our products; and
- an increase in product liability insurance premiums or an inability to maintain product liability insurance coverage.

Our inability to maintain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our products. Any agreements we may enter into in the future with collaborators in connection with the development or commercialization of our products may entitle us to indemnification against product liability losses, but such indemnification may not be available or adequate should any claim arise. In addition, many of our agreements require us to indemnify third parties and these indemnification obligations may exceed the coverage under our product liability insurance policy.

Our products may be associated with undesirable adverse reactions or have other properties that could result in significant negative consequences.

Undesirable adverse reactions associated with our products could cause us, institutional review boards, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in a restrictive product label or the delay, denial or withdrawal of regulatory approval by the FDA. For example, even though Xtampza ER was generally well tolerated by patients in our clinical trials, in some cases there were adverse reactions, one of which was a serious adverse event, moderate in severity, of gastroesophageal reflux.

If we or others identify undesirable adverse events associated with our products, a number of potentially significant negative consequences could result, including:

- we may be forced to suspend marketing of the product;
- regulatory authorities may withdraw their approvals of the product or impose restrictions on its distribution;
- regulatory authorities may require additional warnings or contradictions in the product label that could diminish the usage or otherwise limit the commercial success of the product;

- we may be required to conduct additional post-marketing studies;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our products.

Our employees, independent contractors, principal investigators, CROs, CMOs, wholesalers, distributors, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, CMOs, wholesalers, distributors, consultants and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates:

- FDA, DEA or similar regulations of foreign regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities;
- manufacturing standards;
- federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by foreign regulatory authorities; or
- laws that require the reporting of financial information or data accurately.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Ethics, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material adverse effect on our business and results of operations, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could have a material adverse effect on our ability to operate our business and our results of operations.

Our relationships with customers and payors are subject to applicable anti-kickback, fraud and abuse, transparency, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings.

Healthcare providers, physicians and payors play a primary role in the recommendation and prescription of our products. Our arrangements with payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products and any product candidates for which we may obtain marketing approval. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other

third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations may affect our ability to operate and expose us to areas of risk, including:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal False Claims Act, which imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute to defraud any healthcare benefit program or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- federal laws requiring drug manufacturers to report annually information related to certain payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership or investment interests held by physicians and their immediate family members, including under the federal Open Payments program, commonly known as the Sunshine Act, as well as other state laws regulating marketing activities and requiring manufacturers to report marketing expenditures, payments and other transfers of value to physicians and other healthcare providers;

- federal government price reporting laws, which require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on our marketed drugs. Participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs, potential liability for the failure to report such prices in an accurate and timely manner, and potentially limit our ability to offer certain marketplace discounts; and

- state equivalents of each of the above laws, including 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 payors, including private insurers; state laws which require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restricting payments that may be made to healthcare providers; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

While we do not submit claims and our customers will make the ultimate decision on how to submit claims, we may provide reimbursement guidance and support regarding our products to our customers and patients. If a government authority were to conclude that we provided improper advice to our customers and/or encouraged the submission of false claims for reimbursement, we could face action by government authorities. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Nonetheless, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur significant costs.

In connection with our research and development activities and our manufacture of materials and products, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our research and development involves the use, generation and disposal of hazardous materials, including chemicals, solvents, agents and biohazardous materials. Although we believe that our safety procedures for storing, handling and disposing of such materials comply with the standards prescribed by state and federal regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. We currently contract with third parties to dispose of these substances that we generate, and we rely on these third parties to properly dispose of these substances in compliance with applicable laws and regulations. We cannot eliminate the risk of contamination or injury from these materials. If these third parties do not properly dispose of these substances in compliance with applicable laws and regulations, we may be subject to legal action by governmental agencies or private parties for improper disposal of these substances. The costs of defending such actions and the potential liability resulting from such actions are often very large. In the event we are subject to such legal action or we otherwise fail to comply with applicable laws and regulations governing the use, generation and disposal of hazardous materials and chemicals, we could be held liable for any damages that result, and any such liability could exceed our resources.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, this insurance may not provide adequate coverage against potential liabilities. We maintain insurance for environmental liability or toxic tort claims, but we may not continue to maintain such insurance in the future, and such insurance, to the extent maintained, may not be adequate to cover liabilities that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

Our business and operations would suffer in the event of computer system failures, accidents or security breaches.

Despite the implementation of security measures, our internal computer systems, and those of our CROs, contract manufacturing organization and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks and other malfeasance, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our commercial and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our commercialization and drug development programs. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further commercialization of our products could be delayed.

Changes in data privacy and protection laws and regulations, or any failure to comply with such laws and regulations, could adversely affect our business and financial results.

Legislators and regulators in the U.S. are proposing new and more robust cybersecurity rules in light of the recent broad-based cyberattacks at a number of companies. These initiatives could increase the cost of developing, implementing or securing our servers and require us to allocate more resources to improved technologies, adding to our information technology and compliance costs. In addition, enforcement actions and investigations by regulatory authorities related to data security incidents and privacy violations continue to increase. The enactment of more restrictive laws, rules, regulations, or future enforcement actions or investigations could impact us through increased costs or restrictions on our business, and noncompliance could result in regulatory penalties and significant legal liability.

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

Natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage, health epidemic (such as the ongoing COVID-19 pandemic) or other event occurred that prevented us from using all or a significant portion of our facilities, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time.

The disaster recovery and business continuity plans we have in place, and the technology that we may rely upon to implement such plans, may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business, financial condition and results of operation.

Risks Related to Our Common Stock

The price of our common stock may be volatile and you may lose all or part of your investment.

The market price of our common stock is highly volatile and may be subject to wide fluctuations in response to numerous factors, some of which are beyond our control. In addition to the factors discussed in these Risk Factors, these factors include:

- the success of competitive products or technologies;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our growth rate;
- the outcome of any patent infringement or other litigation that may be brought by or against us, including the ongoing Purdue and Teva litigation matters;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- results of clinical trials of our products or those of our competitors;
- regulatory or legal developments in the United States;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;

- the recruitment or departure of key personnel;
- the level of expenses related to our products or clinical development programs;
- actual or anticipated variations in our quarterly operating results;
- the number and characteristics of our efforts to in-license or acquire additional products;
- introduction of new products or services by us or our competitors;
- failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other shareholders;
- changes in accounting practices;
- significant lawsuits, including patent or shareholder litigation;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions;
- publication of research reports about us, our competitors or our industry, or positive or negative recommendations or withdrawal of research coverage by securities or industry analysts; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including very recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks stated above could have a material adverse effect on the market price of our common stock.

As we operate in the pharmaceutical and biotechnology industry, we are especially vulnerable to these factors to the extent that they affect our industry or our products. In the past, securities class action litigation has often been initiated

against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

Actual or potential sales of our common stock by our directors or employees, including our executive officers, pursuant to pre-arranged stock trading plans or otherwise could cause our stock price to fall or prevent it from increasing for numerous reasons, and actual or potential sales by such persons could be viewed negatively by investors.

In accordance with the guidelines specified under Rule 10b5-1 of the Exchange Act and our policies regarding stock transactions, our directors and employees, including our executive officers, could adopt stock trading plans pursuant to which they may sell shares of our common stock from time to time in the future. Generally, sales under such plans by our executive officers and directors require public filings. Actual or potential sales of our common stock by such persons could cause our common stock to fall or prevent it from increasing for numerous reasons. For example, a substantial number of shares of our common stock becoming available (or being perceived to become available) for sale in the public market could cause the market price of our common stock to fall or prevent it from increasing. Also, actual or potential sales by such persons could be viewed negatively by investors.

Future issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our shareholders and could cause our stock price to fall.

Significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell substantial amounts of common stock or securities convertible into or exchangeable for common stock. These future issuances of common stock or common stock-related securities, together with the exercise of outstanding options and any additional shares issued in connection with acquisitions, if any, may result in material dilution to our investors. Such sales may also result in material dilution to our existing shareholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock.

We are subject to anti-takeover provisions in our amended and restated articles of incorporation and amended and restated bylaws and under Virginia law that could delay or prevent an acquisition of our company, even if the acquisition would be beneficial to our shareholders.

Certain provisions of Virginia law, the state in which we are incorporated, and our amended and restated articles of incorporation and amended and restated bylaws could hamper a third party's acquisition of us, or discourage a third party from attempting to acquire control of us. These provisions include:

- a provision allowing our Board of Directors to set the terms of and issue preferred stock with rights senior to those of the common stock without any vote or action by the holders of our common stock. The issuance of preferred stock could adversely affect the rights and powers, including voting rights, of the holders of common stock;
- advance written notice procedures and notice requirements with respect to shareholder proposals and shareholder nomination of candidates for election as directors;
- a provision that only the Board of Directors, the chairman of the Board of Directors or the president may call a special meeting of the shareholders;
- the application of Virginia law prohibiting us from entering into certain transactions with the beneficial owner of more than 10% of our outstanding voting stock for a period of three years after such person first reached that level of stock ownership, unless certain conditions are met;
- a provision dividing our Board of Directors into three classes, each serving three-year terms;

- the requirement that the authorized number of our directors be changed only by resolution of our Board of Directors;
- a provision that our Board of Directors shall fill any vacancies on our Board of Directors, including vacancies resulting from a Board of Directors' resolution to increase the number of directors;
- limitations on the manner in which shareholders can remove directors from the Board of Directors;
- the lack of cumulative voting in the election of directors; and
- the prohibition on shareholders acting by less-than-unanimous written consent.

These provisions also could limit the price that certain investors might be willing to pay in the future for shares of our common stock. In addition, these provisions make it more difficult for our shareholders to remove our Board of Directors or management or elect new directors to our Board of Directors.

We may fail to qualify for continued listing on The NASDAQ Global Select Market which could make it more difficult for investors to sell their shares.

Our common stock is listed on The NASDAQ Global Select Market ("NASDAQ"). As a NASDAQ listed company, we are required to satisfy the continued listing requirements of NASDAQ for inclusion in the Global Select Market to maintain such listing, including, among other things, the maintenance of a minimum closing bid price of $1.00 per share and shareholders' equity of at least $10.0 million. There can be no assurance that we will be able to maintain compliance with the continued listing requirements or that our common stock will not be delisted from NASDAQ in the future. If our common stock is delisted by NASDAQ, we could face significant material adverse consequences, including:

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

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

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting. We are required, under Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment must include disclosure of

any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting.

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

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations reflect the reality that judgments can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

The exercise of options and warrants and other issuances of shares of common stock or securities convertible into or exercisable for shares of common stock will dilute your ownership interests and may adversely affect the future market price of our common stock.

Sales of our common stock in the public market, either by us or by our current shareholders, or the perception that these sales could occur, could cause a decline in the market price of our securities. All of the shares of our common stock held by those of our current shareholders may be immediately eligible for resale in the open market either in compliance with an exemption under Rule 144 promulgated under the Securities Act, or pursuant to an effective resale registration statement that we have previously filed with the SEC. Such sales, along with any other market transactions, could adversely affect the market price of our common stock.

As of March 31, 2020, there were outstanding options to purchase an aggregate of 4,034,214 shares of our common stock at a weighted average exercise price of $17.44 per share, of which options to purchase 1,916,510 shares of our common stock were then exercisable. In addition, as of March 31, 2020, we had an outstanding warrant with Assertio to purchase 1,041,667 shares of our common stock at an exercise price of $19.20 per share. The exercise of options and warrants at prices below the market price of our common stock could adversely affect the price of shares of our common stock. Additional dilution may result from the issuance of shares of our common stock in connection with collaborations or manufacturing arrangements or in connection with other financing efforts.

Any issuance of our common stock that is not made solely to then-existing shareholders proportionate to their interests, such as in the case of a stock dividend or stock split, will result in dilution to each shareholder by reducing his, her or its

percentage ownership of the total outstanding shares. Moreover, if we issue options or warrants to purchase our common stock in the future and those options or warrants are exercised you may experience further dilution. Holders of shares of our common stock have no preemptive rights that entitle them to purchase their pro rata share of any offering of shares of any class or series.

We have broad discretion in the use of our cash and cash equivalents, and, despite our efforts, we may use them in a manner that does not increase the value of our shareholders' investment.

We have broad discretion in the use of our cash and cash equivalents, and investors must rely on the judgment of our management regarding the use of our cash and cash equivalents. Our management may not use cash and cash equivalents in ways that ultimately increase the value of our common stock. Our failure to use our cash and cash equivalents effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the commercialization of our products. We may invest our cash and cash equivalents in short-term or long-term, investment-grade, interest-bearing securities. These investments may not yield favorable returns. If we do not invest or apply our cash and cash equivalents in ways that enhance shareholder value, we may fail to achieve expected financial results, which could cause the price of our common stock to decline.

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

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our capital stock will be our shareholders' sole source of gain for the foreseeable future.

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

RECENT SALES OF UNREGISTERED SECURITIES

There were no unregistered sales of equity securities during the period covered by this Quarterly Report on Form 10-Q.

PURCHASE OF EQUITY SECURITIES

The following table sets forth purchases of our common stock for the three months ended March 31, 2020:

Period	(a) Total number of shares purchased [1]	(b) Average Price Paid per Share	(c) Total number of shares purchased as part of publicly announced plans or programs	(d) Maximum number of shares that may yet be purchased under the plans or programs
January 1, 2020 through January 31, 2020	3,008	$ 21.61	-	-
February 1, 2020 through February 29, 2020	59,098	$ 21.62	-	-
March 1, 2020 through March 31, 2020	958	$ 15.92	-	-
Total	63,064	$ 21.53	-	-

(1) All of the shares were transferred to us from employees in satisfaction of minimum tax withholding obligations associated with the vesting of restricted stock units during the period.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits.

Exhibit Number	Exhibit Description
4.1	Indenture, dated as of February 13, 2020, between Collegium Pharmaceutical, Inc. and The Bank of New York Mellon Trust Company, N.A., as trustee.(1)
4.2	First Supplemental Indenture, dated as of February 13, 2020, between Collegium Pharmaceutical, Inc. and The Bank of New York Mellon Trust Company, N.A., as trustee.(1)
4.3	Form of certificate representing the 2.625% Convertible Senior Notes due 2026 (included as Exhibit A to Exhibit 10.2).(1)
10.1	Purchase Agreement, dated as of February 6, 2020, by and between Collegium Pharmaceutical, Inc. and Assertio Therapeutics, Inc.(2)
10.2	Loan Agreement, dated as of February 6, 2020, by and among the Company, its subsidiaries, BioPharma Credit PLC, as collateral agent and lender, and BioPharma Credit Investments V (Master) LP, as lender.(2)
10.3	First Amendment to Loan Agreement, dated as of February 24, 2020, by and among the Company, its subsidiaries, BioPharma Credit PLC, as collateral agent and lender, and BioPharma Credit Investments V (Master) LP, as lender.(filed herewith)
10.4*	License Agreement (U.S.), dated as of January 13, 2015, by and among Grünenthal GmbH, Janssen Research & Development, LLC, Assertio Therapeutics, Inc. and Collegium Pharmaceutical, Inc. (filed herewith).
10.5*	Consent Agreement, dated January 30, 2020, by and among Grünenthal GmbH, Assertio Therapeutics, Inc. and Collegium Pharmaceutical, Inc. (filed herewith).
10.6	Amended and Restated Bylaws of Collegium Pharmaceutical, Inc.(3)
31.1	Certification of Chief Executive Officer pursuant to Rules 13a- 14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2	Certification of Chief Financial Officer pursuant to Rules 13a- 14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
101.INS	Inline XBRL Instance 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	The cover page from Collegium Pharmaceutical's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, formatted in Inline XBRL

* Certain portions of the exhibits that are not material and would be competitively harmful if publicly disclosed have been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K. Copies of the unredacted exhibits will be furnished to the Commission upon request.

(1) Previously filed as an exhibit to the registrant's Current Report on Form 8-K filed with the Commission on February 13, 2020.

(2) Previously filed as an exhibit to the registrant's Current Report on Form 8-K filed with the Commission on February 10, 2020.

(3) Previously filed as an exhibit to the registrant's Current Report on Form 8-K filed with the Commission on December 4, 2017

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.

COLLEGIUM PHARMACEUTICAL, INC.

Date:	May 7, 2020	By:	/s/ JOSEPH CIAFFONI Joseph Ciaffoni *Chief Executive Officer* *(Principal executive officer)*
Date:	May 7, 2020	By:	/s/ PAUL BRANNELLY Paul Brannelly *Chief Financial Officer* *(Principal financial and accounting officer)*

FIRST AMENDMENT
TO
LOAN AGREEMENT

This First Amendment to the Loan Agreement (defined below) (this "**Amendment**"), dated as of February 24, 2020 (the "**Effective Date**"), is entered into by and among COLLEGIUM PHARMACEUTICAL, INC., a Virginia corporation (as "**Borrower**"), the Guarantors from time to time party thereto, BIOPHARMA CREDIT PLC, a public limited company incorporated under the laws of England and Wales (as the "**Collateral Agent**" and a "**Lender**") and BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP, a Cayman Islands exempted limited partnership (as a "**Lender**").

RECITALS

WHEREAS, Borrower, Lenders and the other parties thereto have entered into that certain Loan Agreement dated as of February 6, 2020 (the "**Loan Agreement**");

WHEREAS, Section 2.2(b) of the Loan Agreement requires generally that principal shall be repaid quarterly on the applicable Payment Dates and Section 2.3(a) of the Loan Agreement requires generally that interest shall be paid quarterly on the applicable Interest Dates;

WHEREAS, Borrower and Lenders have agreed that principal shall be repaid and interest shall be paid, generally, on the last day of each applicable calendar quarter; and

WHEREAS, in accordance with Section 11.5(a) of the Loan Agreement, Borrower and Lenders desire to amend the Loan Agreement on the terms and conditions set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the premises and intending to be legally bound by this Amendment, the undersigned hereby agrees and declares as follows:

SECTION 1. Definitions; Interpretation. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan Agreement. The rules of interpretation set forth in the first paragraph of Section 13.1 of the Loan Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2. Amendment to Loan Agreement.

(a) The Loan Agreement shall be amended by deleting in its entirety Section 2.2(b)(i) of the Loan Agreement and replacing it as follows:

"(i) Subject to clause (ii) below, with respect to each Term Loan, Borrower shall make equal quarterly payments of principal of such Term Loan commencing on the first Payment Date on or immediately following the 3rd-month anniversary of the Closing Date and continuing on each subsequent Payment Date; provided, that if any such Payment Date is not a Business Day, the applicable payment shall be due and payable on the first Business Day immediately after such date."

(b) The Loan Agreement shall be amended by deleting in its entirety Section 2.2(b)(ii) of the Loan Agreement and replacing it as follows:

"(ii) The amount of the outstanding aggregate principal amount of the Term Loans to prepaid with the Equity Proceeds Prepayment, if any, shall be applied to reduce the remaining amortization payments in the inverse order of maturity starting with the quarterly amortization payment payable on the Payment Date that is the Term Loan Maturity Date; or if such date is not a Business Day, on the first Business Day immediately after such date."

(c) The Loan Agreement shall be amended by deleting in its entirety the defined term "Payment Date" in Section 13.1 of the Loan Agreement and replacing it as follows:

""**Payment Date**" means, with respect to the Term Loans and as the context dictates: (a) the first Interest Date on or immediately following the 3rd-month anniversary of the Closing Date; (b) thereafter, each succeeding Interest Date; and (c) the Term Loan Maturity Date."

SECTION 3. Representations and Warranties; Reaffirmation.

(a) Borrower hereby represents and warrants to each Lender and the Collateral Agent as follows:

(i) Borrower has all requisite power and authority to enter into this Amendment and to carry out the transactions contemplated hereby.

(ii) This Amendment has been duly executed and delivered by Borrower and is the legally valid and binding obligation of Borrower, enforceable against Borrower in accordance with its respective terms, except as may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws relating to or limiting creditors' rights generally or by equitable principles relating to enforceability.

(iii) The execution, delivery and performance by Borrower of this Amendment have been duly authorized and do not (A) conflict with any of Borrower's Operating Documents, (B) contravene, conflict with, constitute a default under or violate any material Requirements of Law, (C) contravene, conflict or violate any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which Borrower or any of its Subsidiaries or any of its or their respective properties or assets may be bound, (D) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except such Governmental Approvals which have already been obtained and are in full force and effect), (E) constitute a material breach of or a material default or an event of default under, or result in or permit the termination or acceleration of, any Material Contract by which Borrower is bound or (F) require any approval of stockholders, members or partners or any approval or consent of any Person except for such approvals or consents which will be obtained on or before the date hereof.

(b) Borrower hereby ratifies, confirms, reaffirms, and acknowledges its obligations under the Loan Documents to which it is a party and agrees that the Loan Documents remain in full force and effect, undiminished by this Amendment, except as expressly provided herein. By

executing this Amendment, Borrower acknowledges that it has read, consulted with its attorneys regarding, and understands, this Amendment.

SECTION 4. References to and Effect on Loan Agreement. Except as specifically set forth herein, this Amendment shall not modify or in any way affect any of the provisions of the Loan Agreement, which shall remain in full force and effect and is hereby ratified and confirmed in all respects. On and after the Effective Date all references in the Loan Agreement to "this Agreement," "hereto," "hereof," "hereunder," or words of like import shall mean the Loan Agreement as amended by this Amendment.

SECTION 5. Governing Law; Venue; Jury Trial Waiver. THIS AMENDMENT SHALL BE GOVERNED BY, AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK, WITHOUT REGARD TO ANY PRINCIPLES OF CONFLICTS OF LAW THAT COULD REQUIRE THE APPLICATION OF THE LAW OF ANY OTHER JURISDICTION. Each of the Credit Parties, Lenders and the Collateral Agent submit to the exclusive jurisdiction of the courts of the State of New York sitting in New York County, and of the United States District Court of the Southern District of New York, and any appellate court from any thereof, and agrees that all claims in respect of any such action, litigation or proceeding may be heard and determined in such New York State court or, to the fullest extent permitted by Requirements of Law, in such Federal court; provided, however, that nothing in this Amendment shall be deemed to operate to preclude the Collateral Agent or any Lender from bringing suit or taking other legal action in any other jurisdiction to realize on the Collateral or any other security for the Obligations, or to enforce a judgment or other court order in favor of the Collateral Agent or any Lender. Each Credit Party expressly submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and each Credit Party hereby waives any objection that it may have based upon lack of personal jurisdiction, improper venue, or *forum non conveniens* and hereby consents to the granting of such legal or equitable relief as is deemed appropriate by such court. Each Credit Party hereby waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to such Credit Party at the address set forth in (or otherwise provided in accordance with the terms of) Section 9 of the Loan Agreement and that service so made shall be deemed completed upon the earlier to occur of such Credit Party's actual receipt thereof or three (3) Business Days after deposit in the U.S. mails, proper postage prepaid.

TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, EACH OF THE CREDIT PARTIES, LENDERS AND THE COLLATERAL AGENT WAIVES ITS RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS AMENDMENT OR ANY TRANSACTION CONTEMPLATED HEREBY, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR ALL PARTIES HERETO TO ENTER INTO THIS AMENDMENT. EACH PARTY HERETO HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

[Signature Page Follows]

IN WITNESS WHEREOF, each of the undersigned has caused this Amendment to be duly executed and delivered as of the date first above written.

COLLEGIUM PHARMACEUTICAL INC.,
as Borrower

By: _____

Name: Joseph Ciaffoni

Title: President and Chief Executive Officer

COLLEGIUM SECURITIES CORPORATION,
as an additional Credit Party

By: _____

Name: Joseph Ciaffoni

Title: President

BIOPHARMA CREDIT PLC,
as Collateral Agent and a Lender

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By _____
Name: Pedro Gonzalez de Cosio
Title: Managing Member

BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP,
as a Lender

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By _____
Name: Pedro Gonzalez de Cosio
Title: Managing Member

Exhibit 10.4

Execution Copy

LICENSE AGREEMENT (U.S.)

between GRÜNENTHAL GMBH

and

JANSSEN PHARMACEUTICALS, INC.

and

JANSSEN RESEARCH & DEVELOPMENT, LLC

Index

CERTAIN PORTIONS OF THE EXHIBIT THAT ARE NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED HAVE BEEN REDACTED PURSUANT TO ITEM 601(B)(10)(IV) OF REGULATION S-K. [***] INDICATES THAT INFORMATION HAS BEEN REDACTED.

EXHIBITS AND SIDE LETTERS	
EXHIBITS	
1.3	CG-5503
1.22	Fully Allocated Manufacturing Costs
1.29	Grünenthal Background Patents
1.63	Initial Regulatory Approval Preparation Plan
1.63.1	Additional Regulatory Approval Preparation Plan
6.5	Calculation of OMP Territory Earned Royalty
10.3 (b)	Cost Allocation Principles
11.6 (a), 1	FDA Form 1571 and Attachment for Section 13
11.6 (a), 2	Grünenthal IND Transfer Letter
11.6 (a), 3	J&J PRD IND Acceptance Letter
11.7(c)	Adverse Event Reporting Procedures for Product
SIDE LETTERS	
1	Supply of CG-5503 for Evaluation of ADF-Formulation
2	Exchange of Data/Information via IntraLinks
3	Delegation of Sponsorship to J&JPRD (Protocol R331333-PAI-2001)
4	Delegation of Sponsorship to J&JPRD (Protocol R331333-PAI-2003)
5a	Delegation of Sponsorship to J&JPRD (Protocol R331333-PAI-007 (J&JPRD) / HP5503/14 (Grünenthal))
5b	Agreement to Approach NPS Pharmaceuticals re U.S. Patent 6,071,970
6	Delegation of Sponsorship to J&JPRD (Protocol R331333-PAI-1005 (J&JPRD); HP5503/13 (Grünenthal))
7	Delegation of Sponsorship to J&JPRD (Protocol R331333-PAI-1002 (J&JPRD); HP5503/16 (Grünenthal), Protocol R331333-PAI-1006 (J&JPRD); HP5503/15 (Grünenthal) and Protocol R331333-PAI-1009 (J&JPRD); HP5503/20 (Grünenthal))
8	Delegation of Sponsorship to J&JPRD (Protocol R331333-PAI-1003 (J&JPRD); HP5503/17 (Grünenthal) and Protocol R331333-PAI-1004 (J&JPRD); HP5503/18 (Grünenthal))
9	Disclosure of Confidential Information to OMP Affiliates
10	Delegation of Sponsorship to J&JPRD (Protocol R331333-PAI-1010 (J&JPRD); HP5503/21 (Grünenthal))
11	Delegation of Sponsorship to J&JPRD (Protocol R331333-PAI-1016

CERTAIN PORTIONS OF THE EXHIBIT THAT ARE NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED HAVE BEEN REDACTED PURSUANT TO ITEM 601(B)(10)(IV) OF REGULATION S-K. [***] INDICATES THAT INFORMATION HAS BEEN REDACTED.

