UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2023

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 001-37635

AXSOME THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**45-4241907**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
One World Trade Center **22nd Floor** **New York, New York**	**10007**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (212) 332-3241

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 during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

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 $0.0001 Per Share	AXSM	The Nasdaq Global Market

There were 43,573,213 shares of the registrant's common stock, $0.0001 par value, outstanding as of May 1, 2023.

AXSOME THERAPEUTICS, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED MARCH 31, 2023

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report, including matters discussed under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words "anticipate," "believe," "estimate," "may," "expect" and similar expressions are generally intended to identify forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under the captions "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this report, as well as other factors which may be identified from time to time in our other filings with the Securities and Exchange Commission, or the SEC, or in the documents where such forward-looking statements appear. All written or oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements. Such forward-looking statements include, but are not limited to, statements about:

- our expectations for increases or decreases in expenses;
- our expectations for the clinical and preclinical development, manufacturing, regulatory approval, and commercialization of our pharmaceutical product candidates or any other products that we may acquire or in-license;
- our estimates of the sufficiency of our existing capital resources combined with future anticipated cash flows to finance our operating requirements;
- our expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities;
- unforeseen circumstances or other disruptions to normal business operations arising from or related to COVID-19;
- our future revenue projections, sales forecasts, and potential peak market data;
- our expectations for becoming profitable on a sustained basis;
- our expectations or ability to enter into marketing and other partnership agreements;
- our expectations or ability to enter into product acquisition and in-licensing transactions;
- our expectations or ability to expand our own commercial infrastructure to manufacture, market and sell our products;
- our expected losses;
- our ability to obtain and maintain intellectual property protection for our products;
- the acceptance of our products by doctors, patients, or payors;
- our stock price and its volatility;
- our ability to attract and retain key personnel;
- the performance of our third-party manufacturers;
- our expectations for future capital requirements; and
- our ability to successfully implement our strategy.

The forward-looking statements contained in this report reflect our views and assumptions only as of the date that this report is signed. Except as required by law, we assume no responsibility for updating any forward-looking statements.

We qualify all of our forward-looking statements by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Axsome Therapeutics, Inc.
Consolidated Balance Sheets
(In thousands, except for share and par value amounts)

	March 31, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 246,515	$ 200,842
Accounts receivables, net	44,793	37,699
Inventories, net	7,940	4,320
Prepaid and other current assets	5,201	2,781
Total current assets	304,449	245,642
Equipment, net	703	722
Right-of-use asset - operating lease	106	420
Goodwill	10,310	10,310
Intangible asset, net	58,089	59,661
Non-current inventory and other assets	15,522	14,721
Total assets	$ 389,179	$ 331,476
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 35,770	$ 38,605
Accrued expenses and other current liabilities	58,774	51,631
Operating lease liability, current portion	108	425
Contingent consideration, current	6,000	5,900
Total current liabilities	100,652	96,561
Contingent consideration, non-current	29,100	31,100
Loan payable, long-term	147,615	94,259
Total liabilities	277,367	221,920
Stockholders' equity:		
Preferred stock, $0.0001 par value per share (10,000,000 shares authorized, none issued and outstanding at March 31, 2023 and December 31, 2022, respectively)	—	—
Common stock, $0.0001 par value per share (150,000,000 shares authorized, 43,548,466 and 43,498,617 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively)	4	4
Additional paid-in capital	719,359	705,885
Accumulated deficit	(607,551)	(596,333)
Total stockholders' equity	111,812	109,556
Total liabilities and stockholders' equity	$ 389,179	$ 331,476

The accompanying notes are an integral part of the consolidated financial statements.

Axsome Therapeutics, Inc.
Consolidated Statements of Operations (Unaudited)
(In thousands, except for per share amounts)

	Three Months Ended March 31,	
	2023	2022
Revenues:		
Product sales, net	$ 28,569	$ —
License revenue	65,735	—
Royalty revenue	272	—
Total Revenues	94,576	—
Operating expenses:		
Cost of revenue (excluding amortization and depreciation)	7,556	—
Research and development	17,793	12,585
Selling, general and administrative	74,191	25,704
Gain in fair value of contingent consideration	(162)	—
Intangible asset amortization	1,572	—
Total operating expenses	100,950	38,289
Loss from operations	(6,374)	(38,289)
Interest expense, net	(2,264)	(1,343)
Income before provision for income taxes	(8,638)	(39,632)
Provision for income taxes	(2,580)	—
Net loss	$ (11,218)	$ (39,632)
Net loss per common share, basic and diluted	$ (0.26)	$ (1.03)
Weighted average common shares outstanding, basic and diluted	43,523,631	38,323,167

The accompanying notes are an integral part of the consolidated financial statements.

Axsome Therapeutics, Inc.
Consolidated Statements of Stockholders' Equity (Unaudited)
(In thousands, except for share amounts)

	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount			
Balance at December 31, 2021	37,816,794	$ 4	$ 424,826	$ (409,199)	$ 15,631
Stock-based compensation	—	—	7,598	—	7,598
Issuance of common stock upon exercise of options	18,015	—	182	—	182
Issuance of common stock upon vesting of RSUs	4,555	—	—	—	—
Issuance of common stock upon financing	1,044,081	—	31,008	—	31,008
Shares tendered for withholding taxes	—	—	(89)	—	(89)
Net loss	—	—	—	(39,632)	(39,632)
Balance at March 31, 2022	38,883,445	4	463,525	(448,831)	14,698
Balance at December 31, 2022	43,498,617	4	705,885	(596,333)	109,556
Stock-based compensation	—	—	12,943	—	12,943
Issuance of common stock upon exercise of options	28,876	—	387	—	387
Issuance of common stock upon vesting of RSUs	20,973	—	—	—	—
Issuance of warrants	—	—	1,011	—	1,011
Shares tendered for withholding taxes	—	—	(867)	—	(867)
Net loss	—	—	—	(11,218)	(11,218)
Balance at March 31, 2023	43,548,466	$ 4	$ 719,359	$ (607,551)	$ 111,812

The accompanying notes are an integral part of the consolidated financial statements.

Axsome Therapeutics, Inc.
Consolidated Statements of Cash Flows (Unaudited)
(In thousands)

	Three Months Ended March 31,	
	2023	2022
Cash flows from operating activities		
Net loss	$ (11,218)	$ (39,632)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	12,943	7,598
Amortization of intangible asset	1,572	—
Amortization of debt discount	584	223
Depreciation	90	37
Gain in fair value of contingent consideration	(162)	—
Amortization of operating lease right-of-use asset	314	275
Change in operating lease liability	(317)	(215)
Changes in operating assets and liabilities:		
Accounts receivable, net	(7,094)	—
Inventories, net	(3,620)	—
Prepaid expenses and other current assets	(2,420)	(2,077)
Non-current inventory and other assets	(801)	—
Accounts payable	(2,835)	(554)
Accrued expenses and other current liabilities	7,143	1,692
Net cash used in operating activities	(5,821)	(32,653)
Cash flows from investing activities		
Purchases of equipment	(71)	(214)
Net cash used in investing activities	(71)	(214)
Cash flows from financing activities		
Proceeds from draw down of debt	55,000	—
Payment of debt issuance costs	(1,217)	—
Proceeds from issuance of common stock upon financing, net	—	31,009
Proceeds from issuance of common stock upon exercise of options	387	182
Payment of contingent consideration	(1,738)	—
Payments of tax withholdings on stock award	(867)	(89)
Net cash provided by financing activities	51,565	31,102
Net (decrease) increase in cash	45,673	(1,765)
Cash at beginning of period	200,842	86,473
Cash at end of period	$ 246,515	$ 84,708
Supplemental disclosures of cash flow information:		
Interest paid	$ 3,216	$ 1,119
Operating lease right-of-use asset obtained in exchange for operating lease liability	561	561

The accompanying notes are an integral part of the consolidated financial statements.

Axsome Therapeutics, Inc.
Notes to Consolidated Financial Statements (Unaudited)
(In thousands, except for share and per share amounts)

Note 1. Nature of Business and Basis of Presentation

Axsome Therapeutics, Inc. (“Axsome” or the “Company”) is a biopharmaceutical company developing and delivering novel therapies for central nervous system (“CNS”) conditions that have limited treatment options. By focusing on this therapeutic area, the Company is addressing significant and growing markets where current treatment options are limited or inadequate. The Company was incorporated on January 12, 2012 in the State of Delaware. The Company’s CNS portfolio includes three not yet approved product candidates, AXS-07, AXS-12, and AXS-14, which are being developed for multiple indications, and two approved products - Auvelity® (the components of which are referred to as “AXS-05” and Sunosi® - both of which are also being developed for further indications. In May 2022, the Company acquired the U.S. rights to Sunosi from Jazz Pharmaceuticals plc ("Jazz"). Sunosi is a product approved by FDA and marketed in the U.S. to improve wakefulness in adult patients with excessive daytime sleepiness (“EDS”) associated with narcolepsy or obstructive sleep apnea, and also approved in Europe in January 2020 by the European Commission. In February 2023, the Company announced a licensing transaction with Atnahs Pharma UK Limited (“Pharmanovia”) to market Sunosi in Europe and certain countries in the Middle East / North Africa.

In August 2022, the Company announced the FDA approval of Auvelity and in October 2022, the U.S. commercial availability of Auvelity. Auvelity is indicated for the treatment of major depressive disorder in adults. The Company aims to become a fully integrated biopharmaceutical company that develops and commercializes differentiated therapies that expand the treatment options available to caregivers and improve the lives of patients living with CNS disorders. The Company refers herein to Sunosi, Auvelity, AXS-07, AXS-12, AXS-14, and its programs to develop additional indications for AXS-05 and solriamfetol, as the Company’s products.

The accompanying unaudited interim consolidated financial statements have been prepared by the Company in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”) for interim information and pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”) for reporting on Form 10-Q. Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. These unaudited interim consolidated financial statements should be read in conjunction with the audited financial statements and related notes included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on February 28, 2023.

In the opinion of management, the unaudited interim consolidated financial statements reflect all adjustments, which are normal recurring adjustments, necessary for the fair presentation of the financial information for the interim periods. The results of operations for the three months ended March 31, 2023 are not necessarily indicative of the operating results for the full fiscal year or any future period.

Liquidity and Capital Resources

The Company has incurred operating losses since its inception and expects to continue to incur operating losses for the foreseeable future and may never become profitable. As of March 31, 2023, the Company had an accumulated deficit of $607.6 million.

The Company’s primary sources of cash have been proceeds from the sales of Sunosi and Auvelity, the issuance and sale of its common stock in public offerings, and the issuance of debt. The Company’s ability to achieve profitability depends on a number of factors, including its ability to obtain regulatory approval for its product candidates, successfully complete any post-approval regulatory obligations and successfully commercialize its product candidates alone or in partnership with third parties. The Company may continue to incur substantial operating losses even as it begins to generate revenues from its product candidates.

The Company believes its existing cash will be sufficient to fund its anticipated operating cash requirements for at least twelve months following the date of this filing. During that time, the Company expects that its expenses will increase primarily due to the commercialization of Sunosi and Auvelity while continuing to further develop the Company's pipeline assets. The Company may use a combination of public and private equity offerings, debt financings, other third-party funding, strategic alliances, licensing arrangements or marketing and distribution arrangements if market conditions are favorable or as a result of other strategic considerations to finance its future cash needs.

The Company’s common stock is listed on the Nasdaq Global Market and trades under the symbol “AXSM”.

Note 2. Summary of Significant Accounting Policies

Significant Risks and Uncertainties

The Company’s operations are subject to a number of factors that can affect its operating results and financial condition. Such factors include, but are not limited to: the results of clinical testing and trial activities of the Company’s product candidates; the Company’s ability to obtain regulatory approval to market its products; competition from products manufactured and sold or being developed by other companies; the price of, and demand for, the Company’s products; the Company’s ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products; and the Company’s ability to raise additional financing. If the Company's commercialization of its products is not financially successful, it will be unable to generate sufficient recurring product revenue to achieve and maintain profitability.

The Company currently has two commercially approved products, Auvelity and Sunosi, and there can be no assurance that the Company’s research and development efforts will result in successfully commercialized products in addition to Auvelity and Sunosi. Developing and commercializing a product requires significant time and capital and is subject to regulatory review and approval as well as competition from other biotechnology and pharmaceutical companies. The Company operates in an environment of rapid change and is dependent upon the continued services of its employees and consultants and obtaining and protecting intellectual property.

Use of Estimates

Management considers many factors in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. This process may result in actual results differing materially from those estimated amounts used in the preparation of the financial statements if these results differ from historical experience, or other assumptions do not turn out to be substantially accurate, even if such assumptions are reasonable when made. In preparing these financial statements, management used significant estimates in the following areas, among others: stock-based compensation expense; the determination of the fair value of the warrants; the accounting for research and development costs; accounting for acquisitions; impairments of goodwill and intangible assets; contingent consideration; chargebacks, cash discounts, sales rebates, returns and other adjustments; and the recoverability of the Company’s net deferred tax assets and related valuation allowance.