	(J&JPRD); HP5503/24 (Grünenthal))
12	Delegation of Sponsorship to J&JPRD (Protocol R331333-PAI-1011 (J&JPRD); HP5503/22 (Grünenthal))
13	KF5503/24 (Title: A One-Year, Randomized, Open-Label, Parallel-Arm, Phase Ill Long-Term Safety Trial, with Controlled Adjustment of Dose, of Multiple Doses of CG5503 PR and Oxycodone CR in Subjects with Chronic Pain); Clinical trial sponsored by J&J PRD, to be conducted in countries of the Grünenthal Territory
14	Clinical trials conducted by J&J PRD in countries of the Grünenthal Territory (namely Phase 1 studies and studies belonging to the ACUTE part of the program)
15	KF5503/16 (Title: A randomized withdrawal, active- and placebo- controlled, double-blind, multicenter Phase III trial assessing safety and efficacy of oral CG5503 PR* in subjects with moderate to sever chronic malignant tumor-related pain); Clinical trial sponsored by J&J PRD, to be conducted in countries of the J&J and the Grünenthal Territory
16a	KF5503/37; R331333-PAI-3017 (Title: A randomized, double-blind, parallel-group, multi-center, active- and placebo-controlled trial to evaluate the analgesic efficacy and safety of multiple doses of CG5503 IR for postoperative pain following bunionectomy); Clinical trial sponsored by Grünenthal and conducted in countries of the OMP Territory
16b	KF5503/38; R331333-PAI-3018 (Title: A Randomized, Double-Blind, Active- and Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy and Safety of Tapentadol Immediate-Release Formulation in the Treatment of Acute Paid From Bunionectomy); Clinical trial sponsored by J&J PRD and conducted in countries of the OMP Territory
17	Clinical Studies using Laser and Mechano-Somatosensory Evoked Potentials
18	Clinical Trial HP5503/62 Evaluation of the safety, tolerability and pharmacokinetics of a 100 mg tapentadol tamper-resistant prolonged- release tablet when the formulation is subjected to mastication compared to 100 mg tapentadol IR tablets swallowed intact in a population of healthy subjects; Clinical trial sponsored by J&J PRD, to be conducted in countries of the Grünenthal Territory
19	KF5503/59; R331333PAI2005: Open-Label Evaluation of the Pharmacokinetic Profile and Safety of Tapentadol Oral Solution for the Treatment of Postsurgical Pain in Children and Adolescents Aged From 6 to Less Than 18 Years, a clinical trial sponsored by J&JPRD, to be conducted in France as a country of the Grünenthal Territory, as well as in the United States, a country of the J&JPRD territory.
20	KF5503/62: A randomized, double-blind, placebo-controlled parallel group, multi-center trial to evaluate the efficacy and safety of multiple dose administration of an intravenous formulation of tapentadol in the treatment of acute pain following bunionectomy

21	KF5503/65; PAI3037: A evaluation of the efficacy and safety of tapentadol oral solution in the treatment of post-operative acute pain requiring opioid treatment in pediatric subjects aged from birth to less than 18 years old, a clinical trial sponsored by Janssen Research & Development, LLC (JRD), operational lead Grünenthal (GRT), to be conducted in countries of the Janssen Territory and Grünenthal Territory

LICENSE AGREEMENT (U.S.)

BETWEEN

GRÜNENTHAL GMBH

AND

JANSSEN PHARMACEUTICALS, INC.,

AND

JANSSEN RESEARCH & DEVELOPMENT, LLC

This License Agreement (U.S.) (the "**Agreement'**) is made by and between

Grünenthal GmbH, a German corporation having a principal place of business at Zieglerstraße 6, 52078 Aachen, mailing address 52099 Aachen, Germany ("**Grünenthal**"),

Janssen Pharmaceuticals, Inc. (successor in interest to Ortho-McNeil Pharmaceutical, Inc.), a Delaware corporation having a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey, 08560 ("**Ortho**"),

Janssen Research & Development, LLC, having a principal place of business at U.S. Route 202, Raritan, NJ 08869 ("**J&J PRD**") (Ortho and J&J PRD hereinafter collectively "**OMP**"), and

Johnson & Johnson, having a principal place of business at One Johnson & Johnson Plaza, New Brunswick, NJ 08933 ("**Johnson & Johnson**") as guarantor according to Article 19 of the Agreement.

Grünenthal and OMP may be referred to individually herein as a "Party" or together as the "**Parties**".

RECITALS

1. The Parties have previously entered into a License Agreement dated February 21, 2003, which License Agreement was amended as of December 23, 2004 and June 21, 2006 and then amended and restated in its entirety in an Amended and Restated License Agreement dated December 28, 2006, which Amended and Restated License Agreement was amended as of June 19, 2007, December 17, 2008, January 16, 2009, May 22, 2009, July 15, 2010 and May 29, 2013 (such Amended and Restated License Agreement, together with all amendments thereto, the "**Combined Territories License Agreement**").

2. The Combined Territories License Agreement granted certain licenses to OMP for Commercialization, Production, Regulatory Approval Preparation, Improvement Patents outside the Field and the right to sublicense for the United States, Canada and Japan.

4. The Parties have decided to separate the territories to which OMP received rights under the Combined Territories License Agreement and to amend and restate the Combined Territories License Agreement in two separate license agreements: this Agreement, relating to rights and obligations in the United States, and the Canada/Japan License Agreement (the "**Canada/Japan License Agreement**"), relating to rights and obligations in Canada and Japan.

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree to amend and restate the Parties' rights and obligations under the Combined Territories License Agreement with respect to the United States as follows:

LICENSE

AGREEMENT (U.S.)

between

GRÜNENTHAL GMBH

and

JANSSEN PHARMACEUTICALS, INC.

and

JANSSEN RESEARCH & DEVELOPMENT, LLC

January 13, 2015

LICENSE AGREEMENT (U.S.)

This License Agreement (U.S.) (this "**Agreement**") is effective as of January 13, 2015 (the "**Effective Date**") by and between Grünenthal GmbH, a German corporation having a principal place of business at Zieglerstraße 6, 52078 Aachen, mailing address 52099 Aachen, Germany ("**Grünenthal**"), Janssen Pharmaceuticals, Inc., a Delaware corporation having a principal place of business at 1125 Trenton- Harbourton Road, Titusville, New Jersey, 08560, and Janssen Research and Development LLC, having a principal place of business at U.S. Route 202, Raritan, NJ 08869 (hereinafter collectively "**OMP**").

Grünenthal and OMP may be referred to individually herein as a "**Party**" or together as the "**Parties**".

Terms not otherwise defined shall have the meaning ascribed to such terms in Article 1 of this Agreement.

a. RECITALS

1. Grünenthal has screened in a [***] program more than [***] compounds and has identified CG-5503 (hereinafter defined) as an interesting drug candidate.

2. Grünenthal has the sole and exclusive ownership of certain Patents claiming CG-5503.

3. Grünenthal has conducted in-vitro and in-vivo testing of CG-5503 and has conducted comprehensive pre-clinical, pharmacology, safety pharmacology toxicology tests of CG-5503.

4. Grünenthal has completed development of an iv, oral and oral slow-release formulation of CG-5503 and all necessary trials to establish proof of principle.

5. Grünenthal was the IND holder in the United States for the Product (hereinafter defined) and established in consultation with the FDA a testing schedule for the Product and conducted Phase I and Phase II clinical trials. The IND in the United States was transferred to OMP prior to the Effective Date.

6. Grünenthal has set up a clinical trial plan in order to obtain Regulatory Approval at approximately the same time in the United States and in the EU.

7. Grünenthal has to comply with the ICH Guidelines and Helsinki Declaration which seek to minimize the number of patients exposed to non-registered new drugs by not duplicating clinical trials in different regions of the world.

8. Grünenthal wants to ensure that the clinical trial plan for the Product in the USA and Canada and the EU is carried out on a consistent and comprehensive basis with a view to ensuring that the necessary Regulatory Approvals are obtained as early as practicable using the best available resources and facilities and in the most efficient and economic manner.

9. Grünenthal aims to Commercialize, by itself or through licensees, Product on a world-wide basis, but at the time of execution of the original Combined Territories License Agreement had no sales organization in the United States.

10. OMP has considerable experience in marketing, promotion, manufacturing and obtaining Regulatory Approvals for pain products in the United States.

11. Accordingly, Grünenthal wishes to grant to OMP, and OMP wishes to obtain from Grünenthal, a license to make, use and sell the Product in the United States.

12. Grünenthal seeks to ensure that it manages the global risk benefit analysis for the Product by pooling all global efficacy and safety data and presenting such to all relevant registration authorities, while acknowledging that certain Regulatory Authorities require studies to be conducted in their specific country.

13. In order to comply with all applicable regulatory rules and regulations and in order to obtain and maintain Regulatory Approvals, Grünenthal and OMP and its Affiliates in their respective Territories have concluded a separate pharmacovigilance agreement.to coordinate their activities, including, but not limited to adverse event reporting.

14. Within the clinical trial plan for achieving Regulatory Approval in the US and the EU which has been developed by Grünenthal and subsequently co-developed by OMP and Grünenthal, Grünenthal is prepared to allocate to, and OMP is prepared to accept, certain responsibilities and activities pertaining to the clinical trial plan so that the Product may be successfully Commercialized by each Party independently in their respective Territories.

15. OMP as licensee for the United States, representing approximately [***] of the world market, is prepared to contribute to the resources and costs of the Regulatory Approval Preparation by bearing [***] of such resources and costs.

16. OMP´s contribution to the Regulatory Approval Preparation is a substantial part of the consideration for the licenses being granted hereunder apart from upfront payments, milestone payments and royalty payments.

17. OMP and Grünenthal have agreed jointly to develop the Grünenthal-ADF- Formulation.

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

ARTICLE 1 DEFINITIONS

1.1 "**ADF Formulation**" means an abuse deterrent formulation or drug delivery system of the Product developed in accordance with RAP Plan 1.62 which includes the OMP-ADF-Formulation and the Grünenthal-ADF-Formulation, which through any of its physical, mechanical, chemical, pharmacokinetic, pharmacodynamic properties, has the potential to reduce abuse, diversion, or other inappropriate use of CG-5503.

1.2 "**Affiliate**" means, with respect to any person or entity, any other person or entity which controls, is controlled by or is under common control with such person or entity. A person or entity shall be regarded as in control of another entity if it owns or controls directly or indirectly at least fifty percent (50%) of the equity securities of the subject entity entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, for the election of the corresponding managing authority).

1.3 "**CG-5503**" means any composition of matter specified on **Exhibit 1.3**.

1.4 "**Combination Product**" means a pharmaceutical Product containing CG- 5503 in combination with one or more other active pharmaceutical ingredient
(s) but excluding New Chemical Entities.

1.5 "**Combination Product Market Exclusivity**" means on a country-by-country basis, the period of time during which, besides the respective Combination Product sold by OMP, there is no other combination product containing CG- 5503 in combination with the same active pharmaceutical ingredient(s) being

sold by a Third Party, other than Affiliates, in the OMP Territory, excluding such combination product containing CG-5503 from such Third Parties for which claims of infringement according to Section 7.9 have not led to a final, non-appealable decision of a court and claims of infringement are continuing to be pursued in court.

1.6 "**Combined Territories License Agreement Effective Date**" means February 21, 2003.

1.7 "**Commercialization**" means any and all activities constituting, using, importing, marketing, distributing, promoting, offering for sale, selling and having sold a Product. When used as a verb, "Commercialize" shall mean to engage in Commercialization.

1.8 "**Commercialization Team**" or "**CT**" shall have the meaning recited in Section 10.4.

1.9 "**Commercially Reasonable and Diligent Efforts**" means those efforts and resources normally used in the pharmaceutical business by [***] pharmaceutical companies for a product or compound owned by it or to which it has rights, which is of similar market potential at a similar stage in its development or product life, taking into account, without limitation, issues of safety and efficacy, product profile, pricing and reimbursement status, the proprietary position of, as applicable, CG-5503 in comparison to other products in a Party's product portfolio, the then prevailing regulatory environment and status with respect thereto, and relevant scientific and commercial factors.

1.10 "**Control**" or "**Controlled**" means the possession of the ability to grant a license or sublicense as provided for herein without violating the terms of any agreement or other arrangements with any Third Party. "Control" expressly includes the right of ownership, in whole or by more than fifty percent (50%).

1.11 "**Core Regulatory Approval Preparation Program**" or "**Core RAP Program**" means the development program for the Product designed to generate all preclinical, clinical and regulatory information required for filing Drug Approval

Applications in the United States, Canada, the EU and Japan. Territory Specific Regulatory Approval Preparation for countries not listed in this definition is not part of the Core Regulatory Approval Preparation Program, unless the Parties mutually agree as recited in Section 11.8.

1.12 "**Cost of Goods Sold**" or "**COGS**" means the Fully Allocated Manufacturing Costs of Product sold plus any royalties paid on such Product under Article 6.

1.13 "**Drug Approval Application**" means any application for Regulatory Approval required before commercial sale or use of a Product as a drug, biologic or therapeutic in a regulatory jurisdiction including, without limitation, reimbursement approvals.

1.14 "**EMEA**" means the European Agency for the Evaluation of Medicinal Products and any successor agency.

1.15 "**EU**" means the supra national community consisting of Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and United Kingdom of Great Britain and Northern Ireland and all other countries which after the Combined Territories License Agreement Effective Date become part of this supra national community. In addition and only for the purpose of this Agreement, Switzerland and the present and future European Economic Area countries (at present: Liechtenstein, Iceland and Norway) shall form part of this definition.

1.16 "**FDA**" means the United States Food and Drug Administration or any successor agency.

1.17 "**Field**" means the Regulatory Approval Preparation, use, manufacture, distribution, marketing and sale of Products for the [***].

1.18 "**First Commercial Sale**" means, with respect to a given Product, the first sale in an arms length transaction and shipment of a Product to a Third Party

other than an Affiliate by OMP in a country in the OMP Territory following applicable Regulatory Approval of the Product in such country.

1.19 "**FTE**" means a full time scientific person dedicated with appropriate credentials and training to the Regulatory Approval Preparation Plan, or in the case of less than a full-time dedicated scientific person, a full-time, equivalent scientific person year, based upon [***].

1.20 "**Fully Allocated Manufacturing Costs**" shall be as defined in **Exhibit 1.22**.

1.21 "**GCP**" means the then current standards for clinical trials for pharmaceuticals, as set forth in the ICH (as defined below) guidelines and applicable regulations promulgated thereunder, as amended from time to time, and such standards of good clinical practice as are required by the EU and other organizations and/or governmental agencies in countries in which a Product is intended to be sold, to the extent such standards are not less stringent than United States or EU GCP.

1.22 "**GLP**" means the then current standards for laboratory activities for pharmaceuticals, as set forth in the FDA's GLP regulations and/or the GLP principles of the Organization for Economic Co-operation and Regulatory Approval Preparation (OECD), as amended from time to time, and such standards of good laboratory practice as are required by the EU and other organizations and/or governmental agencies in countries in which a Product is intended to be sold, to the extent such standards are not less stringent than United States or EU GLP.

1.23 "**GMP**" means (i) the regulatory requirements for current good manufacturing practices promulgated by the FDA under the U.S. Food, Drug and Cosmetic Act, 21 C.F.R. § 210 et seq. ("**FD&C Act**") and under the Public Health Service Act, Biological Products, 21 C.F.R. §§ 600-610 ("**PHS Act**"), as the same may be amended from time to time; and (ii) such standards of good

manufacturing practice as are required by the EU and other organizations and/or governmental agencies in countries in which a Product is intended to be manufactured or sold, to the extent such standards are not less stringent than United States or EU GMP. Bulk development (active pharmaceutical ingredient "**API**") and commercial manufacturing will comply with the current ICH Q7A guidelines. During development phase, the clinical supplies for studies conducted in the US will comply with cGMP according to FDA. For studies conducted in the EU, clinical supplies will comply with annex 13 of the EU GMP guideline.

1.24 "**Grünenthal-ADF-Formulation**" means any formulation or drug delivery system which is a ADF Formulation useful for delivery of CG-5503 including, but not limited to, sustained release matrix tablet formulations of the Product and other formulations or drug delivery systems developed by or for Grünenthal based on Grünenthal technology or Grünenthal Know-How but specifically excluding an OMP-ADF-Formulation.

1.25 "**Grünenthal-ADF-Formulation Patent**" means any Patent Controlled by Grünenthal and claiming a Grünenthal-ADF-Formulation and/or Grünenthal- ADF-Formulation Improvement.

1.26 "**Grünenthal Know-How**" means Information which (i) Grünenthal discloses to OMP under this Agreement or specifically in anticipation of this Agreement; and (ii) is within the Control of Grünenthal, and (iii) is confidential as defined in Article 8.

1.27 "**Grünenthal Background Patent**" means any Patent filed, published or issued as of the Combined Territories License Agreement Effective Date relevant or pertaining to the Field which is directed to, but is not limited to, a method, apparatus, material, process of manufacture or use of CG-5503 or Product and which Patent is Controlled by Grünenthal or its Affiliates on the Combined Territories License Agreement Effective Date, however, not including Grünenthal-ADF-Formulation Patents. Grünenthal Background Patents include those listed in **Exhibit 1.29**.

1.28 "**Grünenthal Patents**" means Grünenthal Background Patents, Improvement Patents Controlled by Grünenthal and Grünenthal-ADF-Formulation Patents.

1.29 "**Grünenthal Territory**" means every country or political subdivision in the world, with the exception of OMP Territory.

1.30 "**ICH**" means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.31 "**Improvement**" means any improvement, enhancement or invention conceived and/or reduced to practice, as a result of activities carried out in connection with RAP, Commercialization or manufacture of Product, by employees or agents of the Parties or a Third Party under a contract with either Party or an Affiliate of either Party during the Term of this Agreement directed to CG-5503, Product or Combination Products, but explicitly excluding OMP Technology or ADF-Formulations.

1.32 "**Improvement Patents**" means any Patent claiming an Improvement.

1.33 "**IND**" means an investigational new drug application filed with the FDA as more fully defined in 21 C.F.R. §312.3 and in EU clinical trial authorisation (CTA) or its equivalent in any country.

1.34 "**Information**" means all information including screens, models, inventions, practices, methods, knowledge, know-how, skill, experience, test data including pharmacological, toxicological and clinical test data, analytical and quality control data and preliminary and final reports thereof, marketing, pricing, distribution, costs, sales, manufacturing data, and patent and legal data or descriptions (to the extent that disclosure thereof would result in loss or waiver of privilege or similar protection) and methods in each case relating to CG-5503 and/or the Product.

1.35 "**Management Committee**" or "**MC**" means a team consisting of the managing director responsible for research and development at Grünenthal and the President of research and development of OMP's Affiliate, Johnson & Johnson Pharmaceutical Research and Development, LLC.

1.36 "**Market Exclusivity**" means, on a country-by-country basis, the period of time during which there is no product containing CG-5503 being sold by a Third Party, other than Affiliates, in the OMP Territory, excluding such product containing CG-5503 from such Third Parties for which claims of infringement according to Section 7.9 have not led to a final, non-appealable decision of a court and such claims of infringement are continuing to be pursued in court.

1.37 "**NDA**" means a new drug application and all supplements filed pursuant to the requirements of the FDA, including all documents, data and other information concerning Product which are necessary for or included in, FDA approval to market a Product as more fully defined in 21 C.F.R. §314.50 et. seq.

1.38 "**Net Sales**" means the gross amount billed, as of the date of invoicing, by OMP or an Affiliate of OMP for sales of a Product to a Third Party which is other than an Affiliate less: to the extent actually allowed or taken for the OMP Territory

(a) normal and customary discounts, including cash discounts, discounts to managed care or similar organizations or government organizations, rebates paid, credited, accrued or actually taken, including government rebates such as Medicaid chargebacks or rebates, and retroactive price reductions or allowances actually allowed or granted from the billed amount, and commercially reasonable and customary fees paid to distributors (other than to a distributor that is an Affiliate of OMP),

(b) credits or allowances actually granted upon claims, rejections or returns of such sales of Products, including recalls, regardless of OMP requesting such recalls,

(c) freight, postage, shipping and insurance charges paid for delivery of such Product, to the extent billed separately on the invoice and paid by the buyer, and

(d) taxes, duties or other governmental charges levied on or measured by the billing amount when included in billing, as adjusted for rebates, charge-backs and refunds to the extent actually paid or allowed by the selling party; and

(e) actual uncollectible accounts receivables determined in accordance with U.S. generally accepted accounting practices, consistently applied.

1.39 "**New Chemical Entity**" means a chemical entity which has or is claimed to have therapeutic activity and is claimed in a composition of matter Patent in the United States or EU.

1.40 "**OMP-ADF-Formulation**" means any formulation or drug delivery system which is an ADF Formulation useful for the delivery of CG-5503 developed by or for OMP including, but not limited to, ADF Formulations based on OMP Technology, but specifically excluding a Grünenthal-ADF-Formulation.

1.41 "**OMP-ADF-Formulation Patent**" means any Patent Controlled by OMP and/or its Affiliates claiming an OMP-ADF-Formulation and/or OMP-ADF-Formulation Improvement.

1.42 "**OMP Know-How**" means Information which (i) OMP discloses to Grünenthal under this Agreement or specifically in anticipation of this Agreement; and (ii) is within the Control of OMP, and (iii) is confidential as defined in Article 8.

1.43 "**OMP Patent**" means any Patent filed, published or issued as of the Combined Territories License Agreement Effective Date, which Patent is Controlled by OMP and/or its Affiliates which would be infringed by the manufacture, use or sale of the Product, and OMP ADF-Formulation Patents and Improvement Patents Controlled by OMP or its Affiliates.

1.44 "**OMP Technology**" means an osmotic system for oral administration which is intended to function by releasing the active agent or agents on a controlled basis within the human gastrointestinal tract after being swallowed, or any component of such system to the extent it is used in the system, and which is Controlled by OMP or its Affiliates.

1.45 "**OMP Territory**" shall mean the United States.

1.46 "**OOP**" means out of pocket expenses related to the Regulatory Approval Preparation Plan and paid to Third Parties.

1.47 "**Patent**" means any issued patents, patent applications and patents issuing therefrom, together with any extensions, registrations, confirmations, reissues, continuations, divisions, continuations-in-part, reexaminations, substitutions or renewals thereof.

1.48 "**Phase I**" means the portion of the clinical program which provides for the first introduction into humans of a Product including small scale clinical studies conducted in normal volunteers or patients to obtain information relating to Product safety, tolerability, pharmacological activity or pharmacokinetics, as more fully defined in 21 C.F.R. 312.21 (a) and such definitions as used by the EU and other organizations and governmental agencies in countries in which the Product is intended to be tested.

1.49 "**Phase II**" means that portion of the clinical program which provides for the definitive, well controlled clinical trials of the Product in patients, including clinical studies conducted in patients and designated to indicate clinical efficacy safety, as well as to obtain an indication of the dosage regimen required as more fully defined in 21 C.F. R. 312.21(b) and such definitions as used by the EU and other organizations and governmental agencies in countries in which the Product is intended to be tested.

1.50 "**Phase III**" means that portion of the clinical program which provides for large scale clinical studies conducted in a sufficient number of patients to establish Product clinical efficacy for one or more indications and its safety, as more fully defined in 21 C.F.R. 312.21 (c) and such definitions as used by the EU and other organizations and governmental agencies in countries in which the Product is intended to be tested.

1.51 "**Phase IIIB**" means product support clinic trials of a Product commenced after the first Drug Approval Application is filed in the United States or the EU, which trials are directed to seeking Regulatory Approval for additional label claims.

1.52 "**Phase IV**" means product support clinical trials of a Product with an approved label claim commenced after receipt of Regulatory Approval for such Product in the country where such trial is being conducted.

1.53 "**Product**" means any pharmaceutical formulations for all and any human use within the Field containing CG-5503 as active pharmaceutical ingredient including Combination Product, but excluding combinations of CG-5503 with one or more New Chemical Entities.

1.54 "**Promotion**" means those activities, including, without limitation, congresses, opinion leader management, physicians meeting, professional education, detailing, advertising and distributing samples of a Product normally undertaken by a pharmaceutical company's sales force to implement marketing plans and strategies aimed at encouraging the appropriate use of a particular Product. When used as a verb, "Promote" shall mean to engage in Promotion.

1.55 "**Proportionate Share**" shall have the meaning set forth in Section 6.1(f).

1.56 "**Regulatory Approval**" means all official approvals by government, pricing, health or drug evaluation authorities (such as National Institute for Clinical Excellence in UK or Commission de Transparence in France) in a country (or supra-national organizations, such as the EMEA) which are required for first use or sale, including, importation, manufacture (where manufacture is required), pricing or reimbursement of a pharmaceutical product in such country where required.

1.57 "**Regulatory Approval Preparation**" or "**RAP**" means all activities performed by or on behalf of either Party with respect to a Product in the United States and the EU in connection with the Core Regulatory Approval Preparation Program or Core Pediatric Program necessary to obtain Regulatory Approval of a Product for the indication under study. "Regulatory Approval Preparation" shall include, without limitation, all activities related to clinical studies of a potential therapeutic in humans including, CM&C, preclinical testing, test method development and stability testing, toxicology, pharmacokinetics, pharmacoeconomic studies, mechanism studies, quality assurance/quality

control, clinical studies, clinical supplies, regulatory affairs, statistical analysis and report writing. When used as a verb, "**Prepare Regulatory Approval**" shall mean to engage in Regulatory Approval Preparation.

1.58 "**Regulatory Approval Preparation Budget**" or "**RAP Budget**" means the budget to carry out the Core Regulatory Approval Preparation Program as contained in the Regulatory Approval Preparation Plan.

1.59 "**Regulatory Approval Preparation Costs**" or "**RAP Costs**" means costs associated with Regulatory Approval Preparation of the Product according to the Core Regulatory Approval Preparation Program and as further defined in the Regulatory Approval Preparation Plan in **Exhibit 1.63 and Exhibit 1.63.1**.

1.60 "**Regulatory Approval Preparation Plan**" or "**RAP Plan**" means the plan and Regulatory Approval Preparation Budget describing the Core Regulatory Approval Preparation Program. An initial Regulatory Approval Preparation Plan is attached hereto as **Exhibit 1.63** and incorporated herein. An additional Regulatory Approval Preparation Plan is attached hereto as **Exhibit 1.63.1** and incorporated herein. All RAP Plans may be modified pursuant to Section 11.1(b).

As for this Agreement and unless otherwise specified the term "**RAP Plan**" shall mean the RAP Plan 1.63 and the RAP Plan 1.63.1 and the respective plans within the Core Pediatric Program.

1.61 "**RAP Subcommittee**" or "**RSC**" shall have the meaning recited in Section 10.3.

1.62 "**Regulatory Authority**" means any national (e.g., the FDA), supra-national (e.g., the European Commission, the Council of the European Union, or the EMEA), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity in each country of the world involved in the granting of Regulatory Approval.

1.63 "**Steering Committee**" or "SC" shall have the meaning set forth in Section 10.1.

1.64 "**Term**" shall have the meaning set forth in Section 15.1.

1.65 "**Territory**" means those countries, possessions, or political subdivision within, as applicable, the OMP Territory or the Grünenthal Territory.

1.66 "**Territory Specific Regulatory Approval Preparation**" or "**Territory Specific RAP**" is defined in Section 11.8.

1.67 "**Third Party**" means any entity other than Grünenthal and OMP.

1.68 "**Trade Secret**" means an Improvement for which deliberately a patent application has not been filed and which is confidential according to Article 8.

1.69 "**United States**" means the United States of America, the District of Columbia and Puerto Rico.

1.70 "**Valid Patent Claim**" means a claim in any unexpired Grünenthal Patent, which has not been held invalid by a non-appealed or unappealable decision by a court or other appropriate body of competent jurisdiction. The scope of a Valid Patent Claim shall be limited to its terms as set forth in the Patent itself and as further defined by any court, body or law of competent jurisdiction.

1.71 "**Year of Sale**" means a 365 day (or 366 day in a leap year) period. The "First Year of Sale" means the Year of Sale beginning on the date of the First Commercial Sale and ending 365 days (or 366 days in a leap year) thereafter.

1.72 "**Agreement**" means this License Agreement.

1.73 "**2004 First Amendment**" means the amendment of the Combined Territories License Agreement effective as of December 23, 2004.

1.74 "**1.63.1 ADF**" means an abuse deterrent formulation for the Product developed in accordance with RAP Plan 1.63.1.

1.75 "**1.63.1 Patents**" means any Patent Controlled by a Party and claiming a 1.63.1 ADF.

1.76 "**Commercial Supply Manufacturing License**" shall have the meaning set forth in Section 2.1(b).

1.77 "**Earned Royalty**" means the OMP Territory Earned Royalty.

1.78 "**Last Patent**" shall have the meaning set forth in Section 6.8(e).

1.79 "**Minimum Royalty for OMP Territory**" shall have the meaning set forth in Section 4.4(a).

1.80 "**Last Combo Patent**" shall have the meaning set forth in Section 6.8(f).

1.81 "**Minimum Royalty for OMP Territory**" shall have the meaning set forth in Section 4.4(a).

1.82 "**OMP Territory Earned Royalty**" shall have the meaning set forth in Section 6.4.

1.83 [Reserved]

1.84 [Reserved]

1.85 "**Responsible Party for Clinical Trials**" means the Party subsequently defined by mutual agreement of the Parties.

1.86 "**Study KF5503/21**" means the bunionectomy phase II b clinical study conducted prior to the Effective Date and referred to by the Parties as "Study KF5503/21."

1.87 [Reserved]

1.88 "**Grünenthal-ADF-Formulation Improvements**" means any improvement, enhancement or invention, other than an Independent ADF Formulation Improvement, conceived and/or reduced to practice, as a result of activities carried out within the scope of any regulatory approval preparation activities and the joint activities of Grünenthal and OMP for the development of the Grünenthal-ADF-Formulation, including but not limited to its manufacture and/or analytics based on Grünenthal technology and/or Grünenthal Know- How by employees or agents of the Parties or a Third Party under a contract with either Party or an Affiliate of either Party during the Term of this Agreement directed to Grünenthal-ADF-Formulation.

1.89 "**OMP-ADF-Formulation Improvements**" means any improvement, enhance- ment or invention, other than an Independent ADF Formulation Improvement, conceived and/or reduced to practice, as a result of activities carried out within the scope of the RAP activities and the joint activities of Grünenthal and OMP for the development of the OMP-ADF-Formulation, including but not limited to its manufacture and/or analytics based on OMP technology and/or OMP Know-How by employees or agents of the Parties or a Third Party under a contract with either Party or an Affiliate of either Party during the Term of this Agreement directed to OMP-ADF-Formulation.

1.90 "**Independent ADF Formulation Improvements"** means any improvement, enhancement or invention conceived and/or reduced to practice, by employees or agents of only one of the Parties or a Third Party under a contract with only one of the Parties or an Affiliate of only one of the Parties during the Term of this Agreement outside the scope of the RAP activities and the joint activities of Grünenthal and OMP for the development of an ADF Formulation as such party can prove by written records and thereafter introduced by such Party into the joint development of a ADF Formulation for the Product under this Agreement which improvement can be used in making not only an ADF Formulation but which can also be used in making other products including but not limited to its manufacture and/or analytics.

1.91 "**Independent ADF Formulation Improvement Patent**" means any Patent claiming an Independent ADF Formulation Improvement.

1.92 "**Phase IIIB2**" means product support clinical trials of the Product other than Phase IIIB, commenced after the first Drug Approval Application is filed in the United States or the EU and prior to receipt of Regulatory Approval in the US or the EU.

1.93 "**Core Pediatric Program**" means all pediatric program elements including preclinical and clinical studies, CM&C work packages and any activities for galenical forms necessary in both the OMP Territory and Grünenthal Territory for conducting clinical studies in pediatric patients, the results of which support Products resulting from either RAP Plan 1.63 and/ or 1.63.1. For the

avoidance of doubt, any element necessary in only one Party's Territory is not part of the Core Pediatric Program.

1.94 "**Post Approval Commitments**" means a study or data collection effort mandated by the applicable Regulatory Authority as a condition of Regulatory Approval in the US or the EU.

1.95 "**Risk Management Plan**" or "**RMP**" means a description of the product specific risk management system in addition to the general description of the pharmacovigilance system and more specific with regard to the EU the Guideline on Risk Management Systems for Medicinal Products for Human Use (EMENCHMP/96268/2005) and with regard to the United States FDA Guidance for Industry: Development and Use of Risk Minimization Action Plans, and a Risk Evaluation Mitigation and Strategy.

ARTICLE 2 LICENSE GRANTS

2.1 Licenses to OMP

(a) Licenses for Commercialization. Grünenthal hereby grants to OMP an exclusive (even as to Grünenthal), royalty bearing, license, within the Field, under the Grünenthal Background Patents, Improvement Patents Controlled by Grünenthal and Grünenthal Know-How, to Commercialize Products within the OMP Territory. OMP shall have the right, to be exercised within [***] after receipt of the notice of an Improvement pursuant to Section 7.3, to refuse to accept a license under know-how or patent rights resulting from such Improvement, or, if accepted, to terminate any such license at any time upon [***] written notice to Grünenthal. In addition, Grünenthal shall have no right to use, import, offer for sale, sell or distribute a product containing CG-5503 in the OMP Territory outside the Field, without the prior written consent of OMP, which shall not be unreasonably withheld. During the Term of this Agreement OMP shall not have any right to sell, offer for sale, distribute and have sold Product for any indication outside the Field or outside the OMP Territory, provided that the foregoing shall not be interpreted to diminish the rights of either Party pursuant to any other license agreement between OMP and Grunenthal, or their Affiliates. Grünenthal hereby grants to

OMP a non-exclusive paid up license within OMP Territory within the Field under the Grünenthal Background Patents, Improvement Patents Controlled by Grünenthal and Grünenthal Know-How to use all Information obtained from Grünenthal's activities conducted under RAP Plan 1.63 and RAP Plan 1.63.1 including Study KF5503/21 for OMP's use in OMP Territory.

(b) Licenses for Production. Grünenthal hereby grants to OMP a non-exclusive royalty bearing, license, within the Field under the Grünenthal Background Patents, Improvement Patents Controlled by Grünenthal and Grünenthal Know-How, to make or have made Products worldwide for the purpose of Commercialization of Products within the OMP Territory under the license for Commercialization granted under Section 2.1(a) ("**Commercial Supply Manufacturing License**").

(c) Licenses For Regulatory Approval Preparation. Grünenthal hereby grants to OMP:

(i) a non-exclusive, paid up worldwide license, within the Field, under the Grünenthal Background Patents, Improvement Patents Controlled by Grünenthal and Grünenthal Know-How for use in carrying out Regulatory Approval Preparation of the Product in the OMP Territory,

(ii) Grünenthal hereby grants to OMP a non-exclusive, paid up license within OMP Territory within the Field under the Grünenthal Background Patents, Improvement Patents Controlled by Grünenthal and Grünenthal Know-How to use all Information obtained from Grünenthal's activities conducted under RAP Plan 1.63 and RAP Plan 1.63.1 including Study KF 5503/21 for OMP's use to obtain Regulatory Approval in OMP Territory.

(d) Licenses for Improvement Patents outside the Field. According to Section 7.4, Grünenthal shall own any Improvement Patent based on joint inventorship. In the situation wherein an employee, agent, officer, or contractor of OMP or OMP's Affiliates is an inventor, Grünenthal grants to OMP a worldwide non- exclusive, paid-up license under all such Improvement Patents for use outside the Field.

(e) Payment for Licenses. The royalties that are payable pursuant to this Section 2.1 are set forth in Article 6.

(f) Right to Sublicense. The licenses granted to OMP pursuant to this Section 2.1 include the right to sublicense to Affiliates of OMP.

2.2 Licenses to Grünenthal

(a) Licenses for Commercialization. OMP hereby grants to Grünenthal an non- exclusive, royalty bearing, license, within the Field under the Improvement Patents directed to Combination Products Controlled by OMP ("**Improvement Combination Patents**") and OMP Know-How, to Commercialize Products within the Grünenthal Territory. OMP hereby grants to Grünenthal a non- exclusive royalty free license within the Field under Improvement Patents Controlled by OMP other than Improvement Combination Patents to Commercialize Products within the Grünenthal Territory; *provided, however,* that Grünenthal shall be responsible for any payments due to a Third Party in the Grünenthal Territory under such Improvement Patents.

(b) Licenses for Production. OMP hereby grants to Grünenthal a non-exclusive royalty bearing, license, within the Field under the Improvement Combination Patents and OMP Know-How, to make or have made Products worldwide solely for the purpose of Commercialization of Products within the Grünenthal Territory under the license for Commercialization granted under Section 2.2(a). OMP hereby grants to Grünenthal a non-exclusive royalty free license within the Field under Improvement Patents other than Improvement Combination Patents to make or have made Products worldwide solely for the purpose of Commercialization of Products within the Grünenthal Territory under the license for Commercialization granted under Section 2.2(a); *provided, however,* that Grünenthal shall be responsible for any payment due to a Third Party in the Grünenthal Territory under such Improvement Patents.

(c) Licenses For Regulatory Approval Preparation. (i)OMP hereby grants to Grünenthal a non-exclusive, paid up worldwide license, within the Field, under the Improvement Patents Controlled by OMP and OMP Know-How for use in carrying out Regulatory Approval Preparation of the Product in the Grünenthal

Territory. (ii) OMP hereby grants to Grünenthal an exclusive, paid up worldwide license to use all Information obtained from OMP's activities conducted under RAP Plan 1.63 and 1.63.1 to obtain Regulatory Approval in Grünenthal Territory.

(d) Payment for Licenses. The royalties that are payable pursuant to Section 2.2 are set forth in Section 6.4(c) of this Agreement.

(e) [Reserved]

(f) Right to Sublicense. The licenses granted to Grünenthal pursuant to this Section 2.2 include the right to sublicense to Affiliates of Grünenthal or to licensees of Grünenthal.

2.3 Conversion of License to OMP to Non-exclusive License.

(a) For Products based on Improvement Patents Controlled by Grünenthal the exclusive rights granted in Sections 2.1(a) shall be converted to a non-exclusive license upon the date OMP has provided notice according to Section 2.3(b) to Grünenthal that OMP or a Third Party having rights from OMP will start Commercialization of a Product based on Improvement Patents in the Grünenthal Territory according to Section 2.2(a).

(b) Notice to Grünenthal to enter market. OMP shall give Grünenthal [***] prior written notice before start of Commercialization of a Product based on Improvement Patent in the Grünenthal Territory (with specific reference to Section 2.3).

ARTICLE 3 MANUFACTURE

3.1 Manufacturing by the Parties. Grünenthal shall be responsible for the manufacture of the Product**,** including the manufacture of bulk active pharmaceutical ingredient and appropriate pharmaceutical formulation for the Grünenthal Territory. OMP shall be responsible for the manufacture of the Product, including the manufacture of bulk active pharmaceutical ingredient and appropriate pharmaceutical formulation, for the OMP Territory and have available the necessary and timely production capacity to supply OMP's

respective markets. Should the manufacturing at separate Grünenthal and OMP sites appear to be economically not feasible, the Parties agree to discuss a solution in good faith.

3.2 Transfer of Manufacturing Know-How. Grünenthal shall supply OMP with the available manufacturing know-how and technical assistance to manufacture Product, including the Grünenthal (Non-ADF SR-Matrix, the Grünenthal formulation currently used in clinical trials) slow release formulation and/or Grünenthal-ADF-Formulation, if so decided by the Parties according to Section 12.1(b), if OMP decides to Commercialize such formulation. Such transfer shall occur in sufficient time to enable the execution of respective activities of the Regulatory Approval Preparation Plan according to the timetables, recited therein, or the appropriate regulatory filings and commercial launch in OMP´s Territory.

3.3 Exchange of Manufacturing Know-how. OMP and Grünenthal will exchange, on a regular and periodic basis, but in no event less than once per year, manufacturing know-how relating to the Product, including with respect to the manufacture of bulk active pharmaceutical ingredient and the ADF Formulation (provided both are manufacturing the same ADF Formulation) and will give experts of the other Party sufficient opportunity to visit the production facility and to view the production process, under appropriate conditions of confidentiality. Significant improvements to the manufacturing process, however, will be communicated promptly to the other Party.

ARTICLE 4 COMMERCIALIZATION

4.1 Commercialization Efforts. OMP shall conduct all activities contemplated by this Agreement in a manner which does not cause any material injury to either the reputation of Grünenthal or to the goodwill of any Product sold in the Grünenthal Territory. Grünenthal shall conduct all activities contemplated by this Agreement in a manner which does not cause any material injury to either the reputation of OMP or to the goodwill of any Product sold in the OMP Territory. Activities contemplated by this Agreement taken due to drug safety

concerns or pursuant to Section 4.2 shall not be considered to cause material injury as mentioned above.

4.2 Pricing. OMP shall have sole decision authority and discretion with respect to all pricing decisions and reimbursement strategies relating to the OMP Territory. Grünenthal shall have sole decision authority and discretion with respect to all pricing decisions and reimbursement strategies relating to all countries in the Grünenthal Territory.

4.3 Marketing Responsibilities/Marketing Materials

(a) In General. With respect to the OMP Territory for OMP, and any EU country for Grünenthal, each Party shall provide to the other Party exemplars for each marketing and promotional platform or campaign for each Product contemporaneous with the implementation of such platform or campaign, provided, however, that no such submission shall be required where there is no material deviation from any prior submission.

(b) Party Name on Product Promotional Materials. Grünenthal shall have the option to be exercised no later than [***] after OMP´s notice (with specific reference to this Section) to Grünenthal of OMP's internal decision to file the Drug Approval Application prior to the envisaged First Commercial Sale in the United States (to the extent permitted by the applicable laws and regulations of each country in which such Product promotional materials are to be presented), to require OMP to include on all Product promotional materials for Product sold in the OMP Territory the name and logo of Grünenthal and shall describe Grünenthal as being licensor of the Product and name and logo of OMP, or the appropriate Affiliate, under a format, style and size to be agreed between the Parties provided, however, that the font or, as applicable, the size to be used for Grünenthal's name and logo shall be no less than fifty percent (50%) of the font or, as applicable, the size to be used for OMP or the appropriate Affiliate's name and logo. To the extent permitted by the applicable Regulatory Authorities, Grünenthal will include on all promotional materials for Product using the OMP-ADF- Formulation sold in its Territory the names and logos of both Grünenthal and

OMP, or the appropriate Affiliate and a logo designating the OMP Technology used in the OMP-ADF-Formulation, under a format, style and size to be agreed between the Parties; *provided, however,* that the font or, as applicable, the size to be used for OMP's or the appropriate Affiliate's name and logo shall be no less than fifty percent (50%) of the font or, as applicable, the size to be used for Grünenthal.

4.4 Minimum Royalties in the OMP Territory

(a) OMP Territory:

(i) Subject to all terms and conditions of this Agreement, OMP shall have to pay for the Product sold in the OMP Territory, the following minimum royalties ("**Minimum Royalty for OMP Territory**") in the OMP Territory beginning with the [***] Year of Sale and ending at the end of the [***] Year of Sale following First Commercial Sale in the OMP Territory pursuant to the Combined Territories License Agreement: Beginning with the [***] Year of Sale, the Minimum Royalty for OMP Territory for a given Year of Sale shall be the royalty due for the prior Year of Sale. [***]. However, in the event, the effective royalties are higher than the Minimum Royalty for OMP Territory, the effective royalty shall apply. In no event shall Minimum Royalty for OMP Territory be payable for more than the first [***] Years of Sale even if the Product is sold in the OMP Territory in a different form or formulation or is a Combination Product.

(ii) If OMP has not achieved the Minimum Royalty for OMP Territory due hereunder for a Year of Sale, OMP shall pay Grünenthal the difference

between the Minimum Royalty for OMP Territory due and the royalties actually paid for that particular Year of Sale. Such difference shall be due and payable as an adjustment when the next OMP Territory Earned Royalty payment is due according to Section 6.12.

(iii) In the event of the abatement or reduction of the OMP Territory Royalties in accordance with Sections 6.8, 6.9 and 6.11, the Minimum Royalty for OMP Territory shall be adjusted proportionately.

(b) [Reserved]

(c) The Minimum Royalty for OMP Territory shall be abated during the calendar year and during any subsequent period in which any of the following conditions exist and are continuing to materially impact the marketing of the Product: The Product(s) have been withdrawn from the market by OMP

(i) in response to a regulatory agency request, threat or order to withdraw or recall such product, or

(ii) for reasons related to safety or product defects pertinent to safety, which in OMP's view, subject to Grünenthal´s approval, which shall not be unreasonably withheld or delayed, warrant a voluntary recall of the Product.

(d) No earlier than [***] following the occurrence of one or more of the following conditions, OMP may notify Grünenthal of such condition(s) and the Parties shall negotiate in good faith the size of any reduction (between 1 and 100%) of the Minimum Royalty for OMP Territory, for the calendar year and any subsequent period in which any of the following conditions exist and are continuing to materially impact the marketing of the Product;

(i) sales are reduced as a result of material regulatory issues which arise in connection with the Product such as "Dear Doctor letters", or

(ii) sales are reduced as a result of material supply problems or lack of supply not caused by OMP or that are a result of a force majeure event.

(iii) sales are reduced as a result of a negative market impact based on a negative drug class effect on the class in which class the Product is contained, or

(iv) sales are reduced as a result of other external impacts, including, but not limited to, governmental price restrictions, parallel import of the Product, compulsory licenses for the Product, changes in managed care treatment protocols

4.5 Promotion Compliance Responsibilities. In the OMP Territory, OMP, in Promoting a Product, and Grünenthal, to the extent Grünenthal participates in a scientific or educational event held in the OMP Territory shall in all material respects conform their practices and procedures relating to such Promotion to the FD&C Act, the PHS Act, the Pharmaceutical Research and Manufacturers of America ("**PhRMA**") Code of Pharmaceutical Marketing Practices (the "**PhRMA Code**") and the American Medical Association ("**AMA**") Guidelines on Gifts to Physicians from Industry (the "**AMA Guidelines**"), as the same may be amended from time to time, and promptly notify the other Party of and provide a copy of any material correspondence or other reports with respect to Promotion of a Product submitted to or received from the FDA, PhRMA or the AMA relating to the FD&C Act, the PHS Act, the PhRMA Code, or the AMA Guidelines.

Each Party shall be fully responsible for disseminating accurate information regarding any Product to its professional sales representatives. The Parties agree to use Commercially Reasonable and Diligent Efforts to exchange copies of their respective promotional materials in the OMP Territory and EU. To the extent a Party engages in communication over the Internet such communication shall clearly implement reasonable safeguards designed to prevent transmission to or access to target audiences in the other Party's Territory.

4.6 Distribution.

(a) Customer Support. OMP shall use Commercially Reasonable and Diligent Efforts to perform all customer support services which require Regulatory

Approval, acquiescence or oversight, including, without limitation, pharmacovigilance, responding to physician inquiries, or professional education.

(b) Recalls. The Parties and their distributing entities shall use good faith and reasonable efforts to coordinate any decision making and communication with respect to issuing a recall, market withdrawal, suspension or correction of any Product, provided that, to the extent required by regulatory timeframes or public safety considerations, each Party shall have the right to make the product recall decision within its Territory. Each Party shall notify the other Party promptly (and in any event within [***] of receipt of written notice) if any Product is alleged or proven to be the subject of a recall, market withdrawal, suspension or correction in any country in its Territory. During the term of this Agreement, each Party shall be responsible for: handling and implementing all recalls and market withdrawals, suspensions or corrections of any Product in its Territory. The other Party will make available to the Party, upon request, all of the other Party's pertinent records that the other Party may reasonably request to assist it in effecting any of the foregoing. A Party shall have no obligation to reimburse or otherwise compensate the other Party for any Losses (as defined in Section 13.1) that may arise in connection with any such recall, market withdrawal, suspension or correction relating to such other Party´s Territory, unless and to the extent such action is due to negligence or willful misconduct in the manufacturing distribution, Promotion and post marketing surveillance activities, of Product, by such Party. Any investigation conducted in connection with such an action shall be undertaken jointly by the Parties.

4.7 [Reserved]

4.8 Contact to Supra National Agencies. Grünenthal shall have the sole right and responsibility to initiate and/or respond to all contacts with supra national agencies (i.e. WHO), other than Regulatory Authorities, worldwide relating to the Products, which are Commercialized. Grünenthal shall retain responsibility for communicating with all such agencies and satisfying all requirements regarding the Products. Each Party shall inform the other Party of the

substance of all communication with all such agencies. OMP shall assist Grünenthal, if Grünenthal requests OMP to do so, and Grünenthal shall, if requested by OMP, consult with OMP in preparing such communications with the relevant supra national agency. Each Party shall be permitted to accompany the other Party to any meeting with such agency, take part in any such communications and receive copies of all such communications. Notwithstanding the foregoing, OMP may respond to any agency's inquiry regarding the Products, in coordination with Grünenthal, if and only if:

(a) in the reasonable opinion of OMP´s counsel, such response is necessary to comply with the requirements of any law, governmental order or regulation, and

(b) OMP has requested the agency to direct the inquiry to Grünenthal instead of OMP, and such agency has refused such request; but in any such event, unless in the considered opinion of OMP's counsel there is a legal prohibition against doing so, OMP shall immediately notify Grünenthal of such agency's inquiry and of OMP's intention to make such response.

ARTICLE 5 TRADEMARK AND APPEARANCE

The Parties have selected and developed different trademarks for their respective Territory i.e. Nucynta® for the OMP Territory and Palexia® and Nucynta® for the Grünenthal Territory. Each Party's trademark will be owned by Grünenthal and upon Grünenthal's request the trademark Nucynta® in the OMP Territory shall be assigned to Grünenthal as described below. In the case of assignment of this Agreement by OMP to a Third Party, OMP shall simultaneously assign the trademark Nucynta® for the OMP Territory to such Third Party. Upon Grünenthal's request, such Third Party shall assign such trademark to Grünenthal. Each Party shall bear the respective costs for such development and maintenance of the trademark in its Territory. Grünenthal grants to OMP a royalty free, exclusive license to use the trademark selected by OMP for the OMP Territory for the Term of the Agreement and after expiration of the Term of Agreement solely in connection with Product and the Field.

ARTICLE 6 PAYMENTS

In consideration of the assignments, rights and licenses granted under this Agreement, OMP agrees to pay (or has paid pursuant to the Combined Territories License Agreement) Grünenthal as follows:

6.1 Considerations of OMP to Grünenthal.

(a) Upfront Payments for OMP Territory.

(i) OMP agreed to pay, and has paid, to Grünenthal a non-refundable upfront payment of $20,000,000.

(ii) The obligation to make this payment, as well as any other payments under Section 6.2, shall not once accrued or paid be affected by any termination under Article 15. A holding of invalidity or unenforceability of any Grünenthal Patent for which no further appeal is or can be taken shall not affect any obligation already accrued hereunder but shall only affect those payments otherwise due under such Grünenthal Patent from the date such holding becomes final.

(b) Milestone Payments in connection with the OMP Territory.

(i) OMP agreed to make, and made, the following non-refundable payments to Grünenthal upon the first occurrence of each milestone event with respect to the Product, during the term of the Combined Territories License Agreement.

Events	Payment
Within [***] of the enrollment of the fifth patient in the first Phase III Clinical Trial	[***]
Within [***] of the first NDA filing in the United States and acceptance for review by the FDA of a NDA	[***]

Events	Payment
Within [***] of the Regulatory Approval in the United States of the first of the Products	[***]

(ii) It is understood that in no event should OMP be obligated to make the payment due on any milestone more than once with respect to the Product, regardless of the number of indications in the Field for which such Product is developed or regardless of the number of different forms or formulations which are developed. In no event shall OMP be obligated to make aggregate milestone payments in the OMP Territory which exceed $25.0 million for the Products in the Field.

No additional royalties, milestones or up front payments shall be due Grünenthal for any modifications to, including addition of, RAP Plans.

(c) Payments in connection with RAP Plan 1.63.1 and OMP Territory Earned Royalty Payments. OMP agreed to pay, and paid, to Grünenthal for the extension of the license for Regulatory Approval Preparation as per Section 2.1(c) and for the provision of all data and documents pertaining to Study KF5503/21 and its use in OMP Territory, a lump sum of twelve million US Dollars ($ 12,000,000). Such lump sum was agreed upon between the Parties based on the estimated costs for the Study KF5503/21 plus a surcharge of fifty percent (50%) of such estimated costs.

(d) [Reserved]

(e) [Reserved]

(f) Proportionate Share. In consideration of the share of the market potential of either Party´s Territory, of the extension of this Agreement through the amendments to this Agreement and further in consideration of Grünenthal's preparation of Study KF 5503/21, all RAP Costs and FTE resources including, without limitation, all preclinical, clinical costs and FTE resources shall be shared between OMP and Grünenthal as follows (each Party's share being its "**Proportionate Share**"):

(i) with regard to Products developed in accordance with the RAP Plan 1.63, so that [***] and

(ii) with regard to Products developed in accordance with RAP Plan 1.63.1 so that [***]:

(x) [***].

(y) [***].

(z) [***].