Revenue Recognition

In accordance with ASC Topic 606, Revenue from Contracts with Customers ("ASC Topic 606") the Company recognizes revenue when the customer obtains control of a promised good or service, in an amount that reflects the consideration that the Company expects to receive in exchange for the good or service. Transfer of control is based on contractual performance obligations, which occurs upon transfer of the title along with the physical transfer of the Company's goods to the customer, as that is when the customer has obtained control of significantly all of the economic benefits and the Company obtains a right of payment.

To determine revenue recognition for arrangements that the Company 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 arrangements that meet the definition of a contract under ASC Topic 606, including when it is probable that the Company 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. For a complete discussion of accounting for product sales, see Product Sales, net (below). Payment terms are typically 90 days or less.

License Agreements

The Company generates revenue from license or similar agreements with pharmaceutical companies for the development and commercialization of certain of our products. Such agreements may include the transfer of intellectual property rights in the form of licenses. Payments made by the customers may include non-refundable upfront fees, payments based upon the achievement of defined milestones, and royalties on sales of products.

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes the transaction price allocated to the license as revenue upon transfer of control of the license. All other promised goods or services in the agreement are evaluated to determine if they are distinct. If they are not distinct, they are combined with other promised goods or services to create a bundle of promised goods or services that is distinct. Optional future services where any additional consideration paid to us reflects their standalone selling prices do not provide the customer with a material right and, therefore, are not considered performance obligations. If optional future services are priced in a manner which provides the customer with a significant or incremental discount, they are material rights, and are accounted for as separate performance obligations.

Contingent milestones at contract inception are estimated at the amount which is not probable of a material reversal and included in the transaction price using the most likely amount method. Milestone payments that are not within the Company's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received and therefore the variable consideration is constrained. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each reporting period, the Company re-evaluates the probability of achieving development or sales-based milestone payments that may not be subject to a material reversal and, if necessary, adjust the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license and other revenue, as well as earnings, in the period of adjustment.

For arrangements that include sales-based royalties, including sales-based milestone payments, and a license of intellectual property that is deemed to be the predominant item to which the royalties relate, revenue is recognized at the later of when the related sales occur or when the performance obligation to which some or all of the royalties have been allocated has been satisfied (or partially satisfied).

Product Sales, net

The Company sells Sunosi and Auvelity in the United States through wholesale distributors (collectively the "Distributors") with whom the Company has entered into formal agreements for delivery to retail pharmacies. The Company sells Sunosi internationally through local distributors for delivery primarily to retail pharmacies and hospitals. For the three months ended March 31, 2023, product sales, net were $12.9 million for Sunosi, including $1.7 million in ex-U.S. markets, and $15.7 million for Auvelity, and includes adjustments for provisions for product sales made in 2022 resulting from changes in estimates of $0.7 million for Auvelity and ($0.3) million for Sunosi.

Reserves for Variable Consideration

The Company's estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of its anticipated performance and all information (historical, current and forecasted) that is reasonably available. These reserves reflect our best estimate of the amount of consideration to which the Company is entitled based on the terms of the contracts. The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that is considered probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the estimates. If actual results in the future vary from our estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

The provision for rebates, discounts, and other incentives is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. Additionally, sales are generally made with a limited right of return under certain conditions. Revenues are recorded net of provisions for rebates, discounts, and other incentives and returns, which are established at the time of sale. The Company uses customer segment utilization mix data, changes to product price, government pricing calculations and prior payment history in order to estimate the variable consideration. Amounts accrued for rebates, discounts, and other incentives are adjusted when trends indicate that adjustment is appropriate and to reflect actual experience.

Trade Discounts and Allowances - The Company generally provides discounts which include incentive fees that are explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, the Company compensates (through trade discounts and allowances) its distributors for distribution services and data. These payments have been recorded as a reduction to product sales as well as a reduction to accounts receivables, net on the consolidated balance sheets.

Product Returns - Consistent with industry practice, the Company generally offers a limited right of return for product that has been purchased from the Company based on the product's expiration date. The Company estimates the amount of its product sales that may be returned and records this estimate as a reduction of revenue in the period the related product sales is recognized, as well as a component of accrued expense and other current liabilities. The Company currently estimates product return liabilities using available industry data and its own sales information.

Chargebacks and Discounts - Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products at prices lower than the list prices charged to distributors. Distributors charge the Company for the difference between what they pay for the product and the ultimate selling price. These reserves are established in the same period that the related product sales are recognized, resulting in a reduction to product sales and accounts receivables, net.

Rebates - Rebates apply to: Medicaid, managed care, and supplemental rebates to all applicable states as defined by the statutory government pricing calculation requirements under the Medicaid Drug Rebate Program. Tricare rebates to the TRICARE third party administrator based on the statutory calculation defined in the agreement with the Defense Health Agency. Part D and Commercial Managed Care rebates are paid based on the contracts with Pharmacy Benefit Managers ("PBMs") and Managed Care Organizations. Rebates are paid to these entities upon receipt of an invoice from the contracted entity which is based on the utilization of the product by the members of the contracted entity. The Company estimates these rebates and records such estimates in the same period the related product sales is recognized, resulting in a reduction to product sales as well as a component of accrued expense and other current liabilities.

Coverage Gap - The Medicare Part D coverage gap is a period of consumer payment for prescription medication costs which lies between the initial coverage limit and the catastrophic-coverage threshold, when the patient is a member of a Medicare Part D prescription-drug program administered by the Centers for Medicare & Medicaid Services. The Company estimates the percentage of goods sold under Coverage Gap and adjusts the transaction price for such discount at the time of sale resulting in a reduction to product sales as well as a component of accrued expense and other current liabilities.

Other Incentives - Other incentives which the Company offers include voluntary patient assistance programs, such as the co-pay assistance program, which are intended to provide financial assistance to qualified commercially-insured patients with prescription drug co-payments required by payers. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product sales as well as a component of accrued expense and other current liabilities.

The Company makes significant estimates and judgments that materially affect its recognition of net product revenue. Claims by third-party payors for rebates, chargebacks and discounts frequently are submitted to the Company significantly after the related sales, potentially resulting in adjustments in the period in which the new information becomes known. The Company will adjust its estimates based on new information, including information regarding actual rebates, chargebacks and discounts for its products, as it becomes available.

License revenue

License revenue consists of the recognition of the upfront payment the Company received from Pharmanovia in February 2023.

Cost of revenue

The Company's cost of revenue consists of cost of product sales related to sales of Sunosi and Auvelity of $2.6 million and a $5.0 million fee sharing expense related to the upfront license revenue received for the three months ended March 31, 2023. Cost of product sales primarily include direct costs (inclusive of material, shipping, handling, and manufacturing costs), overhead and product royalties. Cost of product sales excludes depreciation and amortization. There were no product sales or license revenue for the three months ended March 31, 2022.

The Company assumed royalty and sales-based milestone commitments of Jazz to SK Biopharmaceuticals Co. Ltd. (“SK”) and Aerial Biopharma, LLC (“Aerial”). SK is the originator of Sunosi and retains rights in 12 Asian markets, including China, Korea, and Japan. In 2014, Jazz acquired from Aerial worldwide rights to Sunosi excluding those Asian markets stated previously. The assumed commitments to SK and Aerial include single-digit tiered royalties based on the Company's sales of Sunosi, and the Company is committed to pay up to $165 million based on revenue milestones and $1 million based on development milestones. Additionally, the Company pays a royalty to Antecip Bioventures II LLC (“Antecip”), an entity owned by Axsome’s Chief Executive Officer and Chairman of the Board, Herriot Tabuteau, M.D., equal to 3.0% of Auvelity net sales.

Foreign Currency Translation

Expenses denominated in foreign currency are translated into U.S. dollars at the exchange rate on the date the expense is incurred. Assets and liabilities of foreign operations are translated at period-end exchange rates. The effect of exchange rate fluctuations on translating foreign currency into U.S. dollars is included in the Statements of Operations and is not material to the Company’s financial statements.

Segment and Geographic Information

Operating segments are defined as components of an enterprise for which separate discrete information is available for evaluation by the chief operating decision maker or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business as one operating segment and reporting unit, which is the business of developing and delivering novel therapies for the management of CNS disorders.

Cash Equivalents

The Company considers all highly liquid investments that have maturities of three months or less when acquired to be cash equivalents. The Company’s cash and cash equivalents includes holdings in checking and overnight sweep accounts. The Company’s cash equivalents, which are money market funds held in a sweep account, are measured at fair value on a recurring basis. As of March 31, 2023, the balance of cash and cash equivalents was $246.5 million, which approximates fair value and was determined based upon Level 1 inputs. The sweep account is valued using quoted market prices with no valuation adjustments applied. Accordingly, these securities are categorized as Level 1.

Concentration of Risk

Concentration of Credit Risk - Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. The Company maintains its cash at financial institutions which exceed insured limits. At March 31, 2023, the majority of the Company’s cash was held by two financial institutions and amounts on deposit were in excess of government-provided insurance limits. The Company places its cash and cash equivalents in what it believes to be high credit quality banks and money market funds and has not recognized any losses from credit risks on such accounts since inception. See Accounts Receivables, net below for further information.

Concentration of Risk, Other - We have a limited number of contract manufacturers for our products. At times we may have only one manufacturer or supplier for a product.

Business Combination

The Company accounted for the Sunosi acquisition as a business combination using the acquisition method of accounting, which requires that all identifiable assets acquired, and liabilities assumed be recorded at their estimated fair values. The excess of the fair value of purchase consideration over the fair values of identifiable assets and liabilities is recorded as goodwill. When determining the fair values of assets acquired and liabilities assumed, management makes significant estimates and assumptions. Critical estimates in valuing certain intangible assets include but are not limited to future expected cash flows from acquired patented technology. Management's estimates of fair value are based upon assumptions believed to be reasonable, but are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates.

As a result of the acquisition of Sunosi from Jazz, the Company recorded goodwill and an intangible asset.

Goodwill

Goodwill is deemed to have an indefinite life and therefore not amortized. The Company tests the carrying amounts of goodwill for recoverability on an annual basis or more frequently if events or changes in circumstances indicate that the asset might be impaired. The Company performs a one-step test in its evaluation of the carrying value of goodwill if qualitative factors determine it is necessary to complete a goodwill impairment test. In the evaluation, the fair value of the relevant reporting unit is determined and compared to its carrying value. If the fair value is greater than the carrying value, then the carrying value is deemed to be recoverable, and no further action is required. If the fair value estimate is less than the carrying value, goodwill is considered impaired for the amount by which the carrying amount exceeds the reporting unit's fair value, and a charge is reported in impairment of goodwill in the Company's consolidated statements of operations. The Company intends to complete its annual goodwill assessment in the fourth quarter. As of March 31, 2023, the Company has determined that it has one reporting unit. The Company has not identified any events or changes in circumstances that indicate the existence of potential impairment of goodwill during the three months ended March 31, 2023.

Intangible Assets

Intangible assets are amortized using the straight-line method over their estimated period of benefit of ten years. The Company evaluates the recoverability of intangible assets periodically by considering events or changes in circumstances that may warrant revised estimates of useful lives or that indicate the asset may be impaired. The Company has not identified any events or changes in circumstances that indicate the existence of potential impairment of intangible assets during the three months ended March 31, 2023.

Contingent Consideration

Consideration paid in a business combination may include potential future payments that are contingent upon the acquired business achieving certain milestones in the future ("contingent consideration"). The royalty payments due to Jazz are a high single-digit royalty on the Company's U.S. net sales of Sunosi in the current indication and a mid single-digit royalty on the Company's U.S. net sales of Sunosi for future indications. Contingent consideration liabilities are measured at their estimated fair value as of the date of acquisition, with subsequent changes in fair value recorded in the consolidated statements of operations during such period a change is recognized. The Company estimates the fair value of the contingent consideration as of the acquisition date and reporting periods thereafter using the estimated future cash outflows based on future sales. Contingent consideration liabilities expected to be settled within 12 months after the balance sheet date are presented in current liabilities, with the non-current portion recorded within total liabilities in the consolidated balance sheets.

Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. Assets and liabilities that are measured at fair value are reported using a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. This hierarchy maximizes the use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

Level 1—Quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2—Inputs other than quoted prices in active markets that are observable for the asset or liability, either directly or indirectly.

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

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

The Company's financial instruments are cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities, current and long-term debt, current and non-current contingent consideration. The carrying values for cash, accounts payable and accrued liabilities reported in the accompanying consolidated financial statements approximate their respective fair values due to their short-term maturities, and therefore, are considered Level 1 within the fair value hierarchy. The carrying value of debt on the Company's balance sheet (see Note 10 – Loan and Security Agreement), is estimated to approximate its fair value as the interest rate approximates the market rate for loans with similar terms and risk characteristics, and therefore, are considered Level 1 within the fair value hierarchy. The key assumptions used to determine the fair value of acquisition-related assets and liabilities are estimated by management, not observable in the market and, therefore considered Level 3 inputs within the fair value hierarchy.

Accounts Receivable, net

The Company's accounts receivable, net, arise from product sales. They are generally stated at the invoiced amount and do not bear interest. Accounts receivable allowances result from chargebacks, prompt pay discounts, and distribution fees.

The Company monitors the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in the customers' credit profiles. During the first quarter of 2023, the Company began distributing products through wholesale customers. The Company estimates expected credit losses of its accounts receivable by assessing the risk of loss and available relevant information about collectability, including historical credit losses, existing contractual payment terms, actual payment patterns of its customers, individual customer circumstances, and reasonable and supportable forecast of economic conditions expected to exist throughout the contractual life of the receivable. The Company has not historically experienced significant credit losses. Based on its assessment, as of March 31, 2023, the Company has not recorded any allowances for doubtful accounts receivable. Receivables from our three largest customers totaled 47% 24% and 24% of the Company's accounts receivable, net, balance as of March 31, 2023.

Debt Issuance Costs

Debt issuance costs consist of costs incurred in obtaining long-term financing. These costs are classified on the consolidated balance sheet as a direct deduction from the carrying amount of the related debt liability. These expenses are deferred and amortized as part of interest expense in the consolidated statement of operations using the effective interest rate method over the term of the debt agreement.

Inventory

The Company values its inventories at the lower of average cost or estimated net realizable value. The remaining inventory associated with the Sunosi acquisition is stated at fair value due to purchase accounting. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and it writes down any excess and obsolete inventories to their estimated net realizable value in the period in which the impairment is first identified. Such impairment charges, if they occur, are recorded within cost of product sales as part of cost of revenue.

The Company capitalizes inventory costs associated with the Company's products after regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Inventory acquired and manufactured prior to receipt of regulatory approval of a product candidate is expensed as research and development expense as incurred. Inventory that can be used in either the production of clinical or commercial product is expensed as research and development expense when selected for use in a clinical manufacturing campaign.

Inventory levels are evaluated for amounts that would be sold within one year. If the level of inventory exceeds the estimated amount that would be sold beyond the next 12 months, the Company classifies the estimate of such inventory as non-current.

Equipment, net

Equipment consists primarily of computer equipment and is recorded at cost. Equipment is depreciated on a straight-line basis over its estimated useful life, which the Company estimates to be three years. When equipment is sold or otherwise disposed of, the cost and related accumulated depreciation are removed from the accounts and the resulting gain or loss is included in operating expenses.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist primarily of employee-related expenses including salaries, benefits, travel, and stock-based compensation expense, contract services, costs incurred to third-party service providers for the conduct of research, preclinical and clinical studies, laboratory supplies, product license fees, consulting and other related expenses. We estimate research, preclinical and clinical study expenses based on services performed, pursuant to contracts with third-party research and development organizations that conduct and manage research, preclinical and clinical activities on our behalf. We estimate these expenses based on discussions with internal management personnel and external service providers as to the progress or stage of completion of services and the contracted fees to be paid for such services. If the actual timing of the performance of services or the level of effort varies from the original estimates, we will adjust the accrual accordingly. Payments associated with licensing agreements to acquire licenses to develop, use, manufacture and commercialize products that have not reached technological feasibility and do not have alternative future use are expensed as incurred. Payments made to third parties under these arrangements in advance of the performance of the related services by the third parties are recorded as prepaid expenses until the services are rendered.

Advertising Costs

Advertising costs are included in selling, general and administrative expenses and are expensed as incurred. The Company considers advertising costs as expenses related to the promotion of the Company's commercial products. For the three months ended March 31, 2023, advertising costs were $21.4 million. The Company did not have commercial products for the three months ended March 31, 2022.

Income Taxes

Income taxes are accounted for under the asset and liability method. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to the differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, operating losses, and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company used the Annual Effective Tax Rate (“AETR”) approach of ASC 740-270, Interim Reporting, to calculate its 2023 interim tax provision and recorded an income tax expense for the three months ended March 31, 2023 of $2.6 million.

The Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not to be sustained upon examination based on the technical merits of the position as well as consideration of the available facts and circumstances. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. As of March 31, 2023, the Company does not believe any material uncertain tax positions are present. In the event the Company determines that accrual of interest or penalties are necessary in the future, the amount will be presented as a component of income tax expense.

Stock-Based Compensation

For stock options issued, the Company estimates the grant date fair value of each option using the Black-Scholes option pricing model. The Black-Scholes model takes into account the expected volatility of the Company’s common stock, the risk-free interest rate, the estimated life of the option, the closing market price of the Company’s common stock and the exercise price. The estimates utilized in the Black-Scholes calculation involve inherent uncertainties and the application of management’s judgment. In addition, the Company recognizes expense for equity award forfeitures as they occur.

For restricted stock units (“RSUs”), the Company issues them in the form of Company common stock. The fair market value of these awards is based on the market closing price per share on the grant date.

For awards subject to service-based vesting conditions, the Company recognizes stock-based compensation expense on a straight-line basis over the requisite service period, which is generally the vesting term. For awards subject to performance-based vesting conditions, the Company recognizes stock-based compensation expense using the accelerated attribution method when it is probable that the performance condition will be achieved. The expense related to the stock-based compensation is recorded within the same financial statement line item as the grantee's cash compensation.

The Company's policy upon exercise of stock options and RSUs is that shares will be issued as new shares drawing on the Company's 2015 Omnibus Incentive Compensation Plan share pool that was adopted by the stockholders in November 2015.

Basic and Diluted Net Loss per Common Share

Basic net loss per share of common stock is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share of common stock includes the effect, if any, from the potential exercise or conversion of securities, such as warrants, stock options, and RSUs, which would result in the issuance of incremental shares of common stock. As the impact of these items is anti-dilutive during periods of net loss, there was no difference between basic and diluted net loss per share of common stock for the three months ended March 31, 2023 and 2022.

Leases

The Company determines if an arrangement is a lease at contract inception. Operating lease assets represent the Company's right to use an underlying asset for the lease term and operating lease liabilities represent the Company's obligation to make lease payments arising from the lease. When evaluating whether a contract contains a lease, the Company considers whether (1) the contract explicitly or implicitly identifies assets that are contractually defined and (2) the Company obtains substantially all of the economic benefits from the use of that underlying asset and directs how and for what purpose the asset is used during the term of the contract.

The Company's lease agreements contain lease and non-lease components. Non-lease components primarily include payments for maintenance and utilities. The Company has applied the practical expedient to combine fixed payments for non-lease components with lease payments and account for them together as a single lease component, which increases the amount of lease assets and corresponding liabilities. Payments under the Company's lease arrangements are primarily fixed, however variable payments, are expensed as incurred and not included in the operating lease asset and liability.

Operating lease assets and liabilities are recognized at the commencement date of the lease based upon the present value of lease payments over the lease term. When determining the lease term, the Company includes options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. The Company uses the implicit interest rate when readily determinable and uses the Company's incremental borrowing rate when the implicit rate is not readily determinable based upon the information available at the commencement date in determining the present value of the lease payments.

The Company's operating leases are reflected in the right-of-use operating asset; operating lease liability, current portion; and operating lease liability, long-term portion in the Company's consolidated balance sheets. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. Short-term leases, defined as leases that have a lease term of 12 months or less at the commencement date, and do not include an option to extend the term or purchase the underlying asset that the Company is reasonably certain to exercise, are excluded from this treatment and are recognized on a straight-line basis over the term of the lease.

Recent Accounting Pronouncements

There have been no recent accounting standards updates that impact the Company's financial statements during the three months ended March 31, 2023.

Note 3. Business Combination

Acquisition of Assets of Jazz Pharmaceuticals

On March 25, 2022, the Company entered into an Asset Purchase Agreement (the "Purchase Agreement") with Jazz, pursuant to which the Company was to acquire commercial and development rights with respect to Sunosi from Jazz (the "Acquisition") in certain U.S. and ex-U.S. markets. The Acquisition occurred in two separate closings. The sale and purchase of Specified Initial Assets as defined and contemplated by the Purchase Agreement occurred on May 9, 2022 ("Initial Closing"), following the satisfaction or waiver of the closing conditions under the Purchase Agreement. The sale and purchase of Specified Ex-U.S. Assets contemplated by the Purchase Agreement occurred on November 14, 2022 following the satisfaction or waiver of the closing conditions under the Purchase Agreement. ("Final Closing" or "Ex-U.S. Closing"). The Company accounted for the Initial Closing as a business combination using the acquisition method of accounting, and the Company accounted for the Final Closing as an asset acquisition.

Under the terms of the Purchase Agreement, the Company received from Jazz worldwide commercial, development, manufacturing, and intellectual property rights to Sunosi, except for certain Asian markets. Jazz received from the Company a total upfront payment of $53 million. In addition, Jazz will receive a high single-digit royalty on the Company's U.S. net sales of Sunosi in the current indication, and a mid single-digit royalty on the Company's U.S. net sales of Sunosi in future indications. The Company also assumed the commitments of Jazz to SK and Aerial. SK is the originator of Sunosi and retains rights in 12 Asian markets, including China, Korea, and Japan. In 2014, Jazz acquired from Aerial worldwide rights to Sunosi excluding those Asian markets as stated previously. The assumed commitments to SK and Aerial include single-digit tiered royalties based on the Company's sales of Sunosi, and additionally, the Company is committed to pay up to $165 million based on revenue milestones and $1 million based on development milestones. The Company financed the transaction via its existing term loan facility with Hercules Capital, Inc.

Preliminary purchase consideration consisted of the following:

Cash at settlement	$	53,000
Fair value of contingent consideration		36,140
Total	$	89,140

The preliminary allocation of the fair value of the Sunosi acquisition is shown in the table below:

	Amounts Recognized as of Acquisition Date (as previously reported)	Measurement Period Adjustments	Purchase Price Allocation
Inventory	$ 10,601	$ —	$ 10,601
Other current assets	3,551	1,587 (1)	5,138
Developed technology	63,800	—	63,800
Goodwill	11,897	(1,587) (1)	10,310
Accrued expenses and other current liabilities	(709)	—	(709)
Total	$ 89,140	$ —	$ 89,140

(1) The adjustment to goodwill resulted from rebates covered by Jazz during the post acquisition period which were provisionally recorded as an asset as of the acquisition date.

The above allocation of the purchase price is based upon certain preliminary valuations and other analyses that have not been finalized as of the date of this filing. As such, the purchase price amount and allocations for this transaction are preliminary estimates including goodwill and other current assets, which may be subject to change within the measurement period.

The net assets were recorded at their estimated fair value. In valuing acquired assets and liabilities, fair value estimates were based primarily on future expected cash flows, market rate assumptions for contractual obligations, and appropriate discount rates.

Inventories acquired included raw materials, work in process and finished goods for Sunosi. Inventories were recorded at their estimated fair values categorized as Level 3. The fair value of finished goods was determined based on the estimated selling price, net of selling costs and a margin on the selling activities. The fair value of work in process was determined based on estimated selling price, net of selling costs and costs to complete the manufacturing, and a margin on the selling and manufacturing activities. The fair value of raw materials was estimated to equal the replacement cost. A step-up in the value of inventory of $1.1 million was originally recorded in connection with the Acquisition and is being amortized through cost of product sales as the underlying product is sold.

Other current assets acquired were sample inventory and the rebates for Sunosi sales by the Company after the Initial Closing to be covered by Jazz.

Intangible assets include acquired developed technology. The fair value of the acquired developed technology asset was determined by applying the income approach, which recognizes that the fair value of an asset is premised upon the expected receipt of future economic benefits such as earnings and cash inflows based on current sales projections and estimated direct costs, using a discount rate of 43.5% that reflects the return requirements of the market. The intangible asset is being amortized over an estimated useful life of 10 years.

Goodwill is considered an indefinite-lived asset and relates primarily to intangible assets that do not qualify for separate recognition, such as the assembled workforce and synergies between the entities. Goodwill of $10.3 million was established as a result of the Acquisition. The Company expects that the entire amount of the purchase price allocated to goodwill will be deductible for U.S. income tax purposes over a 15-year period.

Accrued expense and other current liabilities acquired were the Company's assumed sales returns liability for Sunosi after the transaction close date related to Jazz sales prior to the Initial Closing.

Pro Forma Consolidated Financial Information (Unaudited)

The following unaudited pro forma summary presents consolidated information of the Company, including Sunosi, as if the business combination had occurred on January 1, 2022, the earliest period presented herein:

	Three Months Ended March 31, 2022
Net revenues	$ 13,464
Net Loss	(61,502)

Note 4. Accounts receivable, net

As of March 31, 2023 and December 31, 2022, accounts receivable, net, consisted of the following:

	March 31, 2023	December 31, 2022
Trade receivables	$ 57,807	$ 46,796
Less: Reserves for Variable Consideration	(13,014)	(9,097)
Accounts Receivable, net	$ 44,793	$ 37,699

Note 5. Goodwill

The following table provides the Company’s goodwill balance as of March 31, 2023. There was no goodwill impairment during the three months ended March 31, 2023.