6.2 Payment of RAP Costs.

With regard to OMP Territory and Grünenthal Territory. Resource plans will be developed initially and updated on a regular basis with approval from the Parties. OOPs will be managed by a common account ("**OOP Account**"), starting on January 1, 2003. The Parties will make reasonable efforts to share the FTE resources according to their Proportionate Share as long as reasonable for the project (time to market, expertise, costs, etc.). The deviation between the Proportionate Share split will be determined and balanced by a common escrow account ("**FTE Account**") every [***] starting on January 1, 2003. The Exceeding FTEs will be charged at the then

existing OMP FTE rate(s) as specified in the RAP Plan. As used herein, "**Exceeding FTEs**" mean the disproportionate amount of FTEs used by one Party compared to the other Party. FTE funds will accrue interest on an annualized basis as calculated using British Bankers Association 12 months Euro LIBOR as fixed two banking days prior to the date on which a Proportionate Share split is determined and balanced. The FTE Account will be carried forward until the end of the Core RAP Program. Each Party will have the opportunity, by providing extra FTEs in order to reduce Exceeding FTEs (provided such are approved in the RAP Plan), to recover parts of its payment into the FTE Account as long as the threshold of [***] is not exceeded. If the rolling balance in favor of one Party exceeds the threshold of [***] the exceeding amount should be paid to the Party who has provided the Exceeding FTEs. The amount in the FTE Account at the end of the Core RAP Program should be paid to the Party who provided the Exceeding FTEs.

(i) Cost Overruns. If actual RAP expenses exceed the RAP Costs and FTE resources approved by the Parties and allocated to one Party ("**Cost Overruns**") in accordance with this Section 6.2, these Cost Overruns shall be shared by the Parties according to its Proportionate Share up to an amount of [***] of the amount approved by the Parties. Additional expenses and FTE resources over and above the [***] limit shall be solely borne by the Party for the activity that resulted in such overage; *provided, however,* that if such Party is able to demonstrate to the reasonable satisfaction of the other Party that such overage is in the interest of both Parties, such overage shall be shared by the Parties according to its Proportionate Share.

The share of Cost Overruns does not apply to RAP expenses allocated to one Party by 100%.

(ii) Records and Audits. During the term of this Agreement, each Party shall keep and maintain accurate and complete records showing the expenses incurred by it in performing its activities under the RAP Plan

during the three (3) preceding calendar years, which books and records shall be in sufficient detail such that RAP Costs can accurately be determined. Upon [***] prior written notice from a Party (the "**Auditing Party**"), the other Party (the "**Audited Party**") shall permit an independent certified public accounting firm of internationally recognized standing and designated by the Parties at its first meeting, to examine the relevant books and records of the Audited Party and its Affiliates as may be reasonably necessary to verify the reports submitted by the Audited Party and the accuracy of any reconciliation report. An examination by a Party under this Section 6.2 shall occur not more than once in any calendar year and shall be limited to the pertinent books and records for any calendar year ending not more than [***] before the date of the request. Once materials or accounts have been audited, no subsequent audit on them may be performed. The accounting firm shall be provided access to such books and records at the Audited Party's facility(ies) where such books and records are normally kept and such examination shall be conducted during the Audited Party's normal business hours. The Audited Party may require the accounting firm to sign a standard non- disclosure agreement before providing the accounting firm access to the Audited Party's facilities or records. Upon completion of the audit, the accounting firm shall provide both OMP and Grünenthal a written report disclosing whether the reports submitted by the Audited Party are correct or incorrect and the specific details concerning any discrepancies. No other information shall be provided to the Auditing Party. If the accountant determines that errors were made in the reports so submitted, the Parties shall promptly correct any errors and make any necessary adjustments. The Auditing Party shall bear all costs and expenses of the audit, provided, however, that if the audit reveals that the Audited Party has incorrectly charged to the OOP Account the lesser of [***] more than entitled to or an amount exceeding [***] more than entitled to, the Audited Party shall bear all costs and expenses of the audit.

6.3 Earned Royalties For Products in OMP Territory. For the OMP Territory, OMP shall pay Grünenthal a royalty for the rights granted based on cumulative moving annual total Net Sales of Products (other than Combination Product) sold by or for OMP, or its Affiliates according to the following schedule:

(a) [***] within the first [***] after First Commercial Sale in OMP Territory;

(b) [***] within the months [***] after First Commercial Sale in OMP Territory if moving annual total Net Sales in OMP Territory do not exceed [***], otherwise, the royalty rate in 6.3(d) or 6.3(e) will apply depending on the moving annual total Net Sales in OMP Territory;

(c) [***] starting at the [***] after First Commercial Sale in OMP Territory provided that moving annual total Net Sales in OMP Territory are below [***];

(d) [***] if moving annual total Net Sales in OMP Territory are greater than or equal to [***] but do not exceed [***];

(e) [***] if moving annual total Net Sales in OMP Territory are equal to or greater than [***].

6.4 Royalties For Combination Products in OMP Territory.

(a) In case of a Combination Product sold by or for OMP, or its Affiliates hereunder in the OMP Territory, the royalties to Grünenthal shall be paid according to the following schedule, collectively with the payments set forth in Section 6.3, the "**OMP Territory Earned Royalties**":

(i) [***] starting at the First Commercial Sale in OMP Territory provided that moving annual total Net Sales in OMP Territory are below [***];

(ii) [***] if moving annual total Net Sales in OMP Territory are greater than or equal to [***] but do not exceed [***];

(iii) [***] if moving annual total Net Sales in OMP Territory are equal to or greater than [***].

In the event that OMP has solely developed a Combination Product the applicable royalty shall be reduced by [***] of Net Sales.

(b) [Reserved]

(c) Royalties For Combination Products For OMP. In the event that OMP has solely developed a Combination Product, Grünenthal shall pay OMP a royalty based on total Net Sales of such Combination Products sold by or for Grünenthal, or its Affiliates in the Grünenthal Territory of [***].

6.5 Royalty Calculation Method. Once the royalty range threshold for the OMP Territory is exceeded (according to Sections 6.3 or 6.4) the increased OMP Territory Earned Royalty is due on total Net Sales.

In [***] of each year, the cumulative sales of the prior [***] period [***] in the OMP Territory shall be compared to the royalty ranges as described above in Sections 6.3 or 6.4, to set the applicable OMP Territory Earned Royalty rate for the cumulative sales of the prior [***] period [***] in the OMP Territory. An example of the OMP Territory Earned Royalty calculation is attached hereto as **Exhibit 6.5**.

6.6 [Reserved]

6.7 [Reserved]

6.8 Royalty Rate Reduction.

(a) Third Party Patents. In the event OMP pays for the OMP Territory a royalty to a Third Party which is other than an Affiliate, pursuant to Section 7.11 of this Agreement, then for the OMP Territory, as applicable, OMP shall be entitled to a credit against the applicable royalty payments due to Grünenthal under

this Agreement of an amount equal to [***] of the royalty actually paid to any such Third Party which is other than an Affiliate, with the credit not to exceed [***] of the applicable royalty rate due to Grünenthal under this Agreement. Additional royalties paid to Third Parties shall not be considered for COGS cap calculations according to Section 6.9.

(b) Compulsory License. If at any time and from time to time a Third Party in any country in the OMP Territory shall, under the right of a compulsory license granted or ordered to be granted by a competent governmental authority, manufacture, use or sell any Product, with respect to which Earned Royalties would be payable pursuant to this Agreement, then OMP shall inform Grünenthal thereof and both Parties shall negotiate in good faith the size of an equitable reduction of the applicable royalty. In principle, the reduction shall be calculated after consideration of the territory concerned, the owner of the compulsory license and its marketing and distribution capability, pricing and other market conditions at the time of granting such compulsory license, the royalty rate of the compulsory license, the life cycle phase of the Product and an equitable distribution of the financial consequences for the Parties.

(c) Competition in OMP Territory.

(i) If, at any time, after a composition of matter Patent claiming CG-5503 is no longer in force and prior to expiration of the last Grünenthal Patent claiming the Product (other than Combination Product), or OMP Patent claiming the Product, OMP loses Market Exclusivity in the OMP Territory, the amount of OMP Territory Earned Royalties payable to Grünenthal according to Section 6.3 on all Products in the OMP Territory shall be reduced by [***]. Thereafter, if as a result of OMP´s loss of Market Exclusivity in the OMP Territory, OMP´s aggregate share of all products containing CG-5503 (excluding Combination Product) as shown in IMS in such country is less than [***], then the amount of OMP Territory Earned Royalties payable to Grünenthal for all Products according to Section 6.3 shall be [***]; when the share is less than [***], the amount of OMP Territory Earned

Royalties payable to Grünenthal according to Section 6.3 shall be [***], and when the share is less than [***], the amount of OMP Territory Earned Royalties payable to Grünenthal according to Section 6.3 shall be [***]. Thereafter, even if there is a further loss of OMP´s share of all products containing CG-5503 in the OMP Territory, the royalty rate reduction shall [***].

(ii) If, at any time, after a composition of matter Patent claiming CG-5503 is no longer in force and prior to expiration of the last Grünenthal Patent claiming that particular Combination Product, or OMP Patent claiming that particular Combination Product, OMP loses Combination Product Market Exclusivity in the OMP Territory, the amount of OMP Territory Earned Royalties payable to Grünenthal according to Section 6.4 on such Combination Product in the OMP Territory shall be [***]. Thereafter, if as a result of OMP´s loss of Combination Product Market Exclusivity in the OMP Territory, OMP´s aggregate share of all combination products as shown in IMS containing CG-5503 and the same active pharmaceutical ingredient(s) in such country is less than [***], then the amount of OMP Territory Earned Royalties payable to Grünenthal according to Section 6.4 for such Combination Product shall be [***]; when the share is less than [***], the amount of OMP Territory Earned Royalties payable to Grünenthal according to Section 6.4 shall be [***], and when the share is less than [***], the amount of OMP Territory Earned Royalties payable to Grünenthal according to Section6.4 shall be [***]. Thereafter, even if there is a further loss of OMP´s share of all combination products containing CG-5503 and the same active pharmaceutical ingredient(s), the royalty rate reduction shall [***]. This mechanism for royalty rate reduction shall be used separately for each particular Combination Product.

(d) [Reserved]

(e) Royalties on Know-How of a Product containing CG-5503 as the sole active pharmaceutical ingredient. On a country-by-country basis, until the last to expire Grünenthal Patent, or OMP Patent claiming the formulation of the Product, under which Earned Royalties are being paid (the "**Last Patent**"), a royalty for Grünenthal Know-How is included in the Earned Royalty rates. After the Last Patent expires, the applicable royalty payable for the period recited in Section 6.11(a) shall be [***].

(f) Royalties on Know-How of Combination Products. On a country-by-county basis, until the last to expire Grünenthal Patent, or OMP Patent claiming the formulation of a particular Combination Product, under which royalties are being paid (the "**Last Combo Patent**"), a royalty for Grünenthal Know-How is included in the Earned Royalty rates. After the Last Combo Patent expires, the applicable royalty payable by OMP for the period recited in Section 6.11(b) shall be [***].

(g) Royalty Rock Bottom.

(i) The total OMP Territory Earned Royalty rate reductions under Sections 6.8(a) through 6.8(f) cannot exceed [***] in the applicable OMP Territory Earned royalty based on the level of moving annual Net Sales in Section 6.3. Notwithstanding the foregoing, the effective OMP Territory Earned Royalty rate shall in no case be below [***] of Net Sales.

(ii) [Reserved]

6.9 Cost of Goods Sold Cap ("**COGS Cap**") in OMP Territory. Cost of Goods Sold in OMP Territory should not exceed [***]. The applicable OMP Territory Earned Royalty rate under consideration of this COGS Cap, shall be calculated in accordance with the timelines mentioned in Section 6.5. In the event the total COGS percentage exceeds the [***] threshold, the incremental percentage over the [***] threshold will be reduced from the OMP Territory

Earned Royalty rate so that the reduction in royalties will result in a total COGS equal to [***]. In any instance where a royalty reduction is in effect (e.g., under Section 6.8) the royalty reduction will also apply to the COGS Cap, such that the COGS Cap is also reduced. For the purposes of Fully Allocated Manufacturing Costs/royalty calculation, the average of the OMP and Grünenthal Fully Allocated Manufacturing Costs, without any internal mark-ups of Affiliates and/or external royalties to licensors of OMP-ADF- Formulation, shall be used. In order to determine the average, each Party shall provide to the other Party its Fully Allocated Manufacturing Costs on an annual basis which shall be subject to audit by the other Party in accordance with Section 6.12(f). The rights to audit (with Grünenthal personnel or outside auditors) the records of OMP and its Affiliates as provided for under this Agreement shall extend to audits of OMP's and its Affiliates' records for purposes of confirming the Cost of Goods contemplated by this Section.

6.10 Minimum Royalties. Minimum Royalty for OMP Territory shall be paid as stipulated in Section 4.4.

6.11 Term For Royalty Payment.

(a) Earned Royalties for the licenses granted and the Grünenthal Know-How provided, payable for any Product containing CG-5503 as sole active pharmaceutical ingredient being sold, shall be paid on a country-by-country basis from the date of First Commercial Sale of such Product until the last to expire of any Grünenthal Patent or OMP Patent licensed hereunder containing a Valid Patent Claim claiming the formulation for such Product (the "**Last Patented Product**"). Earned Royalties solely for Grünenthal Know-How payable under Section 6.8(e) for the Last Patented Product being sold shall be paid on a country-by-country basis from the date of expiration of the last to expire of any such Grünenthal Patent or OMP Patent licensed hereunder containing a Valid Patent Claim claiming the Last Patented Product until the generic equivalent (as defined by the then current FDA regulations) enters the market ("**Generic Market Event**"), at which time the applicable OMP Territory Earned Royalty solely for Grünenthal Know-How payable under Section 6.8(e) shall cease.

(b) Earned Royalties payable for the licenses granted and the Grünenthal Know- How provided for each Combination Product being sold shall be paid on a country-by-country basis from the date of the First Commercial Sale of each such Combination Product until the last to expire of any Grünenthal Patent or OMP Patent licensed hereunder containing a Valid Patent Claim claiming the formulation of the Combination Product (the "**Last Combo Product**"). Earned Royalties solely for Grünenthal Know-How payable for the particular Combination Product being sold on a country-by-country basis from the date of expiration of the last to expire of any such Grünenthal or OMP Patent licensed hereunder containing the particular Combination Product until an applicable Generic Market Event, at which time the applicable OMP Territory Earned Royalty solely for Grünenthal Know-How payable under Section 6.8(f) shall cease.

6.12 Royalty Reports and Records. The following Sections 6.12(a) and (b) shall apply for the OMP Territory.

(a) During the term of this Agreement and commencing with the First Commercial Sale of Product, OMP shall furnish, or cause to be furnished to Grünenthal, written reports, including the applicable royalty payment due, within sixty (60) days following the end of each [***] for which royalties are due, showing:

(i) the detailed calculation of monthly Net Sales of all Products sold by OMP and its Affiliates during the calendar half-year;

(ii) the detailed calculation of Earned Royalties, payable in U.S. Dollars, which shall have accrued hereunder in respect to such Net Sales;

(iii) the exchange rates used, if any, in determining the amount of Dollars; and

(iv) any withholding taxes required to be paid from such Earned Royalties.

(b) All Earned Royalties payments to be made by OMP to Grünenthal shall be made in U.S. Dollars within [***] following the end of [***]

for which such Earned Royalties are due, to a Grünenthal bank account.

(c) [Reserved]

(d) To the extent it is necessary to convert currencies for OOPs development costs incurred pursuant to the RAP plan, such reconciliation shall be made in Euros using the applicable arithmetic average exchange rate for converting the applicable currency to the Euro as published by the European Central Bank on the last business day of each month during the period (quarter).

(e) OMP shall keep accurate records in sufficient detail to enable Earned Royalties and other payments payable hereunder to be determined. OMP shall be responsible for all Earned Royalties and late payments that are due to Grünenthal that have not been paid by OMP and its Affiliates. Late payments shall accrue interest on an annual basis at a rate of [***].

(f) OMP and its Affiliates shall maintain complete and accurate records, in accordance with United States generally accepted accounting principles, which are relevant to costs, expenses and payments under this Agreement and such records shall be open during reasonable business hours for a period of three (3) years from creation of individual records for examination at Grünenthal's expense and not more often than once each year by a certified public accountant or other representative selected by Grünenthal and acceptable to OMP for the sole purpose of verifying the correctness of calculations or such costs, expenses or payments made under this Agreement. In the absence of material discrepancies (in excess of [***]) in any request for reimbursement resulting from such audit, the accounting expense shall be paid by Grünenthal. If material discrepancies do result, OMP shall bear the reasonable audit expense. Any records or accounting information received from OMP shall be Confidential Information for purposes of Article 8.

6.13 Taxes.

(a) OMP will make all payments to Grünenthal under this Agreement without deduction or withholding for taxes except to the extent that any such deduction or withholding is required by law in effect at the time of payment.

(b) Any tax required to be withheld on amounts payable under this Agreement will promptly be paid by OMP on behalf of Grünenthal to the appropriate Governmental Authority, and OMP will furnish Grünenthal with proof of payment of such tax. Any such tax required to be withheld will be an expense of and borne by Grünenthal.

(c) OMP and Grünenthal will cooperate with respect to all documentation required by any taxing authority or reasonably requested by OMP to secure an exemption or reduction in the rate of applicable withholding taxes.

(d) If OMP had a duty to withhold taxes in connection with any payment it made to Grünenthal under this Agreement but OMP failed to withhold, and such taxes were assessed against and paid by OMP, then Grünenthal will indemnify and hold harmless OMP from and against such taxes (including interest). If OMP makes a claim under this Section 6.13(d), it will comply with the obligations imposed by Section 6.13(b), as if OMP had withheld taxes from a payment to Grünenthal.

(e) OMP shall, in consultation with Grünenthal, take all legally available and reasonable steps to mitigate any circumstances in OMP's control which arise and which would result in any amount becoming subject to deduction or withholding of taxes pursuant to subclause (a) of this clause, unless Grünenthal would reasonably be expected to be entitled to a credit or refund for such deduction or withholding at any time.

6.14 Grünenthal As Licensee. The provisions of Sections 6.5, 6.8(a) through 6.8(e), 6.10, 6.11 through 6.13, and 6.16 shall apply with equal force to Grünenthal in the event that Grünenthal is the licensee of any Combination Product.

6.15 Remittance.

(a) Payments from OMP to Grünenthal required to be denominated in USD shall be made to Grünenthal as beneficiary to [***] or another bank account as provided by Grünenthal.

(b) Payments from OMP to Grünenthal required to be denominated in EUR shall be made to Grünenthal as beneficiary to [***] or another bank account as provided by Grünenthal.

(c) [Reserved]

6.16 No Overlapping Royalties. Notwithstanding any other provision of this Agreement, in no event shall any Earned Royalty provided for under any Section of this Agreement be paid with respect to any sale of a specific Product to the extent a payment has been paid pursuant to any other Section of this Agreement with respect to such sale of the same specific Product provided that the higher payment amount is paid.

6.17 Payments to or Reports by Affiliates. Any payment required under any provision of this Agreement to be made to either Party or any report required to be made by either Party shall be made to or by an Affiliate of such Party if designated as the appropriate recipient or reporting entity.

ARTICLE 7 IMPROVEMENTS/OWNERSHIP OF INTELLECTUAL PROPERTY

7.1 Ownership of Intellectual Property and Patent Rights on Combined Territories License Agreement Effective Date. Unless otherwise stipulated in this Agreement the intellectual property position of the Parties remains unchanged under this Agreement.

7.2 Maintenance of Grünenthal Background Patents. Grünenthal agrees to prosecute, maintain and extend - where possible - all Grünenthal Background

Patents. This does not apply to Grünenthal-ADF-Formulation Patents unless it is mutually agreed under Section 12.1(b) to develop the Grünenthal-ADF- Formulation.

7.3 Disclosure of Improvements. Each Party shall disclose to the other Party any Improvement as soon as reasonably possible after creation. Any information on the OMP-ADF-Formulation or Grünenthal-ADF-Formulation shall only be shared under a separate, mutual secrecy agreement as provided for by Section 12.1(b).

7.4 Ownership of Improvement Patents and Improvements. Inventorship for Improvements which are inventions, shall be determined in accordance with U.S. patent laws for determining inventorship and ownership of Improvement Patents and Improvements shall be determined based on inventorship. Notwithstanding the foregoing, in the event of Improvements conceived and/or reduced to practice by employees, agents, officers, contractors or Affiliates of both Parties ownership of any such Improvements and resulting Improvement Patents shall be assigned solely to Grünenthal. In connection with Improvements which do not result in Improvement Patents or a Trade Secret and where an employee, agent, officer, contractor or Affiliate of OMP contributed, both Parties shall have an unrestricted right to use such Improvement for any purpose. During the Term of this Agreement, Grünenthal shall, at its sole expense, file, prosecute, maintain and defend Improvement Patents which are owned by Grünenthal. OMP agrees to cause its employees, agents, officers, contractors or Affiliates to cooperate fully with Grünenthal in the preparation, filing and prosecution of any Improvement Patent wherein an employee, agent, officer, contractor or Affiliate of OMP contributed, and, with respect to such Improvement Patent, to execute any necessary assignments to Grünenthal. During the Term of this Agreement OMP shall at its own expense file, prosecute, maintain and defend all Improvement Patents which are owned by OMP.

7.5 Filing of Improvement Patents. All Improvement Patents will be filed at least in the U.S. and European Patent Office. Each Party shall give prior written notice to the other Party of the countries in which it intends to file, including conflict

proceedings, re-examinations, reissuance, oppositions and revocation proceedings and abandonment and the other Party shall have the right at that Party's expense to continue prosecution in countries for which the other Party intends to abandon. The Parties agree to use reasonable efforts to ensure that any Improvement Patent filed outside of the United States prior to a U.S. filing will be in a form sufficient to establish the date of original filing as a priority date for the purposes of a subsequent U.S. Filing.

7.6 Extensions. Each Party shall file and prosecute to obtain extensions of its respective OMP Patent or Grünenthal Patent in the Field in any countries in which such extensions are available. Each Party shall provide such assistance as may reasonably be required for the other Party to fulfil its foregoing obligations.

7.7 Ownership of ADF-Formulation Patents and ADF-Formulation Improvements.

(a) Inventorship for ADF-Formulation Patents shall be determined in accordance with U.S. patent laws for determining inventorship. OMP-ADF-Formulation Improvements and/or inventions relating to OMP-ADF-Formulations shall be solely owned by OMP, regardless of inventorship. During the Term of this Agreement, OMP shall, at its sole expense, file, prosecute, maintain and defend OMP ADF-Formulation Patents. Grünenthal agrees to cause its employees, agents, officers, contractors or Affiliates to cooperate fully with OMP in the preparation, filing and prosecution of any OMP ADF-Formulation Patent wherein an employee, agent, officer, contractor or Affiliate of Grünenthal or contractor of Grünenthal's Affiliate contributed as an inventor, and, with respect to such OMP ADF-Formulation Patent, to execute any necessary assignments to OMP. OMP shall comply with the duties under German laws regarding invention by employees (Arbeitnehmererfinderrecht) with regard to the rights of any employee, agent, officer, contractor of Grünenthal or its Affiliates.

Grünenthal ADF-Formulations Improvements and/or inventions relating to Grünenthal ADF-Formulations shall be solely owned by Grünenthal, regardless of inventorship. During the Term of this Agreement, Grünenthal

shall, at its sole expense, file, prosecute, maintain and defend Grünenthal ADF-Formulation Patents. OMP agrees to cause its employees, agents, officers, contractors or Affiliates to cooperate fully with Grünenthal in the preparation, filing and prosecution of any Grünenthal ADF-Formulation Patent wherein an employee, agent, officer, contractor or Affiliate of OMP or contractor of OMP's Affiliate contributed as an inventor, and, with respect to such Grünenthal ADF-Formulation Patent, to execute any necessary assignments to Grünenthal.

(b) Inventorship for Independent ADF Formulation Improvements which are inventions, shall be determined in accordance with U.S. patent laws for determining inventorship and Independent ADF Formulation Improvement Patents and Independent ADF Formulation Improvements shall be owned by the Party that has introduced such Independent ADF Formulation Improvements Patents and Independent ADF Formulation Improvements into the joint development of an ADF Formulation for the Product under this Agreement. During the Term of this Agreement, Grünenthal shall, at its sole expense, file, prosecute, maintain and defend Independent ADF Formulation Improvement Patents which are owned by Grünenthal. During the Term of this Agreement OMP shall at its own expense file, prosecute, maintain and defend all Independent ADF Formulation Improvement Patents which are owned by OMP.

7.8 Notice. The Parties shall promptly inform each other of any information that comes to their attention involving actual or apparent infringements or misappropriations by any Third Party of any Patent, Know-How or trademark licensed in this Agreement. The Parties shall also promptly inform each other of any claims of alleged infringement made by any Third Party against either Party or its respective Affiliates or sublicensees resulting from the manufacture, import, offer for sale, sale or use of the Product.

7.9 Infringement Claims Against Third Parties. If any Grünenthal Patent is infringed by a Third Party which is other than an Affiliate in any country in connection with the manufacture, use and sale of a Product in such country, Grünenthal shall have the primary right, but not the obligation to institute,

prosecute, and control any action or proceeding with respect to such infringement of any such Grünenthal Patent by counsel of its own choice and at its own expense, with OMP having the primary right in connection with OMP Patents at OMP´s own expense. If the Party having the primary right fails to bring an action or proceeding or otherwise accomplishes to stop the infringement within one hundred eighty (180) days after a request by the other Party to do so, the other Party shall have the right to bring and control any suit for infringement under this Section, and the Party bringing any such suit shall bear all costs and expenses of the suit and shall retain any damages or other monetary awards recovered. The Party bringing suit under this Section 7.9 shall keep the other Party reasonably informed as to the progress of the suit and all settlement discussions. A settlement or consent judgment or other voluntary final disposition of a suit brought by a Party under this Section may not be entered into without the prior written consent of the Party owning the Patent which is the subject matter of the suit (which consent shall not be unreasonably withheld or delayed); provided that such settlement, consent judgment or other disposition does not admit the invalidity or unenforceability of any Patent; and provided further, that any rights to continue the infringing activity in such settlement, consent judgment or other disposition shall be limited to the product or activity that was the subject of the suit.

7.10 Assistance. In the event of any patent infringement litigation involving the Product and any Patent, the non-prosecuting or non-defending Party shall render such reasonable assistance as may be requested by the prosecuting or defending Party in connection with such infringement actions. If one Party requests the other Party's reasonable assistance in connection with such infringement claims or actions, the requesting Party shall reimburse the other Party for such direct, documented out-of-pocket expenses as are reasonably incurred during the course of its providing such requested assistance. Before incurring such expenses, the Parties shall in good faith agree in writing on the nature and extent of assistance to be rendered.