	Goodwill
Balance at December 31, 2022	$ 10,310
Goodwill impairment	—
Balance at March 31, 2023	**$ 10,310**

Note 6. Intangible Asset

The gross carrying amount and net book value of the Company's intangible asset are as follows:

	Estimated fair value	Remaining Weighted-Average Useful Life
Balance at December 31, 2022	$ 59,661	
Amortization Expense	(1,572)	9-years
Net Book Value at March 31, 2023	$ 58,089	

Based on finite-lived intangible assets recorded as of March 31, 2023, and assuming the underlying assets will not be impaired and that we will not change the expected lives of the assets, future amortization expenses were estimated as follows:

	Estimated Amortization Expense
2023	6,375
2024	6,392
2025	6,375
2026	6,375
2027	6,375
Thereafter	26,197
Total	$ 58,089

Note 7. Fair Value of Financial Instruments

In connection with the Sunosi acquisition, the Company pays a royalty on net sales of Sunosi to Jazz. The discounted cash flow method used to value this contingent consideration includes inputs of not readily observable market data, which are Level 3 inputs. The fair value of the contingent consideration is reflected as current accrued contingent consideration of $6.0 million and non-current contingent consideration liability of $29.1 million in the consolidated balance sheet as of March 31, 2023.

The fair value of financial instruments measured on a recurring basis is as follows:

March 31, 2023	Level 1	Level 2	Level 3	Total
Liabilities:				
Contingent consideration	$ —	$ —	$ 35,100	$ 35,100

December 31, 2022	Level 1	Level 2	Level 3	Total
Liabilities:				
Contingent consideration	$ —	$ —	$ 37,000	$ 37,000

The fair value of the contingent consideration are marked-to-market each reporting period and was remeasured at March 31, 2023. Changes in the fair value of the contingent considerations as of March 31, 2023 is as follows:

	Contingent Consideration
Balance at December 31, 2022	$ 37,000
Gain in fair value of contingent consideration	(162)
Payments	(1,738)
Balance at March 31, 2023 (Level 3)	**$ 35,100**

The recurring Level 3 fair value measurements of contingent consideration for which a liability is recorded include the following significant unobservable inputs:

			As of March 31, 2023	As of December 31, 2022
	Valuation Methodology	Significant Unobservable Input	Weighted Average (range, if applicable)	Weighted Average (range, if applicable)
Contingent consideration	Probability weighted income approach	Discount rate	13.8%	12.0%
		Revenue discount rate	20.9%	20.9%

The fair value measurement of the contingent consideration is sensitive to the change in discount rates. As of March 31, 2023, if the discount rate increases or decreases by approximately 1%, the fair value of the contingent consideration would range from $33.6 million to $36.8 million. As of March 31, 2023, if the revenue discount rate increases or decreases by approximately 1%, the fair value of the contingent consideration would range from $34.0 million to $36.3 million.

Note 8. Inventory

As of March 31, 2023 and December 31, 2022, inventory consisted of the following:

	March 31, 2023	December 31, 2022
Raw materials	$ 3,825	$ 2,473
Work in process	11,357	13,964
Finished goods	7,267	1,591
Total	$ 22,449	$ 18,028

There were no material inventory reserves as of March 31, 2023. Non-current inventory, which consists of raw materials and work in progress inventory, is included in non-current inventory and other assets in the Company's consolidated balance sheets. Non-current inventory is anticipated to be consumed beyond our normal operating cycle.

The following table summarizes the balance sheet classification of the Company's inventory for each of the periods indicated:

	March 31, 2023	December 31, 2022
Balance sheet classification		
Inventories, net	$ 7,940	$ 4,320
Non-current inventory and other assets	14,509	13,708
Total	$ 22,449	$ 18,028

Note 9. Accrued Expenses and Other Current Liabilities

At March 31, 2023 and December 31, 2022 accrued expenses and other current liabilities consisted of the following:

	March 31, 2023	December 31, 2022
Accrued research and development	$ 3,789	$ 4,714
Accrued compensation	7,271	11,284
Accrued selling, general and administrative	9,529	6,596
Accrued sales discounts, rebates and allowances	30,426	26,545
Accrued royalties	6,464	1,617
Accrued interest	1,295	875
Total	$ 58,774	$ 51,631

Note 10. Loan and Security Agreement

Hercules Capital, Inc.

Third Amendment to the Loan Agreement

On January 9, 2023, the Company entered into a Third Amendment (the "Third Amendment") to its Loan and Security Agreement, dated as of September 25, 2020 (as amended by that certain First Amendment to Loan and Security Agreement, dated as of October 14, 2021, and as further amended by the Second Amendment to Loan and Security Agreement, dated as of March 27, 2022) (the “Loan Agrement”) with Hercules Capital, Inc., a Maryland corporation (“Hercules”), in its capacity as administrative agent and collateral agent, and the other financial institutions or entities party thereto as lenders.

The Third Amendment amended the terms of the Loan Agreement to, among other things:

- Extend the maturity date to January 1, 2028, unless the Company meets certain revenue targets as described in the Loan Agreement, in which case the Company can extend the maturity date to January 1, 2029;
- Increase the aggregate principal amount under the Loan Agreement from $300.0 million to $350.0 million;
- Subject to the terms and conditions in the Loan Agreement, change the Term Loan Advance amounts and dates available under the Tranche 1 Advance (as defined in the Loan Agreement) through Tranche 5 Advance (as defined in the Loan Agreement), including increasing the Tranche 1 Advance from one tranche of $95.0 million to five sub-tranches of $95.0 million, $55.0 million, $30.0 million, $35.0 million and $35.0 million, respectively, changing the Tranche 2 Advance (as defined in the Loan Agreement) from three sub-tranches of $35.0 million, $35.0 million and $30,.0 million to one tranche of $25.0 million, changing the Tranche 3 Advance (as defined in the Loan Agreement) from two sub-tranches of $15.0 million and $5.0 million to one tranche of $75.0 million, and removing the Tranche 4 Advance (as defined in the Loan Agreement) and Tranche 5 Advance entirely;
- Revise the interest rate applicable to extensions of credit under the Loan Agreement to equal (a) if the prime rate is greater than or equal to 7.00%, the greater of either (i) the prime rate plus 2.20%, and (ii) 9.95%, but in no event greater than 10.70%, and (b) if the prime rate is less than 7.00%, 9.70%;
- Increase the minimum cash requirement of the Company to $30.0 million; and
- Require the Company to pay a facility fee equal to 0.75% of the amount of principal actually funded pursuant to the Tranche 1B Advance (as defined in the Loan Agreement), Tranche 1C Advance (as defined in the Loan Agreement), Tranche 1D Advance (as defined in the Loan Agreement), Tranche 1E Advance (as defined in the Loan Agreement), Tranche 2 Advance and Tranche 3 Advance.

On October 14, 2021, the Company entered into a First Amendment to the Loan and Security Agreement with Hercules. On March 27, 2022, in connection with the Acquisition (as described above), the Company entered into a Second Amendment to the Loan and Security Agreement (the “Second Amendment”) with Hercules. The Second Amendment closed on May 9, 2022 concurrently with the closing of the Acquisition.

As collateral for the obligations, the Company has granted to Hercules a senior security interest in all of the Company’s right, title, and interest in, to and under all of the Company’s property, inclusive of intellectual property, which includes one of the Company’s existing license agreements (the “License Agreement”) with Antecip, an entity owned by Axsome’s Chief Executive Officer and Chairman of the Board, Herriot Tabuteau, M.D., subject to limited exceptions. Antecip consented to the collateral assignment of the License Agreement, among other things, under a direct agreement (the “Direct Agreement”) with the Company and Hercules.

The Loan Agreement contains customary representations, warranties and covenants, including covenants by the Company limiting additional indebtedness, liens (including a negative pledge on intellectual property and other assets), guaranties, mergers and consolidations, substantial asset sales, investments and loans, certain corporate changes, transactions with affiliates and fundamental changes. At the initial closing, there were no applicable financial covenants contained in the Loan Agreement. Only after additional amounts are drawn down by the Company in the future, if the Company decides to do so, under the terms set forth in the Loan Agreement, there will be certain limited financial covenants that will apply, including:

- Effective upon closing of the Third Amendment of the Loan Agreement, the Company at all times thereafter must maintain cash in an account or accounts in which Hercules has a first priority security interest, in an aggregate amount greater than or equal to $30.0 million, plus the amount of the Company’s accounts payable under U.S. GAAP not paid after the 180th day following the invoice for such account payable (such amount, the “Qualified Cash A/P Amount”).

- The Company must meet, beginning as of the reporting period ended June 30, 2023, any of the following conditions: (A) ensure that at all times its market capitalization exceeds $1.5 billion, and that it maintains cash in an account which Hercules has a first priority security interest in an amount not less than 50% of the sum of the outstanding principal amount of the Term Loan Advances (as defined in the Loan Agreement) *plus* the Qualified Cash A/P Amount, (B) ensure that at all times that it maintains cash in an account which Hercules has a first priority security interest in an amount not less than 95% of the sum of the outstanding principal amount of the Term Loan Advances *plus* the Qualified Cash A/P Amount, or (C) achieve at least 60% of the net product revenue per the board of directors approved forecast solely from the sale of AXS-05, AXS-07, and Sunosi (which may include royalty, profit sharing, or sales-based milestone revenue recognized in accordance with GAAP, but will not include any upfront or non-sales-based milestone payments under business development or licensing transactions), measured on a trailing six-month basis as of the date of the Company's most recent quarterly financial statement, determined on a quarterly basis.
- Axsome Malta Ltd., a company organized under the laws of the Republic of Malta, shall not hold Cash (as defined in the Loan Agreement) outside of the United States in excess of $3.0 million in the aggregate at any time, which was amended to $10.0 million on May 8, 2023.
- Restrictions on the Company's ability to incur additional indebtedness, pay dividends, encumber its intellectual property, or engage in certain fundamental business transactions, such as mergers or acquisitions of other businesses, with certain exceptions.

The Company's obligations under the Loan Agreement are subject to acceleration upon the occurrence of specified events of default, including payment default, insolvency and a material adverse change in the Borrower's business, operations or financial or other condition.

In addition, the Company is required to pay certain end of term charges, including (A) an initial end of term charge of $4.45 million and (B) a subsequent end of term charge of (i) 1.10% of the aggregate amount of all Tranche 1A Advances *plus* (ii) 4.95% of the aggregate amount of all Term Loan Advances (other than Tranche 1A Advances) funded. The end of term charges are being accreted into interest expense using the effective interest rate method over the term of the loan.

If the Maturity Extension Conditions (as defined in the Loan Agreement) are satisfied, the Company must pay an Extension End of Term Charge equal to 1.00% of the aggregate amount of all Term Loan Advances outstanding as of the date on which the Maturity Extension Conditions are satisfied, in addition to the end of term charges described above.

The Company may, at its option prepay the term loans in full or in part, subject to a prepayment penalty equal to (i) 2.0% of the principal amount prepaid if the prepayment occurs prior to February 1, 2024, (ii) 1.5% of the principal amount prepaid if the prepayment occurs on or after February 1, 2024 but prior to February 1, 2025, and (iii) 1.0% of the principal amount prepaid if the prepayment occurs on or after February 1, 2025 but prior to February 1, 2026.

The Company evaluated whether the Third Amendment entered into in January 2023 represented a debt modification or extinguishment in accordance with ASC 470-50, *Debt – Modifications and Extinguishments*. As the present value of the cash flows under the terms of the Third Amendment is less than 10% different from the remaining cash flows under the terms of the Second Amendment, the Third Amendment was accounted for as a debt modification. The unamortized balance of debt discount costs incurred in connection with those loans and additional debt discount costs incurred in connection with entry into the Third Amendment are being amortized through maturity in January 2028 utilizing the effective interest rate method.

Loan Interest Expense and Amortization

The interest expense, amortization expense for the final payment fee and debt discount related to the issuance costs and warrants for our debt is as follows:

	Three Months Ended March 31,	
	2023	2022
Interest expense	$ 3,635	$ 1,124
Amortization of final payment fee	250	98
Amortization of debt discount related issuance costs and warrants	334	125

The outstanding debt and unamortized debt discount balances are as follows:

	March 31, 2023	December 31, 2022
Total Outstanding Debt	$ 150,000	$ 95,000
Add: accreted liability of final payment fee	1,662	1,363
Less: unamortized debt discount, long-term	(4,047)	(2,104)
Less: current portion of long-term debt	—	—
Loan payable, long-term	$ 147,615	$ 94,259

Scheduled Principal Payments on Outstanding Debt, as of March 31, 2023, are as follows:

2023	—
2024	—
2025	—
2026	—
2027	—
Thereafter	150,000
Total principal payments outstanding	$ 150,000

The Company was in compliance with all covenants and requirements of its financing arrangements as of and during the three months ended March 31, 2023.

Note 11. Commitments and Contingencies

Operating Leases

For the three months ended March 31, 2023 and 2022, the Company had the following operating lease expense:

		Three Months Ended March 31,	
	Statement of Operations Location	2023	2022
Total operating lease expense	Selling, general and administrative	$ 318	$ 291

Future minimum lease payments of the Company’s operating leases as of March 31, 2023 were as follows:

2023	$ 108
Total lease payments	108
Less imputed interest	—
Present value of operating lease liabilities	$ 108

In August 2022, the Company entered into an agreement to extend the lease of 22 Cortlandt Street through April 30, 2023. As of March 31, 2023, the remaining lease term for the Company's operating lease was 0.1 years with a discount rate of 6.0%. The interest rate implicit in lease contracts is typically not readily determinable and as such, the Company uses its incremental borrowing rate based on the information available at the lease commencement date, which represents an internally developed rate that would be incurred to borrow, on a collateralized basis, over a similar term, an amount equal to the lease payments in a similar economic environment.

During the second quarter of 2023, the sublease for the Company's new headquarters at One World Trade Center commenced. See Note 17 - Subsequent Event for further information.

Note 12. Net Loss per Common Share

The following table sets forth the computation of basic and diluted net loss per common share (in thousands, except share and per share amounts):

	Three Months Ended March 31,	
	2023	2022
Basic and diluted net loss per common share:		
Net loss	$ (11,218)	$ (39,632)
Weighted average common shares outstanding—basic and diluted	43,523,631	38,323,167
Net loss per common share—basic and diluted	$ (0.26)	$ (1.03)

The following potentially dilutive securities outstanding at March 31, 2023 and 2022 have been excluded from the computation of diluted weighted average shares outstanding, as they would be anti-dilutive:

	March 31,	
	2023	2022
Stock options	8,038,119	6,219,030
Restricted stock units	787,134	667,366
Warrants	69,520	15,541
Total	8,894,773	6,901,937

Note 13. Stockholders' Equity

Capital Structure

In December 2019, the Company entered into a sales agreement (the "December 2019 Sales Agreement") with SVB Securities LLC (formerly known as SVB Leerink LLC) ("SVB Securities"), pursuant to which the Company may sell up to $80 million in shares of the Company's common stock from time to time through SVB Securities, acting as the Company's sales agent, in one or more at-the-market offerings utilizing an automatic shelf registration statement (the "2019 Shelf Registration Statement") the Company filed with the SEC on December 5, 2019 for the issuance of common stock, preferred stock, warrants, rights, debt securities and units. SVB Securities is entitled to receive a commission of 3.0% of the gross proceeds for any shares sold under the December 2019 Sales Agreement. The December 2019 Sales Agreement was replaced by the March 2022 Sales Agreement (see below).

In March 2022, the Company entered into a sales agreement (the "March 2022 Sales Agreement") with SVB Securities, pursuant to which the Company may sell up to $200 million in shares of the Company's common stock from time to time through SVB Securities, acting as the Company's sales agent, in one or more at-the-market offerings utilizing the 2019 Shelf Registration Statement. SVB Securities is entitled to receive a commission of up to 3.0% of the gross proceeds for any shares sold under the March 2022 Sales Agreement. The March 2022 Sales Agreement supersedes the December 2019 Sales Agreement, dated December 5, 2019, by and between the Company and SVB Securities. The Company exhausted sales of its shares of the Company's common stock under its prior at-the-market offering program.

In August 2022, the Company filed a prospectus supplement to the 2019 Shelf Registration Statement for the issuance and sale, if any, of up to an additional $250 million in shares of the Company's common stock The Company will pay SVB Securities a commission of up to 3.0% of the gross sales proceeds of any shares sold through SVB Securities, acting as sales agent, under the March 2022 Sales Agreement.

In December 2022, in connection with the 2022 Shelf Registration Statement (as defined below), the Company filed a new sales agreement prospectus to replace the prior prospectus supplement filed in August 2022 associated with the expired 2019 Shelf Registration Statement. The new sales agreement prospectus covered the issuance and sale by the Company of up to the same $250 million of our common stock that may be issued and sold from time to time through SVB Securities, as the Company's sales agent, under the March 2022 Sales Agreement.

The Company did not utilize the March 2022 Sales Agreement with SVB Securities during the three months ended March 31, 2023.

The holders of shares of common stock are entitled to one vote for each share of common stock held at all meetings of stockholders and written actions in lieu of meetings. The holders of shares of common stock are entitled to receive dividends, if and when declared by the board of directors.

Shelf Registration Statement

On December 2, 2022, the Company filed an automatic shelf registration statement ("2022 Shelf Registration Statement") with the SEC for the issuance of common stock, preferred stock, warrants, rights, debt securities and units. It became effective upon filing with the SEC and is currently the Company's only active shelf registration. Through the date of this report, the Company has not issued common stock pursuant to such shelf registration statement.

Under SEC rules, the 2022 Shelf Registration Statement allows for the potential future offer and sale by the Company, from time to time, in one or more public offerings of an indeterminate amount of the Company's common stock, preferred stock, debt securities, and units at indeterminate prices. At the time any of the securities covered by the 2022 Shelf Registration Statement are offered for sale, a prospectus supplement will be prepared and filed with the SEC containing specific information about the terms of any such offering.

Equity Incentive Plans

There were 1,241,793 shares available for the issuance of stock options or stock-based awards under the Company's 2015 Omnibus Incentive Compensation Plan at March 31, 2023.

Stock Options

The following table sets forth the stock option activity for the three months ended March 31, 2023:

	Number of shares	Weighted average exercise price	Weighted average contractual term	Aggregate intrinsic value
Outstanding at December 31, 2022	6,617,728	$ 31.80		
Granted	1,536,960	65.27		
Exercised	(28,876)	12.77		
Forfeited	(87,693)	51.01		
Outstanding at March 31, 2023	8,038,119	$ 38.06	7.5	$ 161,918
Vested and expected to vest at March 31, 2023	8,038,119	$ 38.06	7.5	$ 161,918
Exercisable at March 31, 2023	3,707,362	$ 22.78	5.7	$ 58,467

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model. The expected term of the Company's stock options has been determined utilizing the "simplified" method as described in the SEC's Staff Accounting Bulletin No. 107 relating to stock-based compensation. The simplified method was chosen because the Company has limited historical option exercise experience due to its short operating history. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for a period approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future. In prior years, expected volatility is based on historical volatilities of similar entities within the Company's industry which were commensurate with the Company's expected term assumption. Starting in 2023, the expected volatility was estimated based on historical volatility information of the Company since the Company's initial public offering in 2015.

The weighted average grant date fair value of options granted was $51.44 per option for the three months ended March 31, 2023. As of March 31, 2023, there was $160.3 million of total unrecognized compensation cost related to non-vested stock options which is expected to be recognized over a weighted average period of 3.1 years. These amounts do not include 6,169 options outstanding as of March 31, 2023, which are performance-based and vest upon the achievement of certain corporate milestones. Stock-based compensation will be measured and recorded if and when it is probable that the milestone will occur.

Restricted Stock Units

The fair value of RSUs is determined on the date of the grant based on the market price of its shares of common stock as of that date. The fair value of the RSUs is recognized as an expense ratably over the vesting period of four years. As of March 31, 2023, total compensation cost not yet recognized related to unvested RSUs was $29.3 million, which is expected to be recognized over a weighted-average period of 3.1 years.

The following table sets forth the RSU activity for the three months ended March 31, 2023:

	Number of shares	Weighted average grant date fair value
Outstanding at December 31, 2022	686,375	$ 31.80
Granted	261,759	53.71
Vested	(152,621)	29.95
Forfeited	(8,379)	45.73
Outstanding at March 31, 2023	787,134	$ 39.30

Stock-based compensation expense recognized for the three months ended March 31, 2023 and 2022 was allocated as follows:

	Three Months Ended March 31,	
	2023	2022
Research and development	$ 2,414	$ 1,809
Selling, general and administrative	10,529	5,789
Total	$ 12,943	$ 7,598

Warrants

The following table summarizes warrant activity for the three months ended March 31, 2023:

	Warrants	Weighted average exercise price
Outstanding at December 31, 2022	50,796	$ 46.75
Issued	18,724	55.01
Exercised	—	—
Outstanding at March 31, 2023	69,520	$ 48.97

Outstanding Warrants

In connection with the entry into the Third Amendment, Hercules received warrants to purchase an aggregate 18,724 shares of the Company's common stock at an exercise price of $55.01 per share ("2023 warrants"). In connection with the entry into the Second Amendment, Hercules received warrants to purchase an aggregate 35,255 shares of the Company's common stock at an exercise price of $31.91 per share ("2022 warrants"), and in connection with the first advance of the 2020 Term Loan, Hercules received warrants to purchase an aggregate 15,541 shares of the Company's common stock at an exercise price of $80.43 per share ("2020 warrants").

The 2023 warrants, 2022 warrants and 2020 warrants were priced using the volume weighted average price of the Company's common stock over the ten-day trading period immediately preceding the initial closing, subject to certain limited adjustments as specified in the warrant. The warrants are exercisable for seven years from the date of issuance. The warrants were classified as a component of stockholders' equity. The relative fair value of the warrants of approximately $1.0 million for the 2023 warrants, $0.8 million for the 2022 warrants, and $0.9 million for the 2020 warrants at the time of issuance, which was determined using the Black-Scholes option-pricing model, was recorded as additional paid-in capital and reduced the carrying value of the debt. The discount on the debt is being amortized to interest expense over the term of the debt utilizing the effective interest rate method.

Note 14. License Agreements

License Agreement with Pharmanovia

In February 2023, Axsome Malta Ltd., a Malta limited company ("Axsome Malta") and a wholly-owned subsidiary of the Company, entered into an exclusive license agreement with Pharmanovia (the "Pharmanovia License Agreement") to commercialize and further develop Sunosi in Europe and certain countries in the Middle East and North Africa (the "Territory"). Under the terms of the Pharmanovia License Agreement, the Company retains its existing interest in the Sunosi intellectual property and licenses those rights in the Territory to Pharmanovia. Pharmanovia is solely responsible for the clinical development and commercialization in the Territory. The Company will continue to manufacture Sunosi and provide product supply to Pharmanovia for an indefinite period of time and the Company will recognize revenue as a component of product sales, net, when performance obligation criteria are met as per the product supply agreement.

In consideration for entering the Pharmanovia License Agreement, the Company received a non-refundable upfront payment of €62.0 million ($65.7 million). The Company also will receive a royalty percentage in the mid-twenties on Sunosi net sales in the Territory, and is eligible to receive sales-based milestone payments totaling up to €94.5 million.

The Company evaluated the Pharmanovia License Agreement under ASC 606 and concluded that Pharmanovia represents a customer in the transaction. The initial transaction price consisted of the non-refundable upfront payment, which was recognized as License Revenue in the first quarter of 2023 as the requirements for revenue recognition under ASC 606 were met. The remaining forms of consideration are variable because they are dependent on the achievement of sales-based or other milestones. The Company evaluated the constraint on variable consideration and concluded that the milestone payments are dependent on regulatory approvals and actions of third parties, and thus are highly susceptible to factors outside the Company's influence. Therefore, at contract inception, the milestones are not included in the transaction price as it is not probable that a significant reversal of revenue would not occur. Sales-based milestones will be recognized as revenue in the period when the related sales threshold is met. All other milestones will be recognized as revenue immediately in the period the underlying milestone is achieved. Any consideration related to sales-based royalties will be recognized when the related sales occur. For the three months ended March 31, 2023, the Company recognized royalty revenue of $0.3 million related to Pharmanovia sales of Sunosi.

Exclusive License Agreement with Pfizer

In January 2020, the Company entered into an exclusive license agreement with Pfizer Inc. ("Pfizer") for Pfizer's clinical and nonclinical data, and intellectual property for reboxetine, the active pharmaceutical ingredient in AXS-12 which the Company is developing for the treatment of narcolepsy. The agreement also provides the Company exclusive rights to develop and commercialize esreboxetine, a new late-stage product candidate referred to as AXS-14, in the U.S. for the treatment of fibromyalgia.

Under the terms of the agreement, Pfizer received 82,019 shares of the Company's common stock having a stated value of $8.0 million, based on the average closing price of the Company's common stock for the ten prior trading days of $97.54, in consideration for the license and rights and also received an upfront cash payment of $3.0 million. The Company determined that the fair value of each share of common stock granted to Pfizer on the closing date of January 9, 2020 was $87.24, based on the closing price of the Company's stock on that date. As a result, the fair value of the stock issued was $7.2 million and therefore, the total research and development expense recognized was $10.2 million related to the Pfizer license agreement during the year ended 2020.

Pfizer can also receive up to $323 million in regulatory and sales milestones, and tiered mid-single to low double-digit royalties on future sales related to the licensed products. Pfizer will also have a right of first negotiation on any potential future strategic transactions involving AXS-12 and AXS-14. During the three months ended March 31, 2023 and 2022, no milestone payments or royalties were paid to Pfizer by the Company.