7.11 Third Party Patents. If a Patent or Patents of a Third Party should exist or should issue to a Third Party in any country in the OMP Territory during the

term of this Agreement, which OMP believes, in its reasonable judgment, may be infringed by the manufacture, use or sale of the Product in such country, and OMP believes in its reasonable judgment, that it would be impractical or impossible to continue to Commercialize or Commercialize the Product without obtaining a royalty bearing license from such Third Party under such Patent or Patents in said country, then OMP shall promptly notify Grünenthal in writing to that effect with legal opinions. OMP and Grünenthal shall [***] towards the Patent of such Third Party under the consideration of the interest of both Parties. However, if the Parties are unable to agree on [***], the dispute will be referred to the responsible managing director of Grünenthal and the President of OMP for resolution. If these individuals cannot agree [***] shall have the right to participate in all negotiations with such Third Party directed to obtain rights to such Patent of the Third Party. [***] shall comply with any [***] in the case where the Parties have reached [***]. In case a license has been obtained from a Third Party OMP may deduct from the amount of royalties due to Grünenthal on Net Sales of Product according to Sections 6.3 and 6.4(a), as applicable, fifty percent (50%) of the Earned Royalty actually paid by OMP to any Third Party according to Section 6.8(a), pursuant to a license entered into under this Section. This Section shall apply vice versa for Grünenthal if Grünenthal is making payments to OMP according to Section 6.4(c). For the purpose of this Section 7.11, Third Party shall exclude Affiliates.

[***].

7.12 Notices Relating to the Act. Grünenthal shall notify OMP of:

(a) the issuance of each U.S. patent included among the Grünenthal Patents including – if the Parties have mutually agreed under Section 12.1(b) to

develop the Grünenthal-ADF-Formulation – the Grünenthal-ADF-Formulation Patents, giving the date of issue and patent number for each such Patent; and

(b) communications pertaining to any patent included among the Grünenthal Patents including – if the Parties have mutually agreed under Section 12.1(b) to develop the Grünenthal-ADF-Formulation – the Grünenthal-ADF- Formulation Patents which Grünenthal receives as patent owner pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984 (hereinafter the "**Act**"), including but not necessarily limited to notices pursuant to §§101 and 103 of the Act from persons who have filed an abbreviated NDA ("**ANDA**") or a "paper" NDA.

7.13 Authorization Relating to Patent Term Extension. Grünenthal hereby authorizes OMP to

(a) provide in any NDA a list of patents which includes Grünenthal Patents that relate to such Product and such other information as OMP believes is appropriate;

(b) commence suit for infringement of Grünenthal Patents under § 271(e) (2) of Title 35 of the United States Code or any other relevant statute in any OMP Territory; and

(c) exercise any rights that may be exercisable by Grünenthal as patent owner under the Act or any other relevant statute in any OMP Territory, including without limitation, applying for an extension of the term of any Patent included in Grünenthal Patents.

In the event that applicable law in any country provides for the extension of the term of any patent included among Improvement Patents or Grünenthal Patents, such as under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, the Supplementary Certificate of Protection of the Member States of the European Union and other similar measures in any other country, the Party owning such Grünenthal Patent or OMP Patent shall, at the other Party's cost for its own Territory, apply for and use its reasonable efforts to obtain such an extension or, should the law require the other Party to so apply, the Party owning the Patent hereby gives permission to

such other Party to do so. OMP and Grünenthal agree to cooperate with one another in obtaining such extension. Each Party agrees to cooperate with the other Party in the exercise of the authorization granted herein and will execute such documents and take such additional action as the may reasonably be necessary in connection therewith, including, if necessary, permitting itself to be joined as a Party in any suit for infringement brought by a Party hereunder.

7.14 Trade Secrets. Upon disclosure by one party of an Improvement to the other Party, the Parties will discuss whether it is appropriate to keep such Improvement as a Trade Secret. In the event the Parties agree to treat such Improvement as a Trade Secret, the Party/Parties who made the Improvement will take the necessary legal or organizational measures to protect such Improvement's secrecy. Should one of the Parties disagree to keep such Improvement as a Trade Secret or no mutually decision be reached within 3 months from disclosure of the Improvement by one Party to the other Party such Improvement shall be filed as a Patent according to Section 7.5 unless otherwise agreed to.

ARTICLE 8 CONFIDENTIALITY

8.1 Confidentiality Exceptions. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that the receiving Party shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any Information and other confidential and proprietary information and materials furnished to it by the other Party or developed by either Party pursuant to this Agreement (collectively, "**Confidential Information**"), except to the extent that it can be reasonably demonstrated by the receiving Party that such Confidential Information:

(a) was in the lawful knowledge and possession of the receiving Party prior to the time it was disclosed to, or learned by, the receiving Party, or was otherwise developed independently by the receiving Party, as evidenced by written records kept in the ordinary course of business, or other documentary proof of actual use by the receiving Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement; or

(d) was disclosed to the receiving Party, other than under an obligation of confidentiality, by a Third Party which is other than an Affiliate who had no obligation to the disclosing Party not to disclose such information to others.

8.2 Authorized Disclosure. Except as expressly provided otherwise in this Agreement, each Party may disclose Confidential Information of the other Party as follows:

(a) to Third Parties under appropriate terms and conditions including confidentiality provisions substantially equivalent to those in this Agreement for consulting, manufacturing, development, external testing and marketing trials with respect to the Products covered by this Agreement, or otherwise as is reasonably necessary to exercise the rights and licenses granted herein (including the right to grant sublicenses according to this Agreement) or

(b) to the extent such disclosure is reasonably necessary in filing or prosecuting patent, copyright and trademark applications, prosecuting or defending litigation, complying with applicable governmental regulations, obtaining Regulatory Approval, conducting preclinical or clinical trials, provided, however, that if a Party is required by law or regulation to make any such disclosure of the other Party's Confidential Information it will (i) , except where impracticable for necessary disclosures, for example in the event of medical emergency, give reasonable advance notice to the other Party of such disclosure requirement, (ii) except to the extent inappropriate in the case of patent applications, will use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed and (iii) only disclose such Confidentiality Information which in the opinion of the disclosing Party's legal counsel is legally required to be disclosed after taking

into due consideration the other Party's opinion provided such opinion can be obtained in a timely manner.

(c) for Confidential Information other than Trade Secrets and information relating to Improvements and inventions, to those natural persons being ultimate beneficial owners of Grünenthal and the supervisory board and advisory board to the extent such disclosure is reasonably necessary or required by law and only to the extent such persons have a right under applicable German law or a need to know and unless already under confidentiality obligation by applicable German law, or under appropriate terms and conditions including confidentiality provisions substantially equivalent to those in this Agreement.

8.3 Survival. This Article 8 shall survive the termination of this Agreement for a period of [***].

8.4 Publications. Notwithstanding any other provision of this Agreement, neither Party shall be free to disclose the results of its activities conducted under this Agreement until [***] without the prior written consent of the other Party (which consent shall not be unreasonably withheld or delayed). The publishing Party shall submit any such proposed publication to the other Party at least [***] in advance to allow review of such planned public disclosure. The reviewing Party shall, within [***] of receiving such proposed publication, inform the publishing Party in writing whether it denies its consent and on what basis. In all other cases the consent shall be deemed given. Notwithstanding the foregoing, the Parties will make reasonable efforts to exchange information relating to and discuss publication strategies relating to Products.

8.5 Public Announcements. Neither Party shall originate any publicity, news release or public announcements, written or oral, whether to the public or press, stockholders or otherwise relating to this Agreement, including their existence, the subject matter to which the agreements relate, performance under the agreements or any of their terms, to any amendment hereto or thereto or performances hereunder or thereunder without the prior written

consent of the other Party, save only such announcements that are required by law to be made or that are otherwise agreed by the Parties. Such announcements shall be brief and factual. If a Party decides to make an announcement required by law, it shall disclose such information only to the extent necessary according to local law and seek to avoid to the maximum possible any disclosure with regard to the financial conditions, chemical structures and names, including INN and substance-code-number. Such party will give the other Party at least [***] advance notice, where possible, of the text of the announcement so that the other Party will have an opportunity to comment upon the announcement. To the extent that the receiving Party reasonably requests that any information in the materials proposed to be disclosed or deleted, the disclosing Party shall request confidential treatment of such information pursuant to Rule 406 of the Securities Act of 1933 or Rule 24b-2 of the Securities Exchange Act of 1934 as amended, as applicable (or any other applicable regulation relating to the confidential treatment of information) so that there be omitted from the materials that are publicly filed any information that the receiving Party reasonably requests to be deleted, unless in the opinion of the disclosing Party's legal counsel such Confidential Information is legally required to be fully disclosed.

ARTICLE 9 REPRESENTATIONS AND WARRANTIES

9.1 Representations and Warranties. Each of the Parties hereby represents and warrants as of the Effective Date as follows:

(a) This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms. The execution, delivery and performance of the Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, to which it is a Party or by which it is bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

(b) Each Party has not granted any right to any Third Party relating to its respective technology in the Field which would conflict with the rights granted to the other Party hereunder.

(c) Each Party Controls all of the rights, title and interest in and to its know-how and its Patents which are licensed hereunder.

9.2 Grünenthal Patent Warranty. Grünenthal warrants as of the Effective Date that it owns the entire right, title and interest in the Grünenthal Patents and that it has given to OMP all material Information requested by OMP prior to the Combined Territories License Agreement Effective Date relating to Grünenthal Patent, Grünenthal Know-How and/or CG-5503 and Product in Grünenthal's possession or under its Control. Nothing in this Agreement shall be construed as a warranty that Grünenthal Patents are valid or enforceable or that their exercise does not infringe any patent rights of Third Parties.

9.3 Grünenthal Product Warranty. Grünenthal represents and warrants that the Product in Phase II clinical trials as of the Combined Territories License Agreement Effective Date which is being licensed hereunder has the chemical structure shown in **Exhibit 1.3**.

9.4 OMP Diligence Warranty. OMP acknowledges and agrees that it has received access to information relating to CG-5503 that OMP deemed necessary to conduct and complete its due diligence relating to CG-5503 to its satisfaction. OMP acknowledges and agrees that Grünenthal has answered all questions of OMP relating to the due diligence of CG-5503, and OMP warrants that it has diligently reviewed all such information, including the Information and information relating to Grünenthal Patent Rights, Grünenthal Know-How and/or CG-5503 and Product provided by Grünenthal.

9.5 OMP Patent Warranty. OMP warrants that as of the Combined Territories License Agreement Effective Date, to the best of their knowledge there are no OMP Patents or Patents of its Affiliates that would be infringed by the Commercialization of CG-5503 in its pharmaceutical formulation as of the Combined Territories License Agreement Effective Date, absent a license granted. If OMP obtains knowledge of such OMP Patents after the Combined

Territories License Agreement Effective Date, OMP warrants that it will not enforce any OMP Patents which exist as of the Combined Territories License Agreement Effective Date to prevent the Commercialization of CG-5503 by Grünenthal in the Grünenthal Territory during the Term and thereafter.

9.6 No Conflicting Rights. From and after the Combined Territories License Agreement Effective Date, neither Party will grant any right to any Third Party relating to its respective technology in the Field which would conflict with the rights granted to the other Party hereunder.

9.7 No Other Representations or Warranties. EXCEPT AS SPECIFICALLY AND EXPRESSLY SET FORTH IN THIS ARTICLE 9, NO PARTY MAKES ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, AT LAW OR IN EQUITY, RELATING TO ITS INTELLECTUAL PROPERTY AND/OR KNOW-HOW, OR ANY OTHER INFORMATION DISCLOSED, REVEALED OR OTHERWISE MADE AVAILABLE BY ONE PARTY TO THE OTHER UNDER THIS AGREEMENT OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, ANY REPRESENTATION OR WARRANTY AS TO VALUE, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR FOR ORDINARY PURPOSES, OR ANY OTHER MATTER.

9.8 No Liability for Consequential Damages. Neither Party shall be liable to the other for incidental or consequential damages arising out of or related to the subject matter of this Agreement.

ARTICLE 10 MANAGEMENT OF REGULATORY APPROVAL PREPARATION ("RAP") AND COMMERCIALIZATION

10.1 Steering Committee.

(a) Establishment of Steering Committee. Within [***], the Parties have established a Steering Committee ("**SC**"), which is composed of four (4) representatives of each Party who were appointed (and may be replaced at any time) by such Party on written notice to the other Party. The representatives from each Party

will collectively have one vote in decisions, with decisions made by unanimous vote.

(b) Authority. The Parties agree that, in voting on matters as described in this Article 10, it shall be conclusively presumed that each voting member of the SC has the authority and approval of such member's respective senior management in casting his or her vote and that decisions of the SC made in accordance with this Article 10 shall be binding upon each of the Parties; provided, however, that the SC, other than as expressly provided for herein, shall not have the authority to amend or modify this Agreement. The members of the SC will undertake reasonable efforts to obtain from their respective senior management the authority to cast their vote prior to the respective meeting, however, in no event later than 10 days after such meeting.

(c) Delegation. The SC shall create such subcommittees or subteams as it may deem necessary or appropriate and may at the same time define the composition and rules of such sub-committees. One such subcommittee that shall be created by the SC shall be a RAP Subcommittee ("**RSC**") which shall be described hereinafter. The RSC shall be led by a representative chosen by Grünenthal.

(d) SC Responsibilities. The SC shall be responsible for overseeing the RAP of Products in OMP´s Territory and the EU. In addition, the SC shall review and approve any recommendations from the RSC with respect to the modification, amendment or departure from the RAP Plan, RAP Budgets for OMP Territory and the EU, RAP Costs and any other financial activities. Any modifications to the RAP Plan (including the work plans, budgets and timelines therein) approved at a SC meeting shall be considered approved and shall constitute an amendment upon SC ratification of the meeting minutes related thereto.

(e) Dispute Resolution. If the members of the SC cannot reach in its meeting a unanimous decision with respect to RAP matters referred to it for approval or the Parties can not agree to meet within [***] of the initial request for a meeting to resolve the dispute, such undecided matters shall be

promptly referred to the Management Committee for decision unless otherwise agreed by the SC.

Unless otherwise agreed by the MC, the meeting of the Management Committee shall be convened by each of its members after co-ordination with the other member and shall take place within [***] after referral to the Management Committee. The meeting shall take place at the place of the Party not hosting the last SC meeting. If the members of the Management Committee cannot reach in its meeting a unanimous decision with respect to RAP matters referred to it for approval or if the meeting does not take place within the timeframe foreseen above, for such undecided matters the procedures for "Final decision-making/Disputes RAP Matters" set forth below in Section 10.2 shall apply.

10.2 Final Decision-Making/Disputes RAP Matters. If the Management Committee cannot agree in its meeting, or unless otherwise agreed by the MC, the final decision on such undecided matters shall be made by Grünenthal for OMP Territory and Grünenthal Territory, except as to Excepted RAP Matters. "**Excepted RAP Matters**" are defined as:

(i) increasing the budget for the RAP Plan by more than 10% of the previously approved RAP Budget,

(ii) altering the RAP Plan in a manner which would change indication(s) for which a Product is being Prepared For Regulatory Approval,

(iii) terminating or suspending a Phase III Clinical Trial prior to completion in accordance with its protocol,

(iv) material issues relating to the initial label, revised label or changes to the label of Product, or

(v) alteration of a protocol which would change one or more endpoints outlined in such protocol and which would materially delay the filing of a Drug Approval Application with a Regulatory Authority.

If a final decision cannot be reached at the Management Committee with respect to any of the Excepted RAP Matters, which have been referred to that level for

resolution or approval, the status quo shall be maintained with respect to Excepted RAP Matters items 10.2 (i) as far as it concerns OMP Territory and Grünenthal Territory and with respect to Excepted RAP Matter 10.2 (ii). As to Excepted RAP Matters item 10.2 (iii), the Phase III Clinical Trial shall be terminated for the affected Territory if an external expert advisory panel recommends termination or the FDA or the EMA orders termination of the Phase III Clinical Trial or suspended for the affected Territory if any safety issue arise that require to immediately put the Phase III clinical trial on hold, otherwise for the not affected Territory the status quo shall be maintained. With respect to Excepted RAP Matter (iv), no label or labeling, or changes to the label of labeling, will be finalized until the Parties reach mutual agreement. As to Excepted RAP Matter item (v), endpoints shall be altered or changed, independent of its effect on timing, if recommended or mandated by a Regulatory Authority, otherwise the status quo shall be maintained.

10.3 RAP Sub-Committee.

(a) Establishment of RSC. After the Combined Territories License Agreement Effective Date, the Parties have established a RAP Subcommittee ("**RSC**") to coordinate all activities with respect to the RAP of Products, within the budgets approved hereunder. The first meeting of the RSC has occurred. The RSC shall be led by a representative chosen by Grünenthal.

(b) RSC Responsibilities. The RSC shall be responsible, with the oversight and approval of the SC, for overseeing the Parties' independent RAP activities hereunder, including, without limitation, coordinating all RAP to be conducted independently by OMP and/or Grünenthal pursuant to the RAP Plan for their respective territories and may propose modifications of the RAP Plan to the SC. The RSC will determine the allocation of costs between OOP and internal FTEs based on the principles of **Exhibit 10.3(b)**. Within its responsibilities, the RSC may decide on certain cost allocations of the annual budget within the limits of such budget. If actual costs of implementing the RAP Plan exceed the total amounts budgeted for expenditure during the relevant period, and will lead to an overage of the annual budget, the RSC will revise, provided that the Parties mutually agree, the RAP Plan and submit it in writing, with an explanation of the variance and the reasons therefore for approval to the SC.

The RSC shall be responsible for implementation of the RAP Plan under the oversight of the SC.

(c) RSC Decision-making. The RSC will operate by consensus. In the event that the RSC members do not reach consensus with respect to a matter that is within the purview of the RSC herein, unresolved disputes will be referred promptly to the SC, where the matter will be dealt with as recited in Sections 10.1 (e) and 10.2.

(d) Accounting/Financial Reporting. Each Party will appoint a representative with expertise in the areas of accounting, cost allocation, budgeting and financial reporting to the RSC. Such representatives shall work under the direction of the SC to provide services to and consult with the RSC in order to address the financial, budgetary and accounting issues which arise in connection with the RAP Plan.

(e) RSC Reporting. The RSC shall monthly prepare and provide the SC with minutes of its meetings summarizing the progress of the RAP.

10.4 Commercialization Team.

(a) Formation of the Commercialization Team. Within [***], a Commercialization Team ("**CT**") has been created, comprised of an equal number of representatives of each Party. The CT shall, during the RAP of Product, coordinate (i) with the RSC those activities deemed necessary for a successful Commercialization of Products in the OMP Territory and Grünenthal Territory, as outlined herein, upon Regulatory Approval. The commercial matters shall be to develop a publication and scientific symposia strategy, develop and implement a strategy for Phase IV Clinical Trials, establishment of key opinion leaders, coordinate and create a calendar of key scientific and clinical meetings which both Parties plan to attend, develop, search and select a single, worldwide trademark to be used by both Parties if Grünenthal exercises its option in Section 5.1(a), create a unified promotional message to target audiences, and all other commercial matters agreed to by the Parties. One representative from each Party shall be designated as that

Party's "**Commercialization Team Leader**" to act as the primary CT contact for that Party.

(b) Dispute Resolution. If the members of the CT cannot reach in its meeting a unanimous decision with respect to commercialization matters referred to it by the RSC or SC or the Parties, then such dispute shall be escalated to the managing director of Grünenthal and President of OMP for their consideration and agreement; and, if they are unable to agree after negotiation, the matter shall default to the status quo. If there is no previously agreed to status quo on a particular issue, then each Party will have final decision making authority for such issue in its respective Territory. In no event, will any such irresolvable disputes arising in the CT be resolved under the dispute resolution process of Sections 10.1(e) and 10.2.

ARTICLE 11 REGULATORY APPROVAL PREPARATION ("RAP")

11.1 RAP Plans.

(a) RAP Plans. The Parties have attached as **Exhibit 1.63** an initial RAP Plan (**" RAP Plan 1.63"**), with the 2004 First Amendment as **Exhibit 1.63.1**, an additional RAP Plan (**"RAP Plan 1.63.1"**). RAP Plan 1.63 and 1.63.1 are prepared and drafted by Grünenthal, revised by Grünenthal in response to comments received from OMP and agreed to by Parties which shall set out the details of the RAPs of the Product on a world-wide basis.

(b) RAP Plan Modifications. The Parties acknowledge that the RAP Plan, as the RAP progresses needs to be revised and modified by the RSC and approved by the SC with regard to OMP Territory and Grünenthal Territory, with Grünenthal taking the lead in the modification process of RAP Plan 1.63 and OMP taking the lead in the modification process of RAP Plan 1.63.1. Disputes shall be resolved as set out in Sections 10.1(e), 10.2; and 10.3(c). Each such revised RAP Plan shall include, without limitation, detailed plans for, as applicable, the RAP activities and clinical studies of Product, designation of which Party is responsible for each task, staffing levels required to carry out such activities (which levels shall be reasonably necessary for the attainment

of the RAP goals, as applicable) including specification of a budget setting forth the estimated expenditures required (RAP Costs and FTE Resources) to carry out such activities, and a detailed budget covering each activity that will be continued or initiated during the next calendar year. If a specific activity would best be undertaken by a Third Party contractor the RAP Plan shall indicate which Party shall manage, account for and be liable for such Third Party contractor.

11.2 Exclusive RAP Relationship. It is understood and agreed by the Parties that, during the Term, the Parties shall work exclusively with each other to Prepare for Regulatory Approval of the Product solely in accordance with and under the terms of this Agreement.

11.3 RAP Efforts.

(a) The Parties agree to coordinate and to carry out all RAP activities as agreed in the RAP Plan. RAP activities will, to the extent practicable, utilize the then- prevailing infrastructure and expertise of each Party in a given activity or with respect to a specific RAP activity.

11.4 RAP Responsibilities. Consistent with its responsibilities under this Agreement and the RAP Plan (particularly, those recited in Article 11), each Party agrees to perform the following, subject to applicable law, including confidentiality, data protection and privacy restrictions,

(a) provide to the other Party all preclinical data, assays and associated materials, protocols, procedures and any other information in such Party's possession that the other Party deems reasonably necessary for the RAP of Product;

(b) conduct all agreed studies and other activities assigned to the respective Party, including human clinical studies for Product; and

(c) file required communications with Regulatory Authorities in either the OMP Territory or the EU as applicable and, as provided for by Section 11.6 and as otherwise reasonably requested by the other Party, consult with the other

Party in preparing such Drug Approval Applications and communications with the relevant Regulatory Authorities in the Territory.

11.5 Clinical Trials.

(a) The Parties will conduct, sponsor, support and/or assist in any clinical trial for the Product, in accordance with the most current version of the RAP Plan and shall provide each other forthwith with all Information gathered in OMP Territory and Grünenthal Territory, including but not limited to clinical data, database information and reports related to clinical trials for the Product reasonably requested by the other Party in a mutually agreed upon format compatible to both Parties' systems. The overall amount of patients included in the various studies and the distribution of patients between the OMP Territory and Grünenthal Territory shall be determined by the Parties after considering the Parties' discussions with Regulatory Authorities in order to support Drug Approval Applications. The Parties will make reasonable efforts to split the overall amount of patients [***] between OMP´s Territory and the EU for Products developed in accordance with RAP Plan 1.63 as long as reasonable for the project (time to market, expertise, costs etc.). All Information, including but not limited to clinical data, database information and reports related to clinical trials for the Product shall be owned by Grünenthal, and during the Term OMP shall have full use of all such Information for the Product, solely for purposes provided for under this Agreement. Subject to Articles 7 and 8 and notwithstanding the foregoing, either Party may use its know-how resulting from the Information for any purpose. All clinical data, database information and reports from such clinical trials for Products shall be in English, centralized and held at Grünenthal, with a duplicate set provided to OMP, for deposit at a site of its own selection.

(b) Both Parties shall inform each other of Post Approval Commitments in their territory and allow the other Party an opportunity to review and comment on how such Party intends to meet such Post Approval Commitments prior to finalization of same. Such comments of the other Party shall be considered in good faith. Section 11.6(e) and Section 11.6(g) shall apply mutatis mutandis. Notwithstanding the above, the decision of the Party in which such Post

Approval Commitment is requested shall be final. The decision shall be communicated to the other Party in due time.

With regard to OMP Territory and the EU the following shall apply:

(i) If the Parties agree on a joint Phase IIIB, Phase IIIB2, or Phase IV study relating to the Product developed under RAP Plan 1.63, the costs for such study will be [***] and if the Product was developed under RAP Plan 1.63.1, [***] of the costs associated with the such study. Each Party shall have full use of all Information and documents arising out of such studies.

(ii) With regard to the EU the costs for all Post Approval Commitments will be borne by Grünenthal if the Post Approval Commitments are requested from the Regulatory Authorities in the EU and by OMP if the Post Approval Commitments are requested from the Regulatory Authorities in the OMP Territory.

(iii) The costs for a jointly agreed upon Core Pediatrics Program, other than Post Approval Commitments, shall be shared between OMP and Grünenthal so that [***]. Each Party shall have full use of all Information and documents arising out of such studies.

(iv) Each party shall bear the costs for the compilation and execution of a Risk Management Plan required for its territory.

(v) If the Parties do not agree on a joint study, the Party conducting such Core Pediatric Program, Phase IIIB, Phase IIIB2 and Phase IV study alone, shall bear all costs related to such study and shall own all Information including, but not limited to, data and clinical reports arising out of such study. The Party conducting any Post Approval Commitments shall own all Information arising out of such Post Approval Commitment. Any such clinical trial shall be the sole and

exclusive property of the Party conducting such study. No person or entity, including the other Party, shall have any right, title or interest therein. However, all completed Pediatric Studies, Phase IIIB, Phase IIIB2, Phase IV studies and Post Approval Commitments shall be included free of charge as supportive in subsequent Drug Approval Applications for the Product. With respect to any Pediatric Study, Phase IIIB, Phase IIIB2 and Phase IV study or Post Approval Commitment conducted by a Party alone, if a Regulatory Authority requests access to or review of data or reports owned by that Party, that Party shall provide to the other Party free of charge such data solely for the purpose of satisfying the request of the Regulatory Authority. Notwithstanding the foregoing, adverse event reporting shall apply to any Core Pediatric Program, Phase IIIB, Phase IIIB2 and Phase IV studies, and Post Approval Commitment. Notwithstanding the foregoing, with respect to the clinical trial KF 5503/68 Part I, the following shall apply:

[***].

(vi) The non-sponsoring party may elect to engage in such study and share the costs up to the date of the first patient enrollment in a clinical study or in the case of other nonclinical studies, the date on which data is first collected in the study without additional costs. Thereafter, the other Party may use data or know-how arising out of any such study either

as a submission to a Regulatory Authority for an extension of the label of the Product (other than solely as requested by a Regulatory Authority) or to support any Commercialization or Promotional activities with respect to any Product for such purposes only if that Party pays to the sponsoring Party an amount equal to [***], unless otherwise agreed to. However, the Parties agree that data or know-how arising out of such study may be used by the other Party free of charge, only and to the extent it is in response to an unsolicited request as reasonably evidenced.