Exclusive License Agreements with Antecip

In 2012, the Company entered into three exclusive license agreements with Antecip, an entity owed by the Company's Chief Executive Officer and Chairman of the Board, Herriot Tabuteau, M.D., in which it was granted exclusive licenses to develop, manufacture, and commercialize Antecip's patents and applications related to the development of AXS-02, AXS-05, and AXS-04, anywhere in the world for human therapeutic, veterinary, and diagnostic use. Pursuant to the agreements, the Company is required to use commercially reasonable efforts to develop, obtain regulatory approval for and commercialize AXS-02, AXS-05, and AXS-04. Under the terms of the agreements, the Company is required to pay to Antecip a royalty equal to 4.5% for AXS-02, 3.0% for AXS-05, and 1.5% for AXS-04, of net sales of products containing the licensed technology by the Company, its affiliates, or permitted sublicensees. These royalty payments are subject to reduction by an amount up to 50.0% of any required payments to third parties. Unless earlier terminated by a party for cause or by the Company for convenience, the agreements shall remain in effect on a product-by-product and country-by-country basis until the later to occur of (i) the applicable product is no longer covered by a valid claim in that country or (ii) 10 years from the first commercial sale of the applicable product in that country. Upon expiration of the agreements with respect to a product in a country, the Company's license grant for that product in that country will become a fully paid-up, royalty-free, perpetual non-exclusive license. If Antecip terminates any of the agreements for cause, or if the Company exercises its right to terminate any of the agreements for convenience, the rights granted to the Company under such terminated agreement will revert to Antecip. The Company began recording royalty payments to Antecip along with the initiation of sales of Auvelity in the fourth quarter of 2022. For the three months ended March 31, 2023, the Company recorded an accrued expense of $0.5 million for royalty payments to Antecip, which is equal to 3.0% of net sales of Auvelity. This is considered to be a related party transaction.

In connection with the 2020 Term Loan, the Company entered into the Direct Agreement with Antecip pursuant to which Antecip consented to the collateral assignment of the License Agreement to Hercules, among other things.

Note 15. Royalty Agreements

Pursuant to the Purchase Agreement, the Company agreed to make non-refundable, non-creditable royalty payments to Jazz equal to a (A) high-single digit royalty for any Current Indication (as defined in the Purchase Agreement), or (B) mid-single digit royalty for any Future Indication (as defined in the Purchase Agreement), of Net Sales (as defined in the Purchase Agreement) in the U.S. Territory (as defined in the Purchase Agreement) made during the applicable Royalty Term (as defined in the Purchase Agreement). There are no royalty payments due to Jazz for Net Sales outside of the U.S. Territory.

At the initial closing, the Company assumed all of the commitments of Jazz to SK and Aerial. SK is the originator of the Product and retains rights in 12 Asian markets, including China, Korea, and Japan. In 2014, Jazz acquired from Aerial worldwide rights to Sunosi excluding those Asian markets stated previously. The assumed commitments to SK and Aerial include single-digit tiered royalties based on the Company's sales of Sunosi, and additionally, the Company is committed to pay up to $165 million based on revenue milestones and $1 million based on development milestones.

Note 16. Income Taxes

The table below presents the Company's provision for income taxes and effective tax rates for all periods presented:

	Three Months Ended March 31,	
	2023	2022
Income before provision for income taxes	$ (8,638)	$ —
Provision for income taxes	$ 2,580	$ —
Effective tax rate	(29.9)%	—%

The Company is subject to income taxes in the United States and foreign jurisdictions in which the Company does business. These foreign jurisdictions have statutory tax rates different from those in the United States. Accordingly, the Company's effective tax rates will vary depending on the relative proportion of foreign to United States income, the utilization of net operating loss and tax credit carry forwards, changes in geographic mix of income and expense, and changes in management's assessment of matters such as the ability to realize deferred tax assets, and changes in tax laws. The Company regularly assesses the likelihood of adverse outcomes resulting from the examination of the Company's tax returns by the Internal Revenue Service, or IRS, and other tax authorities to determine the adequacy of our income tax reserves and expense. Should actual events or results differ from the Company's current expectations, charges or credits to our income tax expense may become necessary.

The increase in the effective tax rate from the three months ended March 31, 2023 as compared to comparable prior period was primarily due to the tax expense associated with income earned from the Company's foreign operations related to the Pharmanovia License Agreement.

The Company did not have any unrecognized tax benefits as of March 31, 2023 related to uncertain tax positions that would impact the effective income tax rate if recognized.

Note 17. Subsequent Events

In February 2023, the Company entered into a sublease for office space for the Company's corporate and executive offices. The sublease commenced in April 2023. The Company will recognize a right-of-use asset - operating lease of $7.8 million, and an operating lease liability, current portion and long-term of $0.3 million and $7.4 million, respectively, at the beginning of the second quarter of 2023.

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

The following discussion and analysis contains forward-looking statements about our plans and expectations of what may happen in the future. Forward-looking statements are based on a number of assumptions and estimates that are inherently subject to significant risks and uncertainties, and our results could differ materially from the results anticipated by our forward-looking statements as a result of many known or unknown factors, including, but not limited to, those factors discussed in "Risk Factors." See also the "Cautionary Note Regarding Forward-Looking Statements" set forth at the beginning of this report.

You should read the following discussion and analysis in conjunction with the unaudited interim consolidated financial statements, and the related footnotes thereto, appearing elsewhere in this report, and in conjunction with management's discussion and analysis and the audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2022 which was *filed with the Securities and Exchange Commission, or SEC, on February 28, 2023*.

Overview

We are a commercial-stage biopharmaceutical company developing and delivering novel therapies for central nervous system, or CNS, conditions that have limited treatment options. By focusing on this therapeutic area, we are addressing significant and growing markets where current treatment options are limited or inadequate. Our portfolio primarily consists of two commercial products and the development programs described below.

Commercial Products

1. ***Auvelity®.*** Auvelity (dextromethorphan-bupropion) is a novel, oral, N-methyl-D-aspartate (NMDA) receptor antagonist with multimodal activity indicated for the treatment of major depressive disorder, also known as MDD. Auvelity was developed by the Company and approved by the U.S. Food and Drug Administration, or the FDA, for the treatment of MDD in August 2022.

2. ***Sunosi®.*** Sunosi (solriamfetol) is a novel, oral medication indicated to the treatment of excessive daytime sleepiness, also known as EDS, in patients with narcolepsy or obstructive sleep apnea. Sunosi was approved for the treatment of EDS in the United States in 2019 and by the European Commission in 2020. We acquired the U.S. rights to Sunosi from Jazz Pharmaceuticals plc, or Jazz, in May 2022 and worldwide ex-U.S. rights (excluding certain Asian markets) from Jazz in November 2022. We have been commercializing Sunosi since we completed these acquisitions. SK Biopharmaceuticals Co. Ltd., is the originator of Sunosi and retains rights in 12 Asian markets, including China, Korea, and Japan. In February 2023, we announced a licensing transaction with Pharmanovia to market Sunosi in Europe and certain countries in the Middle East / North Africa.

Development Programs

When used in programs for further development, we refer to the proprietary dextromethorphan-bupropion combination contained in Auvelity as "AXS-05." AXS-05 is a novel, oral, investigational NMDA receptor antagonist with multimodal activity under development for the treatment of Alzheimer's disease agitation, or AD agitation, and smoking cessation. AXS-05 utilizes a proprietary combination and dose of dextromethorphan and bupropion, and Axsome's metabolic inhibition technology, to modulate the delivery of the components. We have completed a Phase 2/3 trial of AXS-05 in AD agitation, which we refer to as the ADVANCE-1 trial. AXS-05 achieved the primary endpoint in the ADVANCE-1 trial. We have also completed the ACCORD trial, a Phase 3, double blind, placebo-controlled, randomized withdrawal trial in patients with AD agitation, and we are conducting an open-label long-term safety study in AD agitation. We are currently conducting the ADVANCE-2 trial, another Phase 3, double blind, placebo-controlled, randomized withdrawal trial in patients with AD agitation. A positive Phase 2 trial for the use of AXS-05 in smoking cessation has been completed under a research collaboration with Duke University.

AXS-07 is a novel, oral, rapidly absorbed, multi-mechanistic, investigational medicine under development for the acute treatment of migraine. AXS-07 consists of MoSEIC™, or Molecular Solubility Enhanced Inclusion Complex, meloxicam and rizatriptan. We have completed two Phase 3 trials of AXS-07 for the acute treatment of migraine, which we refer to as the MOMENTUM and INTERCEPT trials. AXS-07 achieved the co-primary endpoints in both the MOMENTUM and INTERCEPT trials. We have also completed an open-label, long-term, safety study of AXS-07 in patients with migraine known as the MOVEMENT trial. In the MOVEMENT trial, administration of AXS-07 resulted in rapid, and substantial relief of migraine pain and associated symptoms and was well tolerated with long term dosing. We submitted an NDA for AXS-07 in 2021, which was accepted, and received a complete response letter, or CRL, from the FDA in April 2022. The principal reasons given in the CRL relate to chemistry, manufacturing, and controls, or CMC considerations.

AXS-12, reboxetine, is a novel, oral, investigational medicine in development for the treatment of cataplexy in narcolepsy. AXS-12 is a highly selective and potent norepinephrine reuptake inhibitor. AXS-12 has been granted FDA Orphan Drug Designation for the treatment of narcolepsy. We have completed a Phase 2 trial with AXS-12, which we refer to as the CONCERT study. We are currently conducting a randomized, placebo-controlled Phase 3 trial with AXS-12 in narcolepsy, which we refer to as the SYMPHONY study, and one open-label long-term safety extension study.

AXS-14, esreboxetine, is a novel, oral, investigational medicine in development for the treatment of fibromyalgia. AXS-14 is a highly selective and potent norepinephrine reuptake inhibitor. Esreboxetine, the SS-enantiomer of reboxetine, is more potent and selective than racemic reboxetine. We have in-licensed data from Pfizer Inc., or Pfizer, that includes a completed Phase 2 trial and Phase 3 trial in fibromyalgia, both of which were positive.

Solriamfetol is the active ingredient in Sunosi. It is an oral, dual-acting dopamine and norepinephrine reuptake inhibitor. We recently announced our intent to conduct a Phase 3 trial of solriamfetol in adults with attention-deficit/hyperactivity disorder.

Additionally, we are currently evaluating other product candidates, which we intend to develop for CNS disorders. We aim to become a fully integrated biopharmaceutical company that develops and commercializes differentiated therapies that increase available treatment options and improve the lives of patients living with CNS disorders.

Since our incorporation in January 2012, our operations to date have included organizing and staffing our company, business planning, raising capital, developing our compounds, engaging in other discovery and preclinical activities and commencing the commercialization of Sunosi and Auvelity. We have raised capital through proceeds from sales of our common stock and warrants to purchase shares of our common stock to equity investors, debt borrowings, and sales of Auvelity and Sunosi. For a further discussion, see the section entitled “Liquidity and Capital Resources” below.

Our ability to become profitable depends on our ability to generate revenue. We have recently begun commercial sales of Sunosi and Auvelity but we have limited experience with commercializing these products.

We have incurred significant operating expenses and net losses since inception. We incurred net losses of $11.2 million and $39.6 million for the three months ended March 31, 2023 and 2022, respectively. Our accumulated deficit as of March 31, 2023 was $607.6 million, and we expect to incur significant expenses and increasing operating losses for the foreseeable future. We expect to incur commercialization expenses for Sunosi and Auvelity as we look to continue to support the growth of both products. We expect to continue to incur expenses in connection with the development of our product candidates, including with respect to conducting clinical trials and seeking regulatory approval for our current product candidates and any other product candidates that we develop or in-license and advance to clinical development. As we continue to seek regulatory approval for our product candidates, we expect to incur significant expenses in order to continue to create an infrastructure and support market readiness for the commercialization of our product candidates, including manufacturing, sales, marketing, and distribution functions. Further, we have incurred and will continue to incur additional costs associated with operating as a public company. Accordingly, we will need additional financing to support our continuing operations. We will seek to fund our operations through public and/or private equity, debt financings or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenue to achieve profitability, and we may never do so.

Year to Date and Recent Developments

Auvelity

In February 2023, we received a Paragraph IV Certification Notice Letter from Teva Pharmaceuticals, Inc., or Teva, providing notification to us that Teva has submitted an Abbreviated New Drug Application to the FDA seeking approval to manufacture, use, or sell a generic version of Auvelity® (dextromethorphan HBr-bupropion HCl). On March 24, 2023, we commenced a patent infringement action against Teva in the United States District Court for the District of New Jersey relating to its Abbreviated New Drug Application.

Sunosi

In February 2023, we entered into a license agreement with Atnahs Pharma UK Limited, or the Pharmanovia License Agreement, to expand commercialization and further develop Sunosi® (solriamfetol) in Europe and certain countries in the Middle East and North Africa.

Corporate

In February 2023, we entered into a sublease with Advance Magazine Publishers d/b/a Conde Nast for the entirety of the twenty-second floor of One Word Trade Center in New York, NY. This space is utilized by the Company for its corporate and executive offices.

Financial

In January 2023, we entered into a Third Amendment to Loan and Security Agreement, or the Third Amendment, with Hercules Capital, Inc, or Hercules. The Third Amendment amends the terms of that certain Loan and Security Agreement, dated as of September 25, 2020 (as amended by that certain First Amendment to Loan and Security Agreement, dated as of October 14, 2021, and as further amended by the Second Amendment to Loan and Security Agreement, dated as of March 27, 2022), or the Loan Agreement, by and among the Company, Hercules and the lenders party thereto.

In March 2023, Silicon Valley Bank (SVB) and Signature Bank were closed and taken over by the Federal Deposit Insurance Corporation (FDIC), which created significant market disruption and uncertainty with respect to the financial condition of a number of banking institutions in the U.S., in particular those with exposure to certain types of depositors and large portfolios of investment securities. At the time of these closures, we had approximately $4.0 million in cash in deposit accounts at SVB. Other Company funds were held at Citibank and on the Company's behalf by a third-party financial institution and invested in U.S. government securities. On March 12, 2023, the U.S. Department of the Treasury announced that the FDIC will fully protect all SVB depositors. The Company has not suffered any losses in connection with the failure of SVB or any other financial institution.

Financial Overview

Revenue

We generated approximately $28.6 million in net revenue from product sales in the three months ended March 31, 2023.

We expect that Sunosi and Auvelity revenues are likely to fluctuate based on demand quarter to quarter. We will not generate revenue from other products unless and until we successfully develop, obtain regulatory approval of, and commercialize one of our current or future product candidates. We have incurred significant operating losses since inception. If we fail to complete the development of our product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenue from such product candidates, and our results of operations and financial position, would be materially and adversely affected. If we enter into licensing or collaboration arrangements, such agreements may generate revenue in the future.

Additionally, in the first quarter of 2023, we recorded license revenue of $65.7 million related to the Pharmanovia License Agreement. See below for more detail.

License Agreement with Pharmanovia

In February 2023, we entered into the Pharmanovia License Agreement, to commercialize and further develop Sunosi® in Europe and certain countries in the Middle East and North Africa, or the Territory. Pharmanovia is a UK-based global lifecycle management healthcare company that focuses on four core therapeutic areas – Oncology, Endocrinology, Neurology and Cardiovascular.

We received an upfront payment of €62.0 million ($65.7 million) during the three months ended March 31, 2023 and are eligible to receive sales-based and other milestones totaling up to €94.5 million. We will receive a royalty percentage in the mid-twenties on net sales of the Licensed Products (as defined in the Pharmanovia License Agreement) in the Territory. For the three months ended March 31, 2023, we recognized royalty revenue of $0.3 million related to Pharmanovia's sales of Sunosi.

A copy of the Pharmanovia License Agreement is included as Exhibit 10.1 to this filing.

Cost of revenue

Cost of revenue includes direct costs of formulating, manufacturing and packaging drug product, overhead costs consisting of labor, customs, stock-based compensation, shipping, outside inventory management, royalty expense, and other miscellaneous operating costs.

Research and Development Expenses

Research and development expenses primarily include preclinical studies, clinical trials, manufacturing costs, employee-related expenses including salaries, benefits, travel, and stock-based compensation expense, contract services, including external research and development expenses incurred under arrangements with third parties, such as contract research organizations, or CROs, facilities costs, overhead costs, depreciation, and other related costs.

Research and development activities are central to our business model. We have and will incur substantial costs beyond our present and planned clinical trials in order to file a new drug application, or NDA, for any of our product candidates. It is difficult to determine with certainty the costs and duration of our current or future clinical trials and preclinical studies, or to what extent we will generate revenue from the commercialization and sale of Sunosi and Auvelity or our product candidates if we obtain regulatory approval. The duration, costs, and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of future clinical trials and preclinical studies, uncertainties in clinical trial enrollment rate, and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability, and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate’s commercial potential.

Management considers many factors in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. This process may result in actual results differing materially from those estimated amounts used in the preparation of the financial statements if these results differ from historical experience, or other assumptions do not turn out to be substantially accurate, even if such assumptions are reasonable when made.

The following table summarizes our research and development expenses for our primary products for the three months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31,	
	2023	2022
Sunosi	$ 2,401	$ -
AXS-05	6,651	6,031
AXS-07	1,979	2,146
AXS-12	2,210	1,882
AXS-14	1,060	241
Other research and development	1,078	476
Stock-based compensation	2,414	1,809
Total research and development expenses	$ 17,793	$ 12,585

Other research and development expenses primarily consist of employee salaries and benefits, facilities and overhead costs.

Selling, general and administrative expenses

Selling, general and administrative expenses primarily consist of salaries and related costs for personnel in executive, commercial, finance, and operational functions, including stock-based compensation and travel expenses. Also included in selling, general and administrative expenses are commercial costs, pre-commercialization costs, facility-related costs, insurance expense, professional fees for legal and accounting services, and patent filing and prosecution costs. Selling, general and administrative expenses are expensed when incurred.

Interest expense, net

Interest expense, net, primarily consists of cash interest and non-cash costs related to our term loans (see “Liquidity and Capital Resources” below for a further discussion). We amortize these costs over the term of our debt agreements as interest expense in our consolidated statement of operations. Interest expense, net also includes interest income earned on cash.

Critical Accounting Policies and Significant Judgments and Estimates

This discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States of America, or U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reported period. In accordance with GAAP, we base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to the critical accounting policies disclosed in our 2022 Annual Report on Form 10-K except for revenue recognition related to license agreements. Our critical accounting policies are described in the notes to the consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Results of Operations

The following table summarizes our results of operations for the periods indicated (in thousands):

	Three Months Ended March 31,	
	2023	2022
Revenues:		
Product sales, net	$ 28,569	$ —
License revenue	65,735	—
Royalty revenue	272	—
Total Revenues	94,576	—
Operating expenses:		
Cost of revenue (excluding amortization and depreciation)	7,556	—
Research and development	17,793	12,585
Selling, general and administrative	74,191	25,704
Gain in fair value of contingent consideration	(162)	—
Intangible asset amortization	1,572	—
Total operating expenses	100,950	38,289
Loss from operations	(6,374)	(38,289)
Interest expense, net	(2,264)	(1,343)
Income before provision of income taxes	(8,638)	(39,632)
Provision for income taxes	(2,580)	—
Net loss	$ (11,218)	$ (39,632)

Comparison of the three months ended March 31, 2023 and 2022

Product sales, net. Auvelity was launched on October 19, 2022 and had U.S. net sales of $15.7 million for the three months ended March 31, 2023. No Auvelity sales were reported by Axsome for the 2022 comparable period reflecting the timing of the Auvelity approval and launch. Additionally, we began selling Sunosi in the U.S. in May 2022 and in certain international markets in November 2022, and recorded net sales of $12.9 million for the three months ended March 31, 2023, which included $1.7 million in ex-U.S. market net sales. No Sunosi sales were reported for the 2022 comparable periods, reflecting the timing of the Sunosi acquisition.

License revenue. We entered into a license agreement with Pharmanovia to commercialize Sunosi in certain ex-U.S. markets. We recognized the upfront payment of $65.7 million from Pharmanovia as license revenue.

Royalty revenue. In connection with the license agreement with Pharmanovia to commercialize Sunosi in certain ex-U.S. markets, we recognized royalty revenue of $0.3 million related to sales of Sunosi by Pharmanovia.

Cost of revenue. Cost of revenue was $7.6 million for the three months ended March 31, 2023 compared to none for the 2022 comparable periods. The cost of revenue consists of $2.6 million in material and production costs for Sunosi and Auvelity and $5.0 million license revenue sharing expense related to the Pharmanovia agreement.

Research and development. Research and development expenses for the three months ended March 31, 2023 were $17.8 million, compared to $12.6 million for the three months ended March 31, 2022, an increase of $5.2 million. The increase was primarily related to higher personnel costs associated with ongoing clinical trials, post-marketing commitments for Auvelity and Sunosi and non-cash stock-based compensation expense.

Selling, general and administrative. Selling, general and administrative expenses for the three months ended March 31, 2023 were $74.2 million, compared to $25.7 million for the three months ended March 31, 2022, an increase of $48.5 million. The increase was primarily related to commercial activities for Auvelity and Sunosi and higher non-cash stock-based compensation expense.

Gain in Fair Value of Contingent Consideration. The change in fair value of contingent consideration was primarily due to the change in significant unobservable inputs such as the discount rates.

Intangible asset amortization. As part of the preliminary purchase price allocation, we determined the identifiable intangible asset is developed technology. We amortize the intangible asset over its useful life of 10 years.

Interest expense, net. Interest expense, net, for the three months ended March 31, 2023 was $2.3 million, compared to $1.3 million for the three months ended March 31, 2022, an increase of $1.0 million. The increase is mainly due to a higher debt balance compared to the prior comparable period due to the execution of the Second Amendment in March 2022 and Third Amendment to the Loan and Security Agreement with Hercules in January 2023.

Provision for income taxes. We recorded tax expense of $2.6 million for the three months ended March 31, 2023 on income earned in foreign jurisdictions in relation to the license revenue recognized from the license agreement with Pharmanovia.

Net loss. Net loss for the three months ended March 31, 2023 was $11.2 million, compared to $39.6 million for the three months ended March 31, 2022, a decrease of $28.4 million. The decrease was primarily due to the upfront payment of $65.7 million from Pharmanovia as license revenue, offset by an increase in selling, general and administrative expenses related to commercial activities related to Sunosi and Auvelity, including sales force and marketing spend, and higher non-cash stock compensation expense.

Liquidity and Capital Resources

Since our inception through March 31, 2023, we have financed our operations primarily through proceeds from equity offerings, debt borrowings and proceeds from product sales. See discussion below.

On December 2, 2022, we filed an automatic shelf registration statement with the SEC for the issuance of common stock, preferred stock, warrants, rights, debt securities and units up to an unlimited amount, which we refer to as the 2022 Shelf Registration Statement. It was declared effective by the SEC upon filing. In the future, we may conduct additional offerings of one or more of these securities utilizing the 2022 Shelf Registration Statement in such amounts, prices and terms to be announced when and if the securities are offered. At the time any of our securities covered by the 2022 Shelf Registration Statement are offered for sale, a prospectus supplement will be prepared and filed with the SEC containing specific information about the terms of any such offering.

In December 2019, we entered into a sales agreement, or the December 2019 Sales Agreement, with SVB Securities LLC, or SVB Securities, pursuant to which we may sell up to $80 million in shares of our common stock from time to time through SVB Securities, acting as our sales agent, in one or more at-the-market offerings utilizing an automatic shelf registration statement we filed with the SEC on December 5, 2019 for the issuance of common stock, preferred stock, warrants, rights, debt securities and units up to an unlimited amount, which we refer to as the 2019 Shelf Registration Statement. SVB Securities is entitled to receive a commission of 3.0% of the gross proceeds for any shares sold under the December 2019 Sales Agreement.

In March 2022, we entered into a sales agreement, or the March 2022 Sales Agreement with SVB Securities, pursuant to which we may sell up to $200 million in shares of our common stock from time to time through SVB Securities, acting as our sales agent, in one or more at-the-market offerings utilizing the 2019 Shelf Registration Statement. SVB Securities is entitled to receive a commission of up to 3.0% of the gross proceeds for any shares sold under the March 2022 Sales Agreement. The March 2022 Sales Agreement supersedes the December 2019 Sales Agreement, by and between the Company and SVB Securities. The Company exhausted sales of its shares of the Company's common stock under its prior at-the-market offering program.

In August 2022, we filed a prospectus supplement to the 2019 Shelf Registration Statement for the issuance and sale, if any, of up to an additional $250 million in shares of our common stock. SVB Securities is entitled to receive a commission of up to 3.0% of the gross proceeds for any shares sold under the March 2022 Sales Agreement.

In December 2022, in connection with the 2022 Shelf Registration Statement, we filed a new sales agreement prospectus to replace the prior prospectus supplement filed in August 2022 associated with the expired 2019 Shelf Registration Statement. The new sales agreement prospectus covered the issuance and sale by us of up to the same $250 million of our common stock that may be issued and sold from time to time through SVB Securities, as the Company's sales agent, under the March 2022 Sales Agreement.

We did not utilize the March 2022 Sales Agreement with SVB Securities during the three months ended March 31, 2023.

In January 2023, we entered into the Third Amendment to the Loan Agreement with Hercules. The Third Amendment increases the size of the Term Loan Advance (as defined in the Loan Agreement) to $350.0 million, reduces the interest rate, and extends the maturity and interest-only period of the Loan Agreement. See the "Contractual Obligations and Commitments - January 2023 Third Amendment to the Loan and Security Agreement – Hercules" section below for more information.

In the future, we may conduct additional offerings of one or more of the securities covered by the 2022 Shelf Registration Statement in such amounts, prices and terms to be announced when and if the securities are offered. At the time any of our securities covered by the 2022 Shelf Registration Statement are offered for sale, a prospectus supplement will be prepared and filed with the SEC containing specific information about the terms of any such offering.

We believe that our current available cash, along with the remaining committed capital from the $350 million term loan facility, is sufficient to fund anticipated operations into cash flow positivity, based on the current operating plan. Because the process of commercializing products and evaluating product candidates in clinical trials is costly and the timing of progress in these trials is uncertain, it is possible that the assumptions upon which we have based this estimate may prove to be wrong, and we could use our capital resources sooner than we currently expect.

Cash Flows

The following table summarizes our primary sources and uses of cash for the periods indicated (in thousands):

	Three Months Ended March 31,	
	2023	2022
Net cash (used in) provided by:		
Operating activities	$ (5,821)	$ (32,653)
Investing activities	(71)	(214)
Financing activities	51,565	31,102
Net increase (decrease) in cash	$ 45,673	$ (1,765)

Operating Activities. Cash used in operating activities for the three months ended March 31, 2023 was $5.8 million as compared to $32.7 million for the three months ended March 31, 2022. The overall cash used in operating activities for the first quarter of 2023 was impacted by the upfront payment of $65.7 million received from Pharmanovia and product sales, net, from Auvelity and Sunosi, offset by cash used in commercial and clinical activities.