With regard to Grünenthal Territory other than the EU, Grünenthal shall bear all costs in connection with Phase IIIB, IIIB2, Phase IV Studies, Core Pediatric Program and Post Approval Commitment.

With regard to Grünenthal Territory other than the EU, the Parties shall obtain the data and know-how of Phase IIIB, Phase IIIB2 and Phase IV Studies and Post Approval Commitments free of charge.

11.6 INDs and Drug Approval Applications.

(a) With regard to OMP Territory Grünenthal shall transmit and has transmitted the FDA Form 1571 and attachment for section 13 (**Exhibit 11.6 (a), 1**) and a letter to the FDA (**Exhibit 11.6 (a), 2**) stating that Grünenthal transfers and assigns IND 61,345 to J&J PRD. Consequently J&J PRD as of the date of the letter will become the official and responsible sponsor of IND 61,345.

Simultaneously with the above mentioned letters of Grünenthal J&J PRD shall send and has sent a letter to the FDA (addressed to the Division Director) (**Exhibit 11.6 (a), 3**) with copies of said letter to Grünenthal GmbH and Grünenthal USA, Inc. confirming that Grünenthal GmbH has agreed to transfer IND 61,345 to J&J PRD and that J&J PRD accepts this transfer along with acknowledging full responsibility for the maintenance of said IND as prescribed under CFR 21 section 312 except as defined in section 13 of the respective Form 1571. Such letter shall also contain the statement that J&J PRD grants to Grünenthal GmbH and/or its US Affiliate, Grünenthal Inc., One

Pluckemin Way, Bedminster, New Jersey 07921, the right of reference to IND 61,345 and the statement that Grünenthal maintains safety responsibility as defined in section 13 of the respective Form 1571. In addition this letter shall be accompanied by an executed FDA Form 1571 signed by J&J PRD which assigns J&J PRD as sponsor.

OMP shall take any and all necessary steps to comply with the documents referred to in this Section 11.6 (a) to FDA granting Grünenthal and/or its US Affiliate a right of reference to IND 61,345 with respect to any INDs, Drug Approval Applications, and Regulatory Approvals with regard to Products. In no event, Grünenthal shall take any action relating to the Product if a negative effect on the safety, efficacy or the commercial potential of the Product can be reasonably anticipated. OMP may revoke the right of reference to IND 61,345 only in case of the entire termination of this Agreement pursuant to Section 15.2(b) (termination by OMP for breach) or 15.3.

(b) Consistent with the then effective RAP Plan in regard to timing, content and scope of INDs and Drug Approval Applications and Regulatory Approvals, OMP shall be responsible for obtaining and filing

(i) further submissions to the referenced transferred IND with regard to OMP Territory, including, but not withstanding, Drug Approval Applications (NDAs) and any and all manners of the seeking of Regulatory Approval(s) for the Product(s) in the OMP Territory, provided, however, no such IND Submission, Drug Approval Application and/or Regulatory Approval may be filed or sought unless they are part of the RAP Plan. OMP shall bear the respective registration fees and all electronic document processing costs.

Grünenthal shall be responsible for obtaining and filing INDs and Drug Approval Applications and seeking Regulatory Approvals for the Product in the Grünenthal Territory and shall bear the respective registration fees and all electronic document processing costs.

Prior to submitting any IND or Drug Approval Application, the Parties shall consult and coordinate in preparing such filings and in reviewing and determining the content and scope thereof. Each Party shall have the right to

review and comment (prior to filing with a Regulatory Authority) on all INDs, Drug Approval Applications or Regulatory Approvals in the OMP Territory and EU of the other Party in accordance with specific timelines or other arrangements agreed upon by the SC, and each Party's comments will be given all due consideration. The same shall apply for all changes (except for immaterial changes) or amendments of INDs, Drug Approval Applications and Regulatory Approvals and request of a Party to the other Party to amend existing INDs. If requested by either Party in writing the INDs and/or applications for a Drug Approval Application and/or application for a Regulatory Approval for Products developed in accordance with RAP Plan 1.63 and/or Products developed in accordance with RAP Plan 1.63.1 shall be split in order to pursue separately with regard to such Products. Grünenthal shall own all INDs, Drug Approval Applications, and Regulatory Approvals for Product in the Grünenthal Territory and OMP shall own all INDs, Drug Approval Applications, and Regulatory Approvals in the OMP Territory, provided, however, such INDs, Drug Approval Applications and Regulatory Approvals are part of the RAP Plan. Each Party shall provide copies of all regulatory documents to the other Party for the United States and the EU, including a copy of any Regulatory Approval of the Product in the United States and the EU, to be used for registration purposes by Grünenthal in the Grünenthal Territory or OMP in the OMP Territory. A centralized electronic repository shall be created and maintained by Grünenthal containing all data generated by the Parties relating to Products in a format to be agreed upon and which is compatible to both Parties' systems. When requested in writing the Parties shall discuss the transfer of safety responsibility.

(c) OMP shall use the INDs, Drug Approval Applications and Regulatory Approvals only

(i) consistent with the then effective RAP Plan in regard to timing, content and scope,

(ii) consistent with the Agreement.

Except as permitted in Sections 11.5 and 11.6, OMP shall not use such INDs or any drug Approval Application or Regulatory Approval as the basis for, or

refer to them in any IND other than the referenced transferred IND, any Approval Applications or Regulatory Approvals that are not part of the RAP Plan, nor permit any third party to do so, and OMP shall not use the data in said INDs, Drug Approval Application or Regulatory Application as part of another or other INDs, Drug Approval Applications or Regulatory Approvals that are not part of the RAP Plan, nor permit any third party to do so.

(d) Each Party shall be responsible for and comply with all legal requirements in connection with the holding of INDs including but not limited to reporting responsibilities and annual updates.

(e) The Parties shall to the extent allowable by law have the right to participate in all meetings and/or telephone conversations with Regulatory Authorities in the OMP Territory and EU and the Parties shall inform each other in due time thereof in advance giving the other party all details necessary. The number of participants and the role of the participants shall be decided by each Party under due consideration of the other Party's concern, if any, and under due consideration of the issues discussed in the meeting and/or telephone conference. All contacts including face-to-face meetings and telephone conversations with the Regulatory Authorities in the OMP Territory and the EU in which the other Party does not participate shall be summarized in writing and transmitted immediately to the other Party and in no case later than within [***] after such contact has taken place.

(f) As applicable and where possible in due time in advance and during the entire Term of this Agreement, each Party, for their respective Territory, shall notify each other of the existence of any material data which have to be reported to the respective Regulatory Authorities in the OMP Territory or the EU, any material documents or reports which have to be filed with the FDA or any other Regulatory Authority in the EU under this Agreement or material communication with such Regulatory Authority. If not possible in due time in advance the Parties shall inform each other at the latest within [***] of such filing or communication and, upon request, shall provide a copy of such document(s) to the other Party.

(g) Except as mentioned in the preceding paragraph and with the exception of immaterial communications any and all other planned communications of the Parties with the Regulatory Authorities in the OMP Territory and the EU, oral or in writing, must be discussed with the other Party, prior to any actual contact with such Regulatory Authority. All drafts of material communication(s) with the Regulatory Authority in the OMP Territory and the EU shall be transmitted in a timely manner in order to give the other party the opportunity to comment such communication(s).

(h) In case of any disagreement between the Parties on planned communications as mentioned above the Parties shall refer the issue to the SC and the SC shall become responsible for deciding such issues. If the members of the SC cannot reach in its meeting an unanimous decision with respect to the communications the dispute resolution of Section 10.1 (e) and 10.2 shall apply.

(i) On request of Grünenthal OMP shall promptly conduct all steps necessary in order to have the concerned IND transferred back to Grünenthal in the respective Territory in case OMP has decided to discontinue activities in the respective Territory with respect to Product development in accordance with RAP Plan 1.63 or the overall activities allocated to OMP in the RAP Plan or OMP intends to withdraw the concerned IND.

(j) Other than with respect to transfers of any or all of the following to Grünenthal upon the termination of this Agreement as provided in this Agreement, at no time during the Term of this Agreement or after expiration of this Agreement, and other than to designated Affiliates, shall OMP transfer title or otherwise attempt in any manner to dispose of any such INDs, Drug Approval Applications or Regulatory Approvals for Products in the OMP Territory and OMP shall maintain any and all such INDs, Drug Approval Applications and Regulatory Approvals.

11.7 Regulatory Meetings and Communications.

(a) Within [***], the RSC has met and agreed upon processes and procedures

for sharing information needed to support each Party's respective regulatory responsibilities, including without limitation, a global safety database relating to Product.

(b) Immediately after confirmation of any meetings with Regulatory Authorities in OMP Territory or the EU, each Party shall notify the other Party of such meeting and both Parties shall have the right to attend any such meetings with Regulatory Authorities set up by the other Party to ensure that the Product is consistently Prepared for Regulatory Approval. The Parties shall cooperate in good faith with respect to the conduct of any inspections by any Regulatory Authority of a Party's or contractor's site and facilities, and each Party shall at a minimum be given the opportunity to attend the summary, or wrap up, meeting with a Regulatory Authority at the conclusion of such site inspection. If such attendance would result in the disclosure to the other Party of confidential information or trade secrets unrelated to the subject matter of this Agreement, the Parties shall enter into a confidentiality agreement covering the unrelated subject matter. To the extent either Party receives written or material oral communication from the FDA or any other Regulatory Authority in the EU relating to any activities subject to this Agreement, the Party receiving such communication shall notify the other Party and provide a copy of any written communication as soon as reasonably practicable and in no case later than three (3) business days thereafter.

(c) Adverse Event Reporting. Notwithstanding anything herein to the contrary, the Parties shall handle adverse events reporting relating to Products as set forth in **Exhibit 11.7(c)**. Further, the Parties agree and acknowledge that OMP may provide information specifically related to OMP Technology, which it obtains under this Section 11.7 to OMP's other clients developing and/or marketing other products using OMP Technology.

11.8 Territory Specific RAP Costs.

(a) Any cost or expense incurred or to be incurred by Grünenthal as a result of regulatory approval preparation activities, to obtain Regulatory Approval outside the OMP Territory and the EU or a territory otherwise included by

mutual agreement in the current version of the RAP Plan ("**Territory Specific RAP**"), shall not be shared under this Agreement.

(b) All Territory Specific RAP must be communicated from Grünenthal to OMP prior to conducting any RAP activities regardless of whether such Territory Specific RAP is included as a RAP Cost under Section 6.2. Grünenthal shall take any comments of OMP into consideration. All Information including, but not limited to, data and clinical reports arising out of any Territory Specific RAP, including, without limitation, any clinical trial, submitted to the Parties pursuant to this Section 11.8, shall be the sole and exclusive property of Grünenthal and no person or entity, including OMP, shall have any right, title or interest therein. However, OMP shall have free of charge full use of all such Information for the Product including but not limited to using such Information as a submission for indication or extension to a Regulatory Authority or to support any Commercialization or Promotion activities with respect to any Product. All such Information relating to Product shall be included in the centralized electronic repository set up by the Parties for use by either Party for the fulfillment of regulatory submissions or legal obligations. However, if, with respect to any activities by OMP, a Regulatory Authority requests access to or review of data or reports owned by Grünenthal, Grünenthal shall provide OMP with such data to comply with the request of the Regulatory Authority under such conditions as will protect its legitimate ownership rights. Notwithstanding the foregoing, adverse event reporting shall apply to any Territory Specific RAP.

11.9 Transfer of Materials. During the Term hereunder, the Parties anticipate that each Party will transfer certain of its proprietary materials to the other Party. Each Party agrees that it will use such materials of the other Party only for the purposes of this Agreement, hereunder, and will not transfer such materials to any Third Party without the consent of the other Party except with respect to Grünenthal's Affiliates and licensees and to OMP´s Affiliates engaged in RAP that need to obtain the proprietary material for the fulfillment of this Agreement. Ownership of proprietary materials made or assembled by a Party or a Third Party during and in furtherance of this Agreement, shall be

determined in accordance with Article 7. Each Party shall have the right to transfer such material to Third Parties under the form of a material transfer agreement agreed upon by the Parties. All transfers of materials pursuant to this Agreement may be charged to the common account as a RAP Cost of the Party transferring such material.

11.10 Compliance with GLP/GCP/GMP. All of the RAP activities, including all tasks specified by the RAP Plan and its associated work plans, shall, in accordance with timelines set forth therein, and shall be done in accordance with GLP, GMP and GCP, as applicable. Each Party is prepared, at its sole discretion, to assist the other Party with regard to GLP, GCP and GMP compliance. With respect to any facility or site at which a Party conducts RAP pursuant to this Agreement, including, where commercially reasonable and within the control of the other Party, Third Party facilities or sites, each Party shall have the right, at its expense, upon reasonable written notice and during normal business hours, to inspect such site and facility and any records relating thereto as is reasonably necessary to verify the other Party's compliance with the terms of this Agreement relating to GLP, GCP and GMP. Such inspection shall be subject to the confidentiality provisions of this Agreement. Each Party agrees, to the extent possible, to include in any contract or other written arrangement with a Third Party relating to such facilities and sites a clause permitting the other Party to exercise its rights under this Section 11.10.

11.11 Failure to perform Duties of RAP Plan. In the event that a Party fails to carry out any of its duties or responsibilities under the RAP Plan, due to reasons within the control of such Party, and such failure shall have continued for [***] after written notice thereof was provided to such failing Party, then the non-failing Party may assume control of the disrupted part of the RAP of Product in the OMP-Territory or EU, as applicable, except for filing of any Drug Approval Applications which shall remain the failing Party's responsibility. The failing Party shall continue to be responsible for its Proportionate Share of the RAP Costs for RAP being conducted by the non- failing Party, along with an [***] such RAP Costs of the activities of which the non-failing Party has assumed control, as compensation to the

non-failing Party for the disruption to the RAP Plan caused by the failing Party. If the non-failing Party has not assumed control over the disrupted part of the RAP of Product and the failure to carry out the duties or responsibilities of the failing Party has continued for [***] after receipt of the above mentioned written notice this failure shall be considered a material breach in accordance with Section 15.2. Such breach may entitle the non-breaching Party to terminate immediately at the end of such [***] period without notice period. If such breach relates to an OMP Territory such right to terminate shall only apply to the OMP Territory, as applicable.

11.12 Combination Products and Products based on Improvements. If it is the intention to jointly develop a Combination Product or Products based on Improvements, the Parties shall cooperate in essentially the same manner as for Product, containing CG-5503 as the sole active pharmaceutical ingredient under this Agreement so that Combination Products and Products based on Improvements can be promptly registered in each Party's Territory. The Parties will discuss in good faith if and how to achieve this goal. If the Parties' cannot agree, the Party conducting such development alone, shall bear all costs related to such development and all Information including, but not limited to, data and clinical reports arising out of such development, including, without limitation, any clinical trial, shall be the sole and exclusive property of the Party conducting such development and no person or entity, including the other Party, shall have any right, title or interest therein. The non-sponsoring Party shall have the option to use data or know-how arising out of any such development as a submission to a Regulatory Authority only if that Party pays to the sponsoring Party an amount equal to [***], unless otherwise agreed to by the Parties.

ARTICLE 12 ADF FORMULATION

12.1 Decision of an abuse deterrent form ("**ADF**") Formulation.

(a) The Parties anticipate that the Product will initially be Commercialized using a Grünenthal formulation currently being used in clinical trials. However, in the event that the filing of a Drug Approval Application in the OMP Territory for the ADF Formulation, (which has been selected according to Section 12.1(b)), would not delay the filing of a Drug Approval Application for the Grünenthal formulation currently used in clinical trials by more than six (6) months, then OMP may file its Drug Approval Application for the selected ADF Formulation.

(b) At present, Grünenthal is working on its own ADF Formulations of the Product and is considering further suitable technologies of abuse deterrent formulations. OMP is considering an OMP-ADF-Formulation incorporating OMP Technology. It is the aim of the Parties to agree, as soon as all relevant data regarding the decision criteria described below are available, on one worldwide ADF Formulation for Commercialization. In advance of agreeing upon a worldwide ADF Formulation, each Party shall, independently of the other Party and objectively, evaluate its own ADF Formulation regarding all main decision criteria. The main decision criteria are:

(i) abuse deterrence potential of various administration routes,

(ii) feasibility of bio-equivalence to the current formulation (non ADF),

(iii) development costs,

(iv) costs of goods,

(v) scope of patent protection,

(vi) development time,

(vii) regulatory aspects,

(viii) legal aspects,

(ix) improvement of overall activity profile.

Thereafter, the Parties shall exchange simultaneously the results of the above mentioned evaluation in written form and shall discuss the merits of each ADF Formulation.

12.2 Development of ADF Formulation.

(a) The Parties have agreed to jointly develop and use the Grünenthal-ADF- Formulation but if the Parties would agree later jointly to use the OMP-ADF- Formulation worldwide,

(i) OMP shall be responsible for all CM&C activities related to the OMP- ADF-Formulation on a worldwide basis. The RAP Plan will be modified, the Parties shall be responsible for its RAP. The RAP Costs incurred after such decision will be shared equally by the Parties. Such RAP will be considered as OOP which will be shared equally by the Parties. The responsibility for the manufacture and supply of the OMP-ADF-Formulation in the Grünenthal Territory shall be based solely upon Grünenthal's exercise of its option in accordance with Section 12.2(a)(v)(a).

(ii) Licenses for Commercialization. OMP hereby grants to Grünenthal and its Affiliates an exclusive (even as to OMP), paid-up license, within the Field under the OMP ADF-Formulation Patents, Independent ADF Formulation Improvement Patents Controlled by OMP and OMP Know- How, to Commercialize Products within the Grünenthal Territory. The license to Commercialize Products based on any OMP ADF-Formulation Patent is subject to a mutual agreement under Section 12.1(b) to develop the OMP ADF-Formulation. Grünenthal shall not have any right to sell, offer for sale, distribute and have sold Product under the OMP ADF-Formulation Patents and OMP Know-How for any indication outside the Field.

(iii) Licenses for Production. OMP hereby grants to Grünenthal and its Affiliates a non-exclusive, paid-up license, within the Field under the OMP ADF-Formulation Patents, Independent ADF Formulation Improvement Patents Controlled by OMP and OMP Know-How, to

make Products worldwide solely for the purpose to Commercialize Products within the Grünenthal Territory. The license to make Products based on OMP ADF-Formulation Patents is subject to a mutual agreement under Section 12.1(b) to develop the OMP-ADF- Formulation and Grünenthal's election under Section 12.2(a)(v)(a) to manufacture the OMP ADF-Formulation.

(iv) License for RAP. OMP hereby grants to Grünenthal and its Affiliates a non-exclusive, paid up worldwide license, within the Field, under the OMP ADF-Formulation Patents, Independent ADF Formulation Improvement Patents Controlled by OMP and OMP Know-How for use in carrying out RAP of the Product. The license to carrying out RAP of the Product based on OMP-ADF-Formulation Patents is subject to a mutual agreement under Section 12.1(b) to develop the OMP ADF- Formulation.

(v) Manufacturing of OMP-ADF-Formulation. In the event that both OMP and Grünenthal elect to Commercialize Product using the OMP-ADF-Formulation, Grünenthal shall have the option to:

(a) install a manufacturing equipment train for the OMP-ADF- Formulation in a Grünenthal facility or a facility of a Grünenthal Affiliate for use exclusively for manufacturing Product and/or Combination Product. OMP shall use and shall cause any applicable Third Party (in as far as OMP is able to achieve such rights) to support Grünenthal in the installment of such manufacturing equipment train and the provision of Grünenthal with the necessary technical training assistance. Such support shall be charged to Grünenthal on a transparent, standard allocated cost basis, or

(b) have OMP manufacture Product with the OMP-ADF-Formulation for Grünenthal at an OMP, OMP Affiliate, or licensor of OMP- ADF-Formulation facility in the EU, if available. Such supply shall be at OMP`s Fully Allocated Manufacturing Cost, without any internal mark-ups. In the case OMP has terminated the

Agreement, OMP will supply Product to Grünenthal at OMP´s Fully Allocated Manufacturing Cost. Additionally, in case of such supply by OMP a royalty of [***] on Net Sales shall be paid by Grünenthal until the last to expire of any OMP-ADF- Formulation Patent which claims the Product. In the event that OMP manufactures Product for Grünenthal, then Grünenthal shall have the right to have a limited number of employees present to oversee such manufacturing work, to inspect OMP´s manufacturing facility, review OMP´s standard operating procedures for manufacturing and inspect related records, upon reasonable notice, during normal business hours, under appropriate conditions of confidentiality. Notwithstanding anything to the contrary in this Agreement, in the event that OMP supplies Product to Grünenthal hereunder, such supply shall be pursuant to the terms of a mutually acceptable supply agreement to be entered into between the Parties, which agreement shall contain reasonable, industry-standard terms. OMP and Grünenthal shall negotiate in good faith a supply agreement on reasonable terms and conditions.

For the purpose of this Section 12.2(a)(v), OMP shall include its Affiliates.

(vi) The Party carrying out RAP of the selected ADF Formulation shall regularly exchange information as set forth, but not limited to, timelines, technology, allocated capacity, dissolution profiles, PK etc., regarding the ADF Formulation and its RAP.

(b) The Parties have agreed jointly on July 23, 2004 to jointly develop and use the Grünenthal-ADF-Formulation in the Grünenthal Territory and OMP Territory. With regard to the above mentioned decision of the Parties the following shall apply:

(i) Grünenthal shall be responsible for all CM&C activities related to the supply of Grünenthal-ADF-Formulation for the Grünenthal Territory. OMP shall be responsible for all CM&C activities related to the supply

of Grünenthal-ADF Formulation for the OMP Territory. The RAP Plan will be modified and the Parties shall be responsible for its RAP on a Grünenthal Territory and OMP Territory-wide basis. The RAP Costs incurred after such decision will be shared equally by the Parties for the OMP Territory and Grünenthal Territory. Each Party shall be responsible for manufacture and supply of the Grünenthal-ADF- Formulation in its Territory. Such RAP for OMP Territory and Grünenthal Territory will be considered an OOP which will be shared equally by the Parties.

(ii) Licenses for Commercialization. Grünenthal hereby grants to OMP and its Affiliates an exclusive (even as to Grünenthal), paid-up license, within the Field under the Grünenthal ADF-Formulation Patents and Independent ADF Formulation Improvement Patents Controlled by Grünenthal to Commercialize Products within the OMP Territory. OMP shall not have any right to Commercialize Product under the Grünenthal ADF-Formulation Patents for any indication outside the Field. OMP shall not have any right to commercialize Product under the Grünenthal-ADF-Formulation Patents outside OMP Territory.

(iii) Licenses for Production. Grünenthal hereby grants to OMP and its Affiliates a non-exclusive, paid-up license, within the Field under the Grünenthal ADF-Formulation Patents, and Independent ADF Formulation Improvement Patents Controlled by Grünenthal; to make Products worldwide for the purpose to Commercialize Products within the OMP Territory under the Commercial Supply Manufacturing License.

(iv) License for RAP. Grünenthal hereby grants to OMP and its Affiliates a non-exclusive, paid up worldwide license, within the Field, under the Grünenthal ADF-Formulation Patents and Independent ADF Formulation Improvement Patents Controlled by Grünenthal for use in carrying out RAP of the Product.

(v) Information Exchange. The Party carrying out RAP of the selected ADF

Formulation shall regularly exchange information as set forth, but not limited to, timelines, technology, allocated capacity, dissolution profiles, PK etc., regarding the ADF Formulation and its RAP.

(c) If the Parties have not agreed to jointly use one ADF Formulation worldwide, both Parties shall have the right to develop their own ADF Formulation and there shall be no dispute resolution mechanism available under Section 10.1(e) and 10.2 relating to selection of the ADF Formulation. If Grünenthal elects not to use the OMP-ADF-Formulation, then Grünenthal shall not be responsible for any development costs associated with the development thereof and vice versa. In such case, the development of different ADF Formulations for the respective Territories should in no case delay the joint Core RAP Program, other than as allowed in Section 12.1(a). Any Party has the right at any time to use the ADF Formulation of the other Party by equally sharing the development costs thereof incurred after the decision not to jointly use one ADF Formulation worldwide, and for future development costs by [***].

12.3 Miscellaneous

(a) The Parties are aware that the ADF Formulation applies only for Products developed in accordance with RAP Plan 1.63.

(b) It is the intention of the Parties to develop a 1.63.1 ADF. Each Party shall inform the other Party of its 1.63.1 ADF in accordance with Section 12.1(b).

(c) OMP hereby grants Grünenthal and its Affiliates an exclusive (even as to OMP) license within the Field under OMP 1.63.1 Patents and OMP Know How, to Commercialize Products within the Grünenthal Territory; a non exclusive license within the Field under the OMP 1.63.1 Patents and OMP Know How, to make Products worldwide solely for the purpose to Commercialize Products within the Grünenthal Territory; a non exclusive license within the Field under the OMP 1.63.1 Patents and OMP Know How for use in carrying out RAP of the Product in Grünenthal Territory, the terms and conditions of which shall be negotiated in good faith by the Parties.

(d) Grünenthal hereby grants to OMP and its Affiliates an exclusive (even as to Grünenthal) license within the Field under the Grünenthal 1.63.1 Patents and Grünenthal Know How to Commercialize Products within the OMP Territory; a non exclusive license within the Field under the Grünenthal 1.63.1 Patents and Grünenthal Know How, to make Products worldwide solely for the purpose to Commercialize Products within the OMP Territory; a non exclusive license within the Field under the Grünenthal 1.63.1 Patents and Grünenthal Know How for use in carrying out RAP of the Product in OMP Territory, the terms and conditions of which shall be negotiated in good faith by the Parties.

(e) If the Parties are developing a 1.63.1 ADF in parallel the decision making process of Section 12.1(b) shall apply.

(f) If a Party has a 1.63.1 ADF developed by a third party the Party engaging the third party shall obtain a worldwide license on such 1.63.1 ADF with the right to sublicense this 1.63.1 ADF to the other Party to this Agreement for use in its Territory at the same conditions as the engaging Party unless otherwise agreed by the Parties.

(g) If the Parties cannot agree on a worldwide 1.63.1 ADF and consequently OMP uses its own 1.63.1 ADF the COGS Cap as per Section 6.7 shall not apply.

12.4 Licenses for Independent ADF Formulation Improvement Patents controlled by OMP and Grünenthal ADF Formulation Patents

(a) OMP grants to Grünenthal a worldwide non-exclusive, paid up license under any Independent ADF Formulation Improvement Patent Controlled by OMP for any product made, used or sold by Grünenthal and/or its Affiliates which product would be covered by at least one claim issued from at least one of the following US Patent Applications Publ. No. [***].

(b) Grünenthal grants to OMP a worldwide non-exclusive, paid-up license under any Grünenthal ADF Formulation Patent Controlled by Grünenthal for any product other than the Product made, used or sold by OMP and/or its Affiliates provided such product would not be covered by any claims issued from the following US Patent Applications Publ. No. [***].

(c) The licenses granted to Grünenthal and OMP respectively pursuant to Section 12.4 (a) and (b) include the right to sublicense to Affiliates or to licensees of Grünenthal and OMP respectively.

ARTICLE 13 INDEMNIFICATION

13.1 Indemnification. Each Party (the "**Indemnifying Party**") shall be solely and completely responsible and liable for, and shall indemnify, defend and hold the other Party (the "**Indemnified Party**") harmless from and against, any and all claims (whether made by a Third Party or the Indemnified Party), losses, damages, liabilities, settlements, penalties, fines, costs and expenses (including, without limitation, reasonable attorneys' fees and expenses), but expressly excluding consequential, special and punitive damages (unless paid to a Third Party as part of a Third Party claim) and lost profits (collectively, the "**Losses**"), arising out of:

(a) the conduct of the research and development program other than clinical trials contemplated herein in the Indemnifying Party's Territory;

(b) the conduct of clinical trials by the Indemnifying Party acting as Responsible Party for Clinical Trials, no matter in which Territory such clinical trials take place;

(c) the manufacture, use, handling, storage, sale, distribution or other disposition of Products (including clinical trial samples) by or on behalf of the Indemnifying Party; except, in the case of clauses (a), (b) and (c) above, to

the extent that such Losses do not also result from the willful misconduct or gross negligence of the Indemnified Party.

13.2 Indemnification Procedures.

(a) In the event that either Party receives notice of a claim with respect to a Product in the Territory, such Party shall inform the other Party as soon as reasonably practicable. The Parties shall confer how to respond to the claim and how to handle the claim in an efficient manner.

(b) In the event that a Party is seeking indemnification under Section 13.1, it shall inform the indemnifying Party of a claim as soon as reasonably practicable after it receives notice of the claim, shall permit the indemnifying Party to assume direction and control of the defense of the claim (including the right to settle the claim solely for monetary consideration), shall cooperate as requested (at the expense of the indemnifying Party) in the defense of the claim, and shall not settle or compromise the claim without the express written consent of the indemnifying Party.

13.3 Insurance. Beginning on the date that the first Product is first administered in a human clinical trial in any country in the Territory, each Grünenthal and OMP shall each have and maintain, each at its own cost, the following insurances:

(a) Commercial General Liability, and Product Liability (maintained for a period of at least five (5) years after the expiration or termination of this Agreement) providing at a minimum, insurance coverage for bodily injury, property damage and liability with respect to the contractual indemnification provisions provided under this Agreement). The policy shall have a limit of no less than twenty five million dollars (US-$25,000,000) for each occurrence of bodily injury up to a maximum of two hundred million dollars (US-$200,000,000) per calendar year, which may include a self-insured retention, and

(b) Foreign Local Coverage: Where required by law, the Party acting as Responsible Party for Clinical Trials of the clinical trial in such country of the

Territory shall obtain foreign local coverages in an amount that, at a minimum, satisfies the legal requirements of that jurisdiction.

(c) Policy Conditions: All policies under (a), (b) and (c) above shall provide that coverage under such policy shall not be suspended, voided, canceled, non- renewed, reduced in scope or the above mentioned limits, except after at least twenty five (25) days written notice has been given to the other Party. In addition, each Party shall provide to the other Party a copy of the certificate(s) of insurance for each policy procured and maintained pursuant to Sections 13.3(a) through (c) above.

In no event shall a Party's failure to request or obtain any such certificate of insurance from the other Party serve to waive that Party's right to insist upon full compliance with the other Party's insurance procurement and maintenance obligations pursuant to this Section 13.3.

The provisions of Section 13.3 shall apply accordingly in case of Commercialization of Products; *provided, however,* that in case of Section 13.3(b) the Party which is required by the laws of the respective jurisdiction is responsible to provide such local coverage.

ARTICLE 14 [Reserved]

ARTICLE 15 TERM AND TERMINATION

15.1 Term.

(a) This Agreement commenced on the Effective Date and shall remain in effect until the expiration, on a country-by-country basis, of OMP's or Grünenthal´s obligation to pay current royalties for the last Commercialized Product or future Products under development, unless earlier terminated as provided in this Article 15 ("**Term**").

Thereafter, subject to the remainder of Article 15, OMP shall have a fully paid up, non-exclusive license to make, use and sell Product under the Grünenthal Patents claiming the Commercialized Products, its use, or the manufacture thereof in the OMP Territory. Rights under all other Grünenthal Patents (the

"**Other Rights**") shall revert to Grünenthal except as provided in Section 15.1(b), and OMP shall promptly transfer to Grünenthal all Drug Approval Application and Regulatory Approvals including all clinical data associated therewith if and when OMP is no longer selling any Product hereunder. Grünenthal shall be free to Prepare Regulatory Approval of and Commercialize Product without any limitations; *provided, however,* that if Grünenthal desires to continue to Prepare Regulatory Approval of or Commercialize the Product utilizing the OMP-ADF-Formulation (provided the Parties had already agreed to jointly use the OMP-ADF-Formulation pursuant to Section 12.1(b)) the licenses and option or rights with regard to manufacture and supply, as set forth in Section 12.2, shall survive.

(b) In case of an ongoing development of Product by OMP and provided such development is conducted using Commercially Reasonable and Diligent Efforts, the Agreement shall not expire, and the Other Rights shall not revert to Grünenthal until OMP´s obligation to pay royalties for the last Product (which may be the Product in development) have ended, unless earlier terminated as provided in this Article 15. For purposes of this Article 15, the term "OMP" shall include each Affiliate or assignee of any rights or obligations of OMP and/or each Affiliate referenced herein.

Upon the expiration of the Agreement, in the event that there is no Product in development hereunder by OMP and no royalties being paid hereunder on any Product being sold by OMP, all rights to Grünenthal Patents shall revert to Grünenthal, except those Grünenthal Patents in which an OMP employee or agent is a joint inventor. In connection with such Grünenthal Patents, OMP shall retain a worldwide, non-exclusive license outside the Field.

OMP Patents shall be retained by OMP except that OMP shall grant to Grünenthal a worldwide exclusive license to Commercialize Product provided Grünenthal is developing or Commercializing Product. Such license shall be royalty bearing at a rate of [***] Net Sales of Product in OMP Territory.

15.2 Termination For Breach.

(a) Either Party may terminate this entire Agreement or this Agreement partly with regard to Products developed in accordance with the RAP Plan 1.63.1 in the event the other Party shall have materially breached or defaulted in the performance of any of its material obligations hereunder with regard to the OMP Territory, and such default shall have continued for [***] after written notice thereof was provided to the breaching Party by the non- breaching Party. Any termination shall become effective at the end of such [***] period unless the breaching Party (or any other party on its behalf) has cured any such breach or default prior to the expiration of the [***] period.

A termination only with regard to Products developed in accordance with RAP Plan 1.63 is excluded.

(b) In the event of termination of this Agreement by OMP, in its entirety or partly with regard to Product developed in accordance with RAP Plan 1.63.1 pursuant to this Section 15.2, the licenses and rights granted to OMP in Article 2 and 12 (if the Parties have previously agreed to jointly develop the Grünenthal-ADF-Formulation) and all obligations of OMP related to such license as set forth in Articles 6 and 7 and all relevant definitions in Article 1 shall survive termination. In addition, if such termination occurs during RAP, then OMP may assume control of all RAP activities of the Product(s) terminated that are relevant or necessary to the filing of any Drug Approval Applications in the OMP Territory and Grünenthal shall provide OMP with all necessary assistance and documentation for OMP to carry out such RAP activities.

(c) In the event of termination of this Agreement by Grünenthal in its entirety or partly with regard to Product developed in accordance with RAP Plan 1.63.1 pursuant to this Section 15.2, the licenses and rights granted to Grünenthal in Articles 2 and 12 (if the Parties have previously agreed to jointly develop the OMP-ADF-Formulation) and all obligations of Grünenthal related to such license as set forth in Articles 6 and 7 and all relevant definitions in Article 1 shall survive termination. All rights granted by Grünenthal related to Product(s) terminated shall revert to Grünenthal and OMP shall promptly

transfer to Grünenthal all INDs, Drug Approval Application and Regulatory Approvals including all clinical data associated therewith in case of entire termination of this Agreement or the respective INDs (if IND relates solely to Product terminated), Drug Approval Applications and Regulatory Approvals including all clinical data associated therewith in case of partly termination. Grünenthal shall not be free to Prepare Regulatory Approval of or Commercialize Product in OMP Territory until this Agreement is terminated with regard to the OMP Territory.

Grünenthal shall be free to prepare Regulatory Approval of and Commercialize Product in OMP Territory without any limitations upon termination of this Agreement in its entirety.

15.3 Termination For Bankruptcy. Notwithstanding Section 18.19, either Party hereto shall have the right to terminate this entire Agreement or this Agreement partly with regard to Products developed in accordance with the RAP Plan 1.63.1 (excluding termination only with regard to Products developed in accordance with the RAP Plan 1.63) forthwith by written notice to the other Party

(a) if the other Party is declared insolvent or bankrupt by a court of competent jurisdiction,

(b) if a voluntary or involuntary petition in bankruptcy is filed in any court of competent jurisdiction against the other Party and such petition is not dismissed within [***] after filing, or

(c) if the other Party shall make or execute an assignment of substantially all of its assets for the benefit of creditors.

(d) In the event of termination of this Agreement by OMP in its entirety or partly with regard to Product developed in accordance with RAP Plan 1.63.1, pursuant to this Section 15.3, the licenses and rights granted to OMP in Articles 2 and 12 (if the Parties have previously agreed to jointly develop the Grünenthal-ADF-Formulation) and all obligations of OMP related to such license as set forth in Articles 6 and 7 and all relevant definitions in Article 1

shall survive termination. In addition, if such termination occurs during RAP, then OMP may assume control of all RAP activities of the Product(s) terminated that are relevant or necessary to the filing of any Drug Approval Applications in the OMP Territory and Grünenthal shall provide OMP with all necessary assistance and documentation for OMP to carry out such RAP activities.

(e) In the event of termination of this Agreement by Grünenthal in its entirety or partly with regard to Product developed in accordance with RAP Plan 1.63.1, pursuant to this Section 15.3, the licenses and rights granted to Grünenthal in Article 2 and 12 (if the Parties have previously agreed to jointly develop the OMP-ADF-Formulation) and all obligations of Grünenthal related to such license as set forth in Articles 6 and 7 and all relevant definitions in Article 1 shall survive termination. All rights granted by Grünenthal related to Product(s) terminated shall revert to Grünenthal and OMP shall promptly transfer to Grünenthal all INDs, Drug Approval Application and Regulatory Approvals including all clinical data associated therewith in case of entire termination of this Agreement or the respective INDs (if IND relates solely to Product terminated), Drug Approval Applications and Regulatory Approvals including all clinical data associated therewith in case of partly termination. Grünenthal shall not be free to Prepare Regulatory Approval of or Commercialize Product in OMP Territory until this Agreement is terminated in its entirety.

15.4 [Reserved]

15.5 Termination After the Start of Phase III.

(a) Either Party may terminate this Agreement

(i) in its entirety, or

(ii) partly for the OMP Territory with regard to Product developed in accordance with RAP Plan 1.63.1

after start of Phase III of the Product(s) and prior to First Commercial Sale of

that Product(s) in OMP Territory, upon [***] prior written notice. In case of such termination, the terminating Party shall still be responsible for its share of planned budgeted OOP during the [***] notice period.

The terminating Party shall also continue to provide [***] of its plan FTE resources for a period of [***] after the date of the notice of termination and thereafter [***] of its plan FTE resources for a further [***] after which time no further FTE`s shall be due for the [***].

(b) (i) If OMP terminates this Agreement under Section 15.5(a) in its entirety, the licenses and rights granted to Grünenthal in Article 2 and 12 (if the Parties have previously agreed to jointly develop the OMP- ADF-Formulation) and all obligations of Grünenthal related to such license as set forth in Articles 6 and 7 and all relevant definitions in Article 1 shall survive termination. All rights granted by Grünenthal shall revert to Grünenthal and OMP shall promptly transfer to Grünenthal all INDs, Drug Approval Application and Regulatory Approvals including all clinical data associated therewith. Grünenthal shall be free to Prepare Regulatory Approval of and Commercialize Product without any limitations.

(ii) If OMP terminates this Agreement under Section 15.5(a) partly with regard to Products developed in accordance with the RAP Plan 1.63.1 the licenses and rights granted to Grünenthal in Article 2 and 12 (if the Parties have previously agreed to jointly develop the OMP-ADF-Formulation) and all obligations of Grünenthal related to such license as set forth in Articles 6 and 7 and all relevant definitions in Article 1 shall survive termination. All rights granted by Grünenthal shall pertaining to Products developed in accordance with RAP Plan 1.63.1 revert to Grünenthal and OMP shall promptly transfer to Grünenthal the respective INDs (if IND relates solely to terminated Product), Drug Approval Applications and Regulatory Approvals including all clinical data associated therewith. Grünenthal shall not be free to Prepare Regulatory Approval of or Commercialize Product in OMP Territory

until this Agreement is terminated in its entirety.

(c) If Grünenthal terminates this entire Agreement under Section 15.5(a), but OMP decides to pursue the Regulatory Approval Preparation of Product, OMP shall obtain a worldwide exclusive license under Grünenthal Patents and Grünenthal Know-How to make, use and sell Product and the licenses granted to Grünenthal under Section 2.2(c)(ii) shall apply to OMP mutatis mutandis, at the following royalty rates:

(i) In the OMP Territory, the Earned Royalty rates as recited in this Agreement shall apply; and

(ii) For the rest of the world outside the OMP Territory:

- at a royalty rate of [***] if Grünenthal terminates before [***] of total planned patients of Phase III have been recruited, or
- at a royalty rate of [***], if Grünenthal terminates after [***] of total planned patients of Phase III have been recruited.

In the event OMP elects to Commercialize Product using ADF Formulation of Grünenthal, an additional royalty of [***] on Net Sales for the OMP Territory and [***] for the Grünenthal Territory shall be paid to Grünenthal. If Grünenthal terminates this Agreement under Section 15.5(a) only with regard to Products developed in accordance with RAP Plan 1.63.1 and OMP decides to pursue the Regulatory Approval Preparation with regard to such Products, Grünenthal shall retain its rights with regard to the Grünenthal Territory and OMP shall not obtain the world-wide exclusive license referred to in Section 15.5(c) first paragraph above. In the event OMP elects to Commercialise such Products using Grünenthal-ADF-Formulation an additional royalty of [***] on Net Sales for the OMP Territory shall be paid to Grünenthal. In case OMP subsequently ceases the Regulatory Approval Preparation of the Product for the OMP Territory this Agreement is automatically terminated in its entirety for the OMP Territory.

(d) Termination during Commercialization. OMP may terminate this Agreement

(i) in its entirety, or

(ii) partly for the OMP Territory with regard to Product developed in accordance with RAP Plan 1.63.1

during Commercialization upon [***] prior written notice.

If OMP terminates this Agreement under this Section 15.5(d), the licenses and rights granted to Grünenthal in Article 2 and 12 (if the Parties have previously agreed to jointly develop the OMP-ADF-Formulation) and all obligations of Grünenthal related to such license as set forth in Articles 6 and 7 and all relevant definitions in Article 1 shall survive termination. All rights granted by Grünenthal with respect to such Product terminated shall revert to Grünenthal and OMP shall promptly transfer to Grünenthal all INDs, Drug Approval Application and Regulatory Approvals including all clinical data associated therewith in case of entire termination of this Agreement or the respective INDs (if IND relates solely to terminated Product), Drug Approval Applications and Regulatory Approvals including all clinical data associated therewith in case of partly termination. Grünenthal shall have the option to request OMP to transfer all rights to such terminated Product back to Grünenthal at any time during the notice period upon [***] written notice. Grünenthal shall not be free to Prepare Regulatory Approval of or Commercialize Product in OMP Territory until this Agreement is terminated in its entirety. Grünenthal shall be free to Prepare Regulatory Approval of and Commercialize any Product without any limitations upon termination of this Agreement in its entirety.

15.6 Termination By OMP.

(a) OMP may terminate this Agreement, at any time, in its entirety upon 30 days prior written notice as a result of :

(i) material data regarding the safety or efficacy of the Product which arise during the Regulatory Approval Preparation of the Product that convincingly indicate a materially and adversely different safety or efficacy profile as compared to the target profile of that Product as of the Combined Territories License Agreement Effective Date, or the effective date of the 2004 First Amendment, as applicable;

(ii) there is a materially adverse regulatory development relating to the approvability in the United States of a Product compared to the registration requirements of that Product as of the Combined Territories License Agreement Effective Date, or the effective date of the 2004 First Amendment, as applicable.

OMP may terminate this Agreement on a Product by Product basis upon 30 days prior written notice only if

(i) material data regarding the safety or efficacy of a Product which arise during the Regulatory Approval Preparation of the Product convincingly indicate a materially and adversely different safety or efficacy profile as compared to the target profile of that Product as of the Combined Territories License Agreement Effective Date, or the effective date of the 2004 First Amendment, as applicable;

(ii) there is a materially adverse regulatory development relating to the approvability in the United States of a Product compared to the registration requirements of that Product as of the Combined Territories License Agreement Effective Date, or the effective date of the 2004 First Amendment, as applicable;

and such material data as referred to in (i) above or materially adverse regulatory development as referred to in (ii) above apply only to such Product terminated. In case such material data and material adverse regulatory development apply also to other Products OMP may terminate this Agreement only in its entirety.

(b) In the event of termination by OMP under Section 15.6(a), OMP shall have no obligation to make payments relating to Regulatory Approval Preparation Costs of the Product(s) terminated which accrue following the effective date of termination, including but not limited to FTE costs, except, however, all initiated and committed OOP which shall be shared. In addition, the licenses and rights granted to Grünenthal in Article 2 and 12 (if the Parties have previously agreed to jointly develop the OMP-ADF-Formulation) and all obligations of Grünenthal related to such license as set forth in Articles 6 and 7 and all relevant definitions in Article 1 shall survive termination. All rights

granted by Grünenthal related to Products terminated shall revert to Grünenthal and OMP shall promptly transfer to Grünenthal all INDs, Drug Approval Applications and Regulatory Approvals including all clinical data associated therewith in case of entire termination of this Agreement or the respective INDs (if IND relates solely to terminated Product), Drug Approval Applications and Regulatory Approvals including all clinical data associated therewith in case of partly termination. Grünenthal shall not be free to Prepare Regulatory Approval of or Commercialize Product in OMP Territory until this Agreement is terminated in its entirety. Grünenthal shall be free to Prepare Regulatory Approval of and Commercialize any Product without any limitations upon termination of this Agreement in its entirety.

15.7 Mutual Termination. In case of a common decision by the SC to terminate the Regulatory Approval Preparation in its entirety for reasons referred to in Section 15.6(a), both Parties will equally share the cost of discontinuation and all licenses hereunder shall terminate.

15.8 Change of Control.

(a) In the event of a Change of Control of OMP. In the event that substantially all of OMP's assets are sold, or greater than 35% of OMP's voting securities are transferred (whether by stock sale, merger, consolidation, reorganization, recapitalization or otherwise with respect to OMP or Johnson & Johnson) to any Third Party, other than Affiliates of OMP, during RAP of Product, joint RAP shall continue, but the Excepted RAP Matters under Section 10.2 shall no longer exist and all final decisions shall be made by Grünenthal.

(b) In the event of a Change of Control of Grünenthal. In the event of an Grünenthal Change in Control (defined below) during RAP of Product, joint RAP shall continue but all final decisions relating to RAP of Product shall no longer be made by Grünenthal but instead will be made by OMP and the Excepted RAP Matters under Section 10.2 shall continue to exist.

(i) Grünenthal Change of Control shall mean any transaction or series of related transactions in which a Third Party (other than Affiliates of Grünenthal or the existing owner of Grünenthal [***]) acquires or becomes the ultimate beneficial owner of (x) more than fifty percent (50%) of the outstanding voting securities of Grünenthal or the surviving entity, whether by merger, consolidation, reorganization, tender offer or similar means, or (y) all or substantially all of the assets of Grünenthal.

(ii) [***].

15.9 [Reserved]

15.10 Surviving Rights. Without limiting this Article 15, Sections 2.1(d), 7.4, 7.7, and 12.4 and Articles 1, 8, 9, 13 and 18 shall survive the expiration and any termination of this Agreement for any reason. The termination of this Agreement for any reason whatsoever shall be without prejudice to any obligations or rights on the part of either Party which have accrued prior to such termination and shall not affect or prejudice any provision of this Agreement which is expressly or by implication provided to come into effect on, or continue in effect after such termination.

15.11 Accrued Rights, Surviving Obligations. Termination, relinquishment or expiration of the Agreement for any reason shall be without prejudice to any obligations which shall have accrued prior to such termination, relinquishment or expiration, including, without limitation, the payment obligations under Article 6 hereof and this Article 15 and any and all damages arising from any breach hereunder. Such termination, relinquishment or expiration shall not relieve either Party from obligations that are expressly indicated to survive termination or expiration of the Agreement. Notwithstanding anything to the

contrary in this Agreement, in the event of termination by a Party after the date of filing of a Regulatory Approval in such Party's Territory, such Party will cooperate with the other Party, to the extent requested by such other Party, in transferring such Regulatory Approval (or filing thereof) to such other Party at such other Party's cost (unless such termination was due to the breach of this Agreement by, insolvency of, or voluntary termination by such Party).

15.12 [Reserved]

15.13 Termination Not Sole Remedy. Termination is not the sole remedy under this Agreement and, whether or not termination is effected, all other remedies will remain available except as agreed to otherwise herein.

ARTICLE 16 DISPUTE RESOLUTION

16.1 Dispute Resolution and Arbitration. In the case of any disputes between the Parties arising from this Agreement, and in case this Agreement does not provide a solution for how to resolve such disputes, the Parties shall discuss and negotiate in good faith a solution acceptable to both Parties and in the spirit of this Agreement. If after negotiating in good faith pursuant to the foregoing sentence, the Parties fail to reach agreement, then Grünenthal's managing director and OMP´s chairman for pharmaceutical sector shall discuss in good faith an appropriate resolution to the dispute. If these executives fail, after good faith discussions undertaken in reasonable promptness, to reach an amicable agreement, then either Party may upon written notice to the other submit to binding arbitration pursuant to Section 16.2.

16.2 Arbitration. In the case of any dispute arising out of or in connection with this Agreement, the Parties shall negotiate in good faith within [***] days after written notice has been given by one Party to the other Party requesting such negotiations. Within this [***] day period, the Parties shall also consider to use mediation. If the Parties do not resolve their dispute within a period of [***] days after written notice was given, the dispute shall be finally settled by binding arbitration under the Rules of Arbitration of the International Chamber of Commerce by three (3) arbitrators, the chairperson

of whom shall be appointed by the two party arbitrators. The seat of arbitration shall be Düsseldorf, Germany and the language of the proceedings shall be English. The Parties agree that any award or decision made by the arbitral tribunal shall be final and binding upon them and may be enforced in the same manner as a judgment or order of a court of competent jurisdiction. The arbitral tribunal shall render its final award within [***] from the date on which the Request for Arbitration by one of the Parties wishing to have recourse to arbitration is received by the ICC Secretariat. The ICC Secretariat may extend this time limit pursuant to a reasoned request from the arbitral tribunal or on its own initiative if it decides it is necessary to do so. The costs of the arbitration shall be fixed and paid as specified in the award. The arbitral tribunal shall determine the dispute by applying the provisions of this Agreement and the governing law set forth in Section 18.7. By agreeing to arbitration, the Parties do not intend to deprive any court of its jurisdiction to issue, at the request of a Party, a pre-arbitral injunction, pre-arbitral attachment or other order in aid of the arbitration proceedings and the enforcement of any award. Without prejudice to such provisional or interim remedies in aid of arbitration as may be available under the jurisdiction of a competent court, the arbitral tribunal shall have full authority to grant provisional or interim remedies and to award damages for the failure of any Party to the dispute to respect the arbitral tribunal's order to that effect.

ARTICLE 17 [Reserved]

ARTICLE 18 MISCELLANEOUS

18.1 Relationship of Parties. For the purposes of this Agreement, each Party is an independent contractor and not an agent or employee of the other Party. Neither Party shall have authority to make any statements, representations, nor commitments of any kind, or to take any action which shall be binding on the other Party, except as may be explicitly provided for herein or authorized in writing.

18.2 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, and all of which together shall be deemed to be one and the same instrument.

18.3 Headings. All headings in this Agreement are for convenience only and shall not affect the meaning of any provision hereof.

18.4 Binding Effect. This Agreement shall inure to the benefit of and be binding upon the Parties and their respective lawful successors and permitted assigns.

18.5 Assignment. Neither Party may assign this Agreement without the prior written consent of the other Party, except that a Party may assign this Agreement in whole or in part to any Affiliate, provided that (i) the assigning Party remains obligated for its Affiliate´s performance of this Agreement, and (ii) the assigning Party provides prior written notice to the other Party of the anticipated assignment. Either Party may assign this Agreement to any party succeeding (by sale, merger, reverse merger or otherwise) to substantially all of the business and operations of such Party subject to the other Party´s right to terminate this Agreement pursuant to Article 15.

18.6 Amendment. This Agreement may be amended, supplemented, or otherwise modified at any time, but only by means of a written instrument signed by both Parties.

18.7 Governing Law. This Agreement and the legal relations among the Parties shall solely be governed by and construed and any dispute arising out of or in connection with this Agreement shall solely be resolved in accordance with, German law, without regard to its conflicts of law rules.

18.8 Severability. In the event of any provisions of this Agreement being or becoming ineffective or of any omission being discovered, the validity of the remaining provisions shall not thereby be affected. In place of the ineffective provisions or for the purpose of rectifying the omission a reasonable arrange- ment shall operate being the nearest legally possible approach to that which

the parties hereto desired or would have desired in consideration of the spirit and object of this Agreement had they considered the point.

18.9 Entire Agreement. This Agreement, together with all Exhibits and Side Letters Nr. 1 through Amended Side Letter Nr. 21, attachments and schedules hereto, constitutes the entire agreement between the Parties with respect to the subject matter hereof; provided, however, that all rights and obligations of the Parties under the Combined Territories License Agreement arising prior to the Effective Date shall be governed by the Combined Territories License Agreement. For the sake of clarity, all rights and obligations of the Parties with respect to Canada and Japan arising on and after the Effective Date of this Agreement shall be governed by Canada/Japan License Agreement. The Parties acknowledge and agree that this Agreement, together with the Canada/Japan License Agreement, amends, restates, supersedes and terminates the Combined Territories License Agreement and all previous agreements between the Parties under the Combined Territories License Agreement.

18.10 Advice of Counsel. OMP and Grünenthal have each consulted counsel of their choice regarding this Agreement, and each acknowledges and agrees that this Agreement shall not be deemed to have been drafted by one Party or another and will be construed accordingly.

18.11 Consents Not Unreasonably Withheld. Whenever provision is made in this Agreement for either Party to secure the consent or approval of the other, that consent or approval shall not unreasonably be withheld, and whenever in this Agreement provision is made for one Party to object to or disapprove a matter, such objection or disapproval shall not unreasonably be exercised.

18.12 Retained Rights. Nothing in this Agreement shall limit in any respect the right of either Party to conduct research and Regulatory Approval Preparation and to market products using such Party's technology other than as herein expressly provided. Furthermore, nothing in this Agreement shall be construed to provide any license, implied or express, under any Patent Controlled by a Party, except to the extent of the express Products for the

particular Regulatory Approval Preparation indications that are the subject of continuing joint Regulatory Approval Preparation and Commercialization pursuant to this Agreement.

18.13 Force Majeure. Neither Party shall lose any rights hereunder or be liable to the other Party for damages or losses on account of failure of performance by the defaulting Party if the failure is occasioned by government action, war, terrorist act, fire, explosion, flood, strike, lockout, embargo, act of God, or any other similar cause beyond the control of the defaulting Party, provided that the Party claiming force majeure has exerted reasonable efforts to avoid or remedy such force majeure; provided, however, that in no event shall a Party be required to settle any labor dispute or disturbance. The Party giving notice shall be excused from such obligations hereunder as it is disabled from performing for so long as it is so disabled; provided, however, that Party commences and continues to take reasonable and diligent actions to cure or remedy such force majeure. In the event of any such force majeure event, the Parties shall meet promptly to determine an equitable solution to the effects of any such event. The term of the agreement shall not be extended by any force majeure.

18.14 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

18.15 No Implied Licenses. No rights to any other patents, know-how or technical information, or other intellectual property rights, other than as explicitly identified herein are granted or deemed granted by this Agreement. Except as otherwise provided herein, no right, express or implied, is granted by the Agreement to use in any manner the name “Grünenthal” or “OMP”, or any other trade name or trademark of the other Party or its Affiliates in connection with the performance of the Agreement.

18.16 Notices. All notices hereunder shall be in writing by mail, courier or personal delivery and shall be deemed given upon receipt thereof. All notices shall be given

- if to Grünenthal,

addressed to:
Grünenthal GmbH
52099 Aachen
Germany
Attention: CEO

With a copy to:

Grünenthal GmbH
52099 Aachen
Germany
Attention: Global Legal

- if to OMP:

addressed to:
Janssen Pharmaceuticals, Inc.
1125 Trenton-Harbourton Road,
Titusville, New Jersey, 08560
Attention: President

With a copy to: Office of General Counsel

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Attention: Corporate Law Leader, Medicines & Nutritionals

18.17 Waiver. Except as specifically provided for herein, the waiver from time to time by either of the Parties of any of their rights or their failure to exercise any remedy shall not operate or be construed as a continuing waiver of same or of any other of such Party's rights or remedies provided in this Agreement.

18.18 Compliance with Laws. The Parties shall comply with all applicable laws, rules, regulations and orders of the United States and applicable European

countries and supra-governmental organizations and all jurisdictions and any agency or court thereof in connection with this Agreement and the transactions contemplated thereby.

18.19 Bankruptcy. All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11, U.S. Code (the "**Bankruptcy Code**"), licenses and rights to "intellectual property" as defined under Section 101(60) of the Bankruptcy Code. The Parties agree that the other Party, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. Each Party agrees during the term of this Agreement to create and maintain current copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, of all such intellectual property. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against one Party under the Bankruptcy Code, the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and same, if not already in its possession, shall be promptly delivered to the other Party

(a) upon any such commencement of a bankruptcy proceeding upon written request therefore by the other Party, unless such Party elects to continue to perform all of its obligations under this Agreement, or

(b) if not delivered under (a) above, upon the rejection of this Agreement by or on behalf of such Party upon written request therefor by the other Party.

18.20 Non-Solicitation. During the Term, neither Party shall solicit, without prior written consent, for employment any employees of the other Party that have been involved in the cooperation or the promotion, marketing and sale of the Product. The Parties agree that the term "solicit" shall not include general solicitations of employment not specifically directed towards a Party´s employees, newspaper or other periodical advertisements, or general searches conducted by professional recruiting firms.

18.21 Contradictions. In case of contradiction of the wording between the body of this Agreement and the Exhibits and/or the Side Letters, the wording of the body of the Agreement shall take precedence over the Exhibits and the Side Letters.

ARTICLE 19 GUARANTEE OF JOHNSON & JOHNSON, JOINT AND SEVERAL LIABILITY

19.1 Johnson & Johnson, the parent corporation of OMP, hereby unconditionally and irrevocably guarantees the performance when due of any and all of the obligations of OMP and/or any other Johnson & Johnson Affiliate having obligations under this Agreement. Notwithstanding the foregoing, the guarantee set forth in this Section 19.1 shall automatically terminate, and shall be of no further force and effect, in the event that (i) this Agreement is assigned by OMP pursuant to Section 18.5 to any person or entity that is not a Johnson & Johnson Affiliate or (ii) OMP or another Johnson & Johnson Affiliate is otherwise no longer a party to this Agreement.

19.2 Each company defined as OMP or to which obligations under this Agreement have been assigned shall be jointly and severally responsible for such obligation.

IN WITNESS WHEREOF, the undersigned have duly executed and delivered this Agreement as a sealed instrument effective as of the Effective Date.

JANSSEN PHARMACEUTICALS, INC.

By: /s/ Michael Grissinger
Name: Michael Grissinger
Title: Authorized Signatory
Date: January 12, 2015

JANSSEN RESEARCH & DEVELOPMENT, LLC

By: /s/ Michael Grissinger
Name: Michael Grissinger
Title: Authorized Signatory
Date: January 12, 2015

GRUNENTHAL GMBH

By: /s/ Prof. Dr. Eric-Paul Paques
Name: Prof. Dr. Eric-Paul Paques
Title: CEO
Date: 2015-01-13

By: /s/ Dr. Alberto Grua
Name: Dr. Alberto Grua
Title: Chief Commercial Officer EU, Australia and Nor America
Date: 2015-01-13

[Signature Page to Licence Agreement (U.S.)]

Solely with respect to Article 19:

JOHNSON & JOHNSON

By: /s/ Eric Jung
Name: Eric Jung
Title: Assistant Secretary
Date: 1/12/2015

[Signature Page to Licence Agreement (U.S.)]

CERTAIN PORTIONS OF THE EXHIBIT THAT ARE NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED HAVE BEEN REDACTED PURSUANT TO ITEM 601(B)(10)(IV) OF REGULATION S-K. [***] INDICATES THAT INFORMATION HAS BEEN REDACTED.

Exhibit 10.5

Execution Copy January 30, 2020

CONSENT AGREEMENT

THIS CONSENT AGREEMENT (this **"Consent Agreement")** is entered into this 30th day of January 2020 (the **"Execution Date")** by and between

GRÜNENTHAL GMBH, organized under the laws of Germany and having its principal office at Zieglerstrabe 6, 52078 Aachen, Germany (hereinafter **"GRÜNENTHAL"),** and

Assertio Therapeutics, Inc. (formerly Depomed, Inc.), and Depo NF Sub, LLC organized under the laws of the State of Delaware and having their principal offices at 100 S. Saunders Road, Suite 300, Lake Forest, IL 60045, USA (hereinafter collectively **"ASRT"),**

and is joined by Collegium Pharmaceutical Inc., and Collegium NF, LLC organized under the laws of the Commonwealth of Virginia and having their principal offices at 100 Technology Center Drive, Suite 300, Stoughton, MA 02072 (hereinafter collectively **"COLL")** upon COLL's execution of a joinder to this Consent Agreement pursuant to paragraph 2 hereof.

WHEREAS, Janssen Pharmaceuticals, Inc., a Delaware corporation having a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey, 08560 and Janssen Research & Development, LLC having a principal place of business at U.S. Route 202, Raritan, New Jersey 08869 **("OMP")** and GRÜNENTHAL entered into a License Agreement dated February 21, 2003, which License Agreement was amended as of December 23, 2004 and June 21, 2006 and then amended and restated in its entirety in an Amended and Restated License Agreement dated December 28, 2006, which Amended and Restated License Agreement was amended as of June 19, 2007, December 17, 2008, January 16, 2009, May 22, 2009, July 15, 2010 and May 29, 2013 (such Amended and Restated License Agreement, together with all amendments thereto, the **"Combined Territories License Agreement")** and then amended and restated in its entirety in two (2) agreements: (a) a License Agreement (U.S.) with an effective date of January 13, 2015, including all amendments and side letters thereto (collectively the **"Agreement"),** pursuant to which inter alia GRÜNENTHAL agreed to license to OMP certain patents and know-how regarding composition of matter CG-5503 and pharmaceutical formulations containing CG-5503 as active pharmaceutical ingredient (the **"Product"),** as well as certain drug delivery systems for delivery of CG-5503, and to grant manufacturing, commercialization and certain other rights to OMP for the Product in the United States of America (the **"Territory")** and (b) a License Agreement (Canada/Japan) with an effective date of January 13, 2015 (the **"Canada/ Japan License Agreement"),** pursuant to which inter alia GRÜNENTHAL agreed to license to OMP certain patents and know-how regarding composition of matter CG-5503 and the Product, as well as certain drug delivery systems for delivery of CG-5503, and to grant manufacturing, commercialization and certain other rights to OMP for the Product in Canada and Japan;

WHEREAS, on January 15, 2015, with GRÜNENTHAL's consent to the Assignment and Consent Agreement entered into January 13, 2015 by OMP and GRÜNENTHAL and joined by ASRT **("OMP Consent"),** OMP and/or one or more of its Affiliates and ASRT and/ or one or more of its Affiliates entered into Asset Purchase Agreement and certain other agreements pursuant to which, on April 2, 2015, ASRT acquired from OMP certain assets and rights related to the Product (including OMP's rights under the Agreement), and ASRT and/ or its Affiliates assumed certain liabilities related to the Product (the **"ASRT Transaction");**

WHEREAS, ASRT and/or one or more of its Affiliates (collectively, the **"Assigning Entities")** and COLL are discussing the possibility of entering into a transaction pursuant to

which it is contemplated that the Assigning Entities will assign to COLL, and COLL will assume from the Assigning Entities all of the Assigning Entities' rights and obligations under the Agreement and to the Product (the **"Transaction");**

WHEREAS, in the event one or more of the Assigning Entities and COLL agree to enter into the Transaction, such Assigning Entities and COLL would enter into one or more definitive agreements setting forth the terms and conditions upon which the Transaction shall be consummated (the **"Definitive Agreements");** and

WHEREAS, ASRT desires to request GRÜNENTHAL's consent to assign to COLL, effective upon the consummation of the Transaction, all of ASRT's rights and obligations (i) under the Agreement, (ii) to the Product and (iii) to the Regulatory Approvals, among other things, as set forth in and pursuant to the terms of the Definitive Agreements, to COLL and GRÜNENTHAL desires to consent to such assignment, subject to the terms and conditions of this Consent Agreement;

NOW, THEREFORE, ASRT, COLL and GRÜNENTHAL agree as follows:

I. As of the Execution Date, GRÜNENTHAL hereby irrevocably consents to the assignment of the Agreement, the Regulatory Approvals and other assets pursuant to the Definitive Agreements, as contemplated in paragraphs 5 and 6 below and under the terms and conditions of this Consent Agreement.

2. In the event one or more of the Assigning Entities and COLL enter into the Definitive Agreements:

2.1. COLL shall execute a joinder to this Consent Agreement in substantially the form of Exhibit A attached hereto, and shall thereafter be a party to this Consent Agreement and shall be fully bound by, and subject to, all of the terms and conditions of this Consent Agreement; and

2.2. within five (5) working days after the execution of the Definitive Agreements, ASRT shall notify GRÜNENTHAL in accordance with paragraph 15 of this Consent Agreement or by electronic correspondence (in text form) to the CEO of GRÜNENTHAL or the Senior Vice President Corporate Development of such execution and deliver to GRÜNENTHAL a copy of such executed joinder.

3. In the event the closing of the Transaction occurs:

3.1. ASRT shall notify GRÜNENTHAL in accordance with paragraph 15 of this Consent Agreement or by electronic correspondence (in text form) to the CEO of GRÜNENTHAL or the Senior Vice President Corporate Development and Licensing within five (5) working days of the closing of the Transaction; and

3.2. the date of such closing shall be referred to as the **"Closing Date"** in this Consent Agreement.

4. If ASRT does not notify GRÜNENTHAL of the closing of the Transaction in accordance with paragraph 3.1 on or before May 31, 2020, then this Consent Agreement shall become null and void and be of no further force and effect.

5. As of the Closing Date, ASRT assigns to COLL with debt discharging effect *(mil schuldbefi'eiender Wirkung)* all of the rights, licenses, claims, obligations and duties of ASRT under or relating to (i) the Agreement, (ii) the Regulatory Approvals and (iii) such other assets relating to the Product as contemplated by the Definitive Agreements. As of the Closing Date, all references in the Agreement to any person defined as ASRT or OMP herein, shall be deemed to refer to COLL, except to the extent otherwise expressly set forth herein. Upon request by ASRT or COLL, GRÜNENTHAL shall provide, for no additional consideration or concessions, all reasonable and customary statements and documents required or useful for the transfer under paragraphs 5 and 6 hereof.

6. As of the Closing Date, COLL hereby accepts such assignment and assumption of rights, licenses, claims, obligations, duties, assets and approvals by way of assumption of contract with debt discharging effect *(im Wege der Vertragsubernahme mit schuldbefreiender Wirkung)* to the same extent and with the same effect, as if COLL had been an original party thereto instead of ASRT, except to the extent otherwise expressly set forth herein; *provided, however,* that COLL does not assume, and COLL shall have no liability to GRÜNENTHAL or its Affiliates with respect to, any Discharged GRÜNENTHAL Claim (as such term is defined in paragraph 10 of this Consent Agreement). As of the Closing Date, GRÜNENTHAL and COLL agree:

6.1. None of COLL or any of its Affiliates may initiate, or assist a Third Party in initiating, a patent re-examination, *inter partes* review, post grant or other patent office proceeding, opposition, litigation, or other court proceeding challenging the validity of any issued U.S. patent within the GRÜNENTHAL Patents licensed under the Agreement.

6.2. COLL shall, during the term of the Agreement use Commercially Reasonable and Diligent Efforts to market, promote, offer for sale, sell and have sold each Product in the Territory **("Promotional Activities").**

6.3. COLL shall permit a certified public accountant or other representative selected by GRÜNENTHAL, and acceptable to COLL, to examine the records of COLL and its Affiliates in accordance with Section 6.12(f) of the Agreement.

7. GRÜNENTHAL, ASRT and COLL, as applicable, agree:

7.1. The periodic business review provided for in Section 4.9 of the Agreement shall be furnished to GRÜNENTHAL by COLL or its Affiliates with respect to its own Promotional Activities with respect to the Product and in accordance with the terms thereof.

7.2. The annual strategic plan information provided for in Section 4.10 of the Agreement shall be furnished to GRÜNENTHAL by COLL or its Affiliates with respect to its anticipated Promotional Activities for the upcoming calendar year and in accordance with the terms thereof.

7.3. GRÜNENTHAL shall limit distribution of the foregoing information provided by COLL or its Affiliates only to its directors, officers, employees or advisers who have a need to access such information in connection with this Consent Agreement and/or the Agreement.

7.4. The COGS Cap as set forth m Section 6.9 of the Agreement shall be inapplicable.

7.5. For the years 2020 and 2021, the following shall apply:

COLL shall pay GRÜNENTHAL a royalty of 14% on Net Sales of Product and ASRT shall pay GRÜNENTHAL a lump sum royalty of [***] (the **"Lump Sum")** for each of the years 2020 and 2021; provided, however, the Lump Sum shall only be payable, as applicable, in the event annual Net Sales of Product (whether generated by COLL, its Affiliates or any Third Party) is less than [***] for each of the years 2020 and 2021.

The applicable royalty amounts shall be calculated and paid by COLL within sixty (60) days following the end of each calendar half-year for which such royalties are due and the Lump Sum, as applicable, shall be calculated and paid by ASRT to GRÜNENTHAL within sixty (60) days of the end of each applicable year.

7.6. For the year 2022 and the following years, the following shall apply:

a) for annual Net Sales of Product (whether generated by COLL, its Affiliates, any Third Party or ASRT) of less than [***] and notwithstanding any other provision of this Consent Agreement and of the Agreement, COLL shall pay GRÜNENTHAL a royalty of 14% of such annual Net Sales of Product in each of such year(s);

b) for annual Net Sales of Product (whether generated by COLL, its Affiliates, any Third Party or ASRT) equal to or greater than [***] and equal to or less than [***], and notwithstanding any other provision of this Consent Agreement and of the Agreement, COLL shall pay GRÜNENTHAL in addition to the payment made under 7.6 (a) above, a royalty of [***] on such amount of annual Net Sales of Product in each of such year(s); and

c) for annual Net Sales of Product (whether generated by COLL, its Affiliates, any Third Party or ASRT) greater than [***], and notwithstanding any other provision of this Consent Agreement and of the Agreement, COLL shall pay GRÜNENTHAL in addition to the payments made under 7.6 (a) and (b) above, a royalty of [***] on such amount of annual Net Sales of Product in each of such year(s).

7.7. For any Product first Commercialized after the expiry of the composition of matter Patent claiming CG-5503 **("New Product")** the following shall apply:

Notwithstanding any other provision of this Consent Agreement and of the Agreement, COLL shall pay GRÜNENTHAL, in addition to the payments under 7.5 and 7.6 of this Consent Agreement with respect to annual Net Sales of Products, a royalty of [***] on annual Net Sales of New Products (whether generated by COLL, its Affiliates, any Third Party or ASRT).

7.8 The applicable royalty amount pursuant to 7.6 and 7.7 shall be calculated and paid by COLL to GRÜNENTHAL within sixty (60) days of the end of each applicable half-year for which such royalties are due.

7.9 GRÜNENTHAL, and COLL will use commercially reasonable efforts to explore the possibility of GRÜNENTHAL supplying Product to COLL and any sublicensee of COLL.

8. This Consent Agreement, unless terminated pursuant to paragraph 4, shall automatically become effective as of the Execution Date and shall continue in effect for the Term of the Agreement, and thereafter in perpetuity; provided, that the provisions of paragraphs 1 through 4, this paragraph 8 and paragraphs 13 through 16 shall become effective on the Execution Date and shall be legally binding on ASRT, GRÜNENTHAL and (upon execution of the joinder pursuant to paragraph 2) COLL as of the Execution Date and the other provisions of this Consent Agreement shall not become effective until the Closing Date.

9. As of the Closing Date, this Consent Agreement shall supersede and replace the Consent Agreement between the parties dated November 30, 2017 (the **"Prior Consent");** provided, however, that (i) any royalty payment obligation of ASRT accrued in 2019 under the Prior Consent and not paid until the Closing Date, shall survive and (ii) such royalties may be paid by COLL directly to GRÜNENTHAL on behalf of ASRT in full satisfaction of such obligation.

10. As of the Closing Date: (a) any claims of ASRT or its Affiliates against GRÜNENTHAL or its Affiliates arising out of the Agreement, the OMP Consent or the Prior Consent are hereby released and discharged; and (b) any claims of GRÜNENTHAL or its Affiliates against ASRT or COLL or any of their respective Affiliates arising out of the Agreement, the OMP Consent - subject to Section 9, the Prior Consent or the Commercialization Agreement by and among ASRT and COLL dated December 4, 2017, as amended **("Discharged GRÜNENTHAL Claims")** are hereby released and discharged; this is an agreement in favor of a third party *(Vertrag zugunsten Driller)* pursuant to Sec. 328 German Civil Code *(BGB)* for the benefit of ASRT's Affiliates and GRÜNENTHAL's Affiliates, as applicable. In addition, effective as of the Closing Date, GRÜNENTHAL hereby irrevocably waives any right that GRÜNENTHAL may have, or may have had, to terminate the Agreement for, or by virtue of, any Discharged GRÜNENTHAL Claim.

11. Notwithstanding any provision of this Consent Agreement to the contrary, the confidentiality obligations set forth in Article 8 of the Agreement shall continue to apply to ASRT and GRÜNENTHAL with respect to any Confidential Information disclosed prior to the Closing Date, until the tenth (10th) anniversary of the Closing Date.

12. Certain Licenses:

12.1. As of the Closing Date, COLL agrees to grant, and to cause its Affiliates to grant, and hereby grants by itself and in the name and on behalf of its Affiliates to ASRT and its Affiliates a non-exclusive, royalty-free sublicense under all rights granted by GRÜNENTHAL to COLL under the Agreement, solely to the extent necessary to enable ASRT and its Affiliates to perform its and their obligations under the Definitive Agreements and related ancillary agreements, and GRÜNENTHAL agrees to consent, and hereby consents to such sublicense.

12.2. As of the Closing Date, GRÜNENTHAL agrees to grant, and to cause its Affiliates to grant, and hereby grants by itself and in the name and on behalf of its Affiliates to COLL and its Affiliates a non-exclusive, royalty-free license that may be sub-licensed to third party suppliers and manufacturers under the GRÜNENTHAL Background Patents, Improvement Patents controlled by GRÜNENTHAL and GRÜNENTHAL Know-How to make or have made Products, and all related activities, worldwide solely for the purpose of Commercialization of Products within Canada by the licensee authorized by GRÜNENTHAL (currently Endo Ventures Ltd.).

13. All definitions used in this Consent Agreement shall have the meaning as set forth in the Agreement, unless expressly defined otherwise in this Consent Agreement. This Consent Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and together shall constitute one and the same agreement binding on all of the parties and shall become effective when one or more counterparts have been signed by a party and delivered to the other parties, it being understood that none of the parties need sign the same counterpart. Each of this Consent Agreement and joinder, following its execution, may be delivered via telecopier machine or other form of electronic delivery, which shall constitute delivery of an execution original for all purposes.

14. This Consent Agreement may be amended, supplemented or otherwise modified at any time, but only by means of a written instrument signed by GRÜNENTHAL, ASRT and COLL.

15. Unless otherwise specified in this Consent Agreement, all notices and other communications given or made pursuant to this Consent Agreement shall be in writing and shall be deemed to have been duly given on the date delivered, if delivered personally, or on the next business day after being sent by reputable overnight courier (with delivery tracking provided, signature required and delivery prepaid), in each case, to the parties at the following addresses, or on the date sent and confirmed by electronic transmission to the telecopier number specified below (or at such other address or telecopier number for a party as shall be specified by notice given in accordance with this paragraph 15):

15.1. If to GRÜNENTHAL:

Grunenthal GmbH
52099 Aachen
Germany
Attention: Global Legal
Fax: +49 241 569 3547

15.2. If to ASRT:

Assertio Therapeutics, Inc.
100 S. Saunders Rd., Suite 300
Lake Forest, IL 60045
Attention: Legal Department

If to COLL:

To the address set forth in Exhibit A.

16. Article 16, Section 18.1, Section 18.2, Section 18.3, Section 18.4, Section 18.7, Section 18.8, Section 18.14 and Section 18.17 of the Agreement shall apply *mutatis mutandis* to this Consent Agreement.

IN WI1NESS WHEREOF, the parties have caused this Consent Agreement to be entered into as of the Execution Date.

GRÜNENTHAL GMBH

By:	/s/ Gabriel Baertschi	By:	/s/ Ralf Radermacher
Name:	Gabriel Baertschi	Name:	Ralf Radermacher
Title:	CEO	Title:	Senior Vice President

ASSERTIO THERAPEUTICS, INC.

By:	/s/ Arthur Higgin
Name:	Arthur Higgin
Title:	CEO

DEPO NF SUB, LLC

By:	/s/ Arthur Higgin
Name:	Arthur Higgin
Title:	CEO

CERTAIN PORTIONS OF THE EXHIBIT THAT ARE NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED HAVE BEEN REDACTED PURSUANT TO ITEM 601(B)(10)(IV) OF REGULATION S-K. [***] INDICATES THAT INFORMATION HAS BEEN REDACTED.

Execution Copy January 30, 2020

EXHIBIT A

FORM OF JOINDER AGREEMENT

JOINDER AGREEMENT dated as of February 6, 2020 made by the undersigned on behalf of Collegium Pharmaceutical Inc. and its wholly owned subsidiary Collegium NF, LLC (the **"Joining Party").**

Reference is hereby made to the Consent Agreement, dated as of January 30, 2020 (the **"Consent Agreement")** by and among GRÜNENTHAL GMBH and ASSERTIO THERAPEUTICS, INC./Depo NF Sub LLC. Capitalized terms used herein without definition shall have the meanings assigned to them in the Consent Agreement.

Pursuant to and in accordance with Consent Agreement, the Joining Party hereby agrees that, upon the execution of this Joinder Agreement, it shall become a party to the Consent Agreement and shall be fully bound by, and subject to, all of the terms and conditions of the Consent Agreement as "COLL" in such capacity as though the undersigned was an original party thereto.

IN WITNESS WHEREOF, the Joining Party hereto has executed this Joinder Agreement as of February 6, 2020

COLLEGIUM PHARMACEUTICAL, INC

By: /s/ Joseph Ciaffoni
Name: Joseph Ciaffoni
Title: President and Chief Executive Officer

Notice Address:

100 Technology Center Drive, Suite 300
Stoughton, MA 02072

Exhibit 31.1

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

I, Joseph Ciaffoni, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Collegium Pharmaceutical, 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.

/s/ JOSEPH CIAFFONI

Joseph Ciaffoni
President and Chief Executive Officer

Date: May 7, 2020

Exhibit 31.2

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

I, Paul Brannelly, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Collegium Pharmaceutical, 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.

/s/ PAUL BRANNELLY

Paul Brannelly
Executive Vice President and Chief Financial Officer

Date: May 7, 2020

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Collegium Pharmaceutical, Inc. (the "Company") for the period ended March 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Joseph Ciaffoni, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

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

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

/s/ JOSEPH CIAFFONI

Joseph Ciaffoni
President and Chief Executive Officer

Date: May 7, 2020

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Collegium Pharmaceutical, Inc. (the "Company") for the period ended March 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Paul Brannelly, Executive Vice President and Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

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

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

/s/ PAUL BRANNELLY

Paul Brannelly
Executive Vice President and Chief Financial Officer

Date: May 7, 2020