Investing Activities. Cash used in investing activities for the three months ended March 31, 2023 was $0.1 million, as compared to $0.2 million for the three months ended March 31, 2022. In first quarter of 2022, we increased our spending on purchase of equipment due to ramp up of commercial activities.

Financing Activities. Cash provided by financing activities was $51.6 million for the three months ended March 31, 2023, which included net proceeds related to the Third Amendment of the Loan and Security Agreement with Hercules of $53.8 million, and proceeds from the issuance of common stock upon exercise of employee stock options of $0.4 million, offset by payment of contingent consideration and tax withholdings on stock award for a total of $2.6 million. Cash provided by financing activities was $31.1 million for the three months ended March 31, 2022, which included net proceeds from the sale of common stock through our Sales Agreement with SVB Securities of $31.0 million and proceeds from the issuance of common stock upon exercise of employee stock options of $0.2 million.

Funding requirements

We have not achieved profitability since our inception and we expect to continue to incur significant losses for the foreseeable future. We expect our losses to increase as we continue the development of and seek regulatory approvals for our product candidates and begin to commercialize any approved products, including Sunosi and Auvelity. We are subject to all of the risks pertinent to the development of new product candidates, and we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may harm our business.

We may need to raise additional financing in the future to fund our operations. In the event that we need additional financing, we may incur additional debt, license certain intellectual property, and seek to sell additional equity or convertible securities that may result in dilution to our stockholders. If we raise additional funds through the issuance of equity or convertible securities, these securities could have rights or preferences senior to those of our common stock and could contain covenants that restrict our operations. There can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. Our future capital requirements will depend on many factors, including:

- the scope, rate of progress, results, and cost of our clinical studies and other related activities;
- our ability to enter into collaborative agreements for the development and commercialization of our product candidates;

- the number and development requirements of any other product candidates that we pursue;
- the costs, timing, and outcome of regulatory reviews of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive marketing approval;
- any product liability or other lawsuits related to our product candidates;
- the expenses needed to attract and retain skilled personnel;
- the general and administrative expenses related to being a public company;
- the revenue, if any, received from commercial sales of our products and product candidates for which we receive marketing approval; and
- the costs involved in preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending our intellectual property-related claims.

Please see “Risk Factors” for additional risks associated with our substantial capital requirements.

Contractual Obligations and Commitments

License agreement with Pfizer

In January 2020, we entered into a license agreement with Pfizer. Under the terms of our exclusive license agreement with Pfizer, Pfizer received 82,019 shares of our common stock having a stated value of $8.0 million, based on the average closing price of our common stock for the ten prior trading days of $97.54, in consideration for the license and rights. Pfizer also received an upfront cash payment of $3.0 million. We determined that the fair value of each share of common stock granted to Pfizer on the closing date of January 9, 2020 was $87.24, based on the closing price of our common stock on that date. As a result, the fair value of the stock issued was $7.2 million.

Pfizer can also receive up to $323 million upon the achievement of certain regulatory and sales milestones, and tiered mid-single to low double-digit royalties on future sales of any such approved clinical products containing compounds reboxetine esreboxetine. Pfizer will also have a right of first negotiation on any potential future strategic transactions involving AXS-12 and AXS-14.

License agreements with Antecip Bioventures

Under three exclusive license agreements with Antecip Bioventures II LLC, or Antecip, an entity owned by our Chief Executive Officer and Chairman of the Board, Herriot Tabuteau, M.D., we are obligated to make specified royalty payments ranging from 1.5% to 4.5%, subject to up to a 50% reduction depending on required payments to third parties, on net sales of our products containing the licensed technology of AXS-02, AXS-05, and AXS-04. The amount, timing, and likelihood of such payments are not known.

In connection with the Loan Agreement (see below), Antecip consented to the collateral assignment of one of the license agreements, among other things, under a direct agreement with us and Hercules.

January 2023 Third Amendment to the Loan and Security Agreement – Hercules

On January 9, 2023, we entered into the Third Amendment to the Loan Agreement, with Hercules, in its capacity as administrative agent and collateral agent, and the other financial institutions or entities party thereto as lenders.

The Third Amendment amended the terms of the Loan Agreement to, among other things:

- Extend the maturity date to January 1, 2028, unless the Company meets certain revenue targets as described in the Loan Agreement, in which case the Company can extend the maturity date to January 1, 2029;
- Increase the aggregate principal amount under the Loan Agreement from $300.0 million to $350.0 million;

- Subject to the terms and conditions in the Loan Agreement, change the Term Loan Advance amounts and dates available under the Tranche 1 Advance (as defined in the Loan Agreement) through Tranche 5 Advance (as defined in the Loan Agreement), including increasing the Tranche 1 Advance from one tranche of $95.0 million to five sub-tranches of $95.0 million, $55.0 million, $30.0 million, $35.0 million and $35.0 million, respectively, changing the Tranche 2 Advance (as defined in the Loan Agreement) from three sub-tranches of $35.0 million, $35.0 million and $30.0 million to one tranche of $25.0 million, changing the Tranche 3 Advance (as defined in the Loan Agreement) from two sub-tranches of $15.0 million and $5.0 million to one tranche of $75.0 million, and removing the Tranche 4 Advance (as defined in the Loan Agreement) and Tranche 5 Advance entirely;
- Revise the interest rate applicable to extensions of credit under the Loan Agreement to equal (a) if the prime rate is greater than or equal to 7.00%, the greater of either (i) the prime rate plus 2.20%, and (ii) 9.95%, but in no event greater than 10.70%, and (b) if the prime rate is less than 7.00%, 9.70%;
- Increase the minimum cash requirement of the Company to $30.0 million; and
- Require the Company to pay a facility fee equal to 0.75% of the amount of principal actually funded pursuant to the Tranche 1B Advance (as defined in the Loan Agreement), Tranche 1C Advance (as defined in the Loan Agreement), Tranche 1D Advance (as defined in the Loan Agreement), Tranche 1E Advance (as defined in the Loan Agreement), Tranche 2 Advance and Tranche 3 Advance.

A copy of the Third Amendment is included as Exhibit 10.2 to this filing.

Royalty Agreements

Pursuant to the Asset Purchase Agreement, dated as of March 25, 2022, or the Purchase Agreement, we agreed to make non-refundable, non-creditable royalty payments to Jazz equal to a (A) high-single digit royalty for any Current Indication or (B) mid-single digit royalty for any Future Indication, of Net Sales in the U.S. Territory made during the applicable Royalty Term (in each case, as those terms are defined in the Purchase Agreement). There are no royalty payments due to Jazz for Net Sales outside of the U.S. Territory.

At the initial closing, we assumed all of the commitments of Jazz to SK Biopharmaceuticals Co. Ltd., or SK and Aerial Biopharma, LLC, or Aerial. SK is the originator of Sunosi and retains rights in 12 Asian markets, including China, Korea, and Japan. In 2014, Jazz acquired from Aerial worldwide rights to Sunosi excluding those Asian markets stated previously. The assumed commitments to SK and Aerial include single-digit tiered royalties based on our sales of Sunosi, and we are committed to pay up to $165.0 million based on revenue milestones and $1.0 million based on development milestones.

World Trade Center Lease

On February 21, 2023, we entered into a Sublease with Advance Magazine Publishers d/b/a Conde Nast for the entirety of the twenty-second floor of One Word Trade Center in New York, NY, or the Sublease. This space is utilized by the Company for its corporate and executive offices. The Sublease commenced on April 7, 2023 and will run for ten (10) years. The Company has a one-time option to terminate the Sublease on its fifth anniversary upon the payment of a fee to the sublandlord. The Company is responsible for base rent under the Sublease and certain additional customary variable costs such as an allocable portion of building taxes and operating expenses. In connection with the Sublease, the Company received certain rent and work concessions from the sublandlord.

A copy of the Sublease is included as Exhibit 10.3 to this filing.

Employees and Human Capital Management

As of May 1, 2023, we had 393 full-time employees. None of our employees are represented by a collective bargaining agreement and we have never experienced any work stoppage. We believe that we maintain good relations with our employees. Our employees are highly skilled, and many hold advanced degrees. Many of our employees have experience with drug development. Our future performance depends significantly upon the continued service of our key scientific, technical and senior management personnel and our continued ability to attract and retain highly skilled employees. We provide our employees with competitive salaries and bonuses, opportunities for equity ownership, development programs that enable continued learning and growth and a robust employment package that promotes well-being across all aspects of their lives. In addition to salaries, these programs include potential annual discretionary bonuses, stock awards, healthcare and insurance benefits, health savings and flexible spending accounts, paid time off, family leave, and flexible work schedules, among other benefits. We took proactive steps throughout the COVID-19 pandemic to protect the health and safety of our employees. We expect to continue to implement these measures until we determine that the COVID-19 pandemic is adequately contained for purposes of our business. We may take further actions, in compliance with all appropriate government regulations, that we determine to be in the best interest of our employees.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined by applicable SEC regulations.

Recent Accounting Pronouncements

Refer to Note 2 – Summary of Significant Accounting Policies to our consolidated financial statements included in Part I, Financial Information, Item 1, Financial Statements, of this Quarterly Report on Form 10-Q for a discussion of recently issued accounting pronouncements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business and from changes in the interest rate on our debt borrowings. These market risks are principally limited to interest rate fluctuations. We had cash of $246.5 million and $200.8 million as of March 31, 2023 and December 31, 2022, respectively. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes. Due to the short-term nature of our investment portfolio and debt agreement, we do not believe an immediate 100 basis point increase in interest rates would have a material effect on the fair market value of our portfolio, and, accordingly, we do not expect our operating results or cash flows to be materially affected by a sudden change in market interest rates.

Foreign Currency Exchange Risk

We contract with vendors and third-party manufactures located in Europe and certain invoices are denominated in foreign currencies. We are therefore subject to fluctuations in foreign currency rates in connection with these agreements, and recognize foreign exchange gains or losses in our statement of operations. We have not historically hedged our foreign currency exchange rate risk. To date, we have not incurred any material effects from foreign currency changes on these contracts.

We do not believe a 10% change in these currencies on March 31, 2023 would have had a material effect on our results of operations or financial condition.

Inflation Risk

Inflation generally affects us by increasing our cost of labor and pricing of contracts. We do not believe that inflation has had a material effect on our business, financial condition, or results of operations during the three months ended March 31, 2023.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures. Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures, as of such date, were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting. During the quarter ended March 31, 2023, there have been no changes in internal controls over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

Except as described herein, we, and our subsidiaries, are currently not a party to, and our property is not currently the subject of, any material pending legal proceedings; however, we may also become involved in various claims and legal actions arising in the ordinary course of business.

Securities Class Action

On May 13, 2022, Evy Gru filed a putative class action complaint captioned Gru v. Axsome Therapeutics, Inc., et. al. in the U.S. District Court for the Southern District of New York against the Company and certain of its current and former officers and one director, or the Securities Class Action. The complaint asserts claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder, and alleges, among other things, that the defendants made false statements and omissions concerning the Company's Chemistry Manufacturing and Controls practices, and its New Drug Application with the FDA, with respect to one of its product candidates, AXS-07. The named plaintiff seeks unspecified damages, fees, interest, and costs. On August 11, 2022, the District Court appointed co-lead plaintiffs in the Gru action. On October 7, 2022, the Gru plaintiffs filed an amended complaint, which contains substantially similar allegations as in the initial complaint. Defendants filed their motion to dismiss the amended complaint on December 16, 2022, which motion remains pending before the court. One of the co-lead plaintiffs, Santoshanand Thakkar, withdrew from the case on January 18, 2023.

Shareholder Derivative Action

On July 21, 2022, Daniel Engel filed a stockholder derivative complaint captioned Engel v. Herriot Tabuteau, et. al. in the U.S. District Court for the Southern District of New York against the Company's current directors, certain of the Company's current and former officers, and the Company (as nominal defendant). On January 27, 2023, Kyle Guterba filed a stockholder derivative complaint captioned Guterba v. Tabuteau, et al. in the U.S. District Court for the Southern District of New York against the Company's current directors, certain of the Company's current and former officers, and the Company (as nominal defendant). The derivative complaints arise out of similar allegations as those made in the Securities Class Action. The plaintiffs assert claims for breach of fiduciary duties against all of the defendants and for contribution for violations of Section 10(b) and 21D of the Exchange Act. The plaintiffs seek unspecified damages, fees, interest, and costs, as well as corporate governance changes. The Engel and Guterba matters were consolidated on February 28, 2023 and are currently stayed pending further proceedings in the Gru matter.

Auvelity Paragraph IV Litigation

On March 24, 2023, we commenced a patent infringement action against Teva relating to Teva's Abbreviated New Drug Application for Auvelity. This action is captioned Axsome Therapeutics, Inc. and Antecip Bioventures II LLC v. Teva Pharmaceuticals, Inc. No. 2:23-CV-01695 in the United States District Court for the District of New Jersey. No substantive proceedings have occurred in this action to date.

ITEM 1A. RISK FACTORS.

The Company is subject to a number of risks that if realized could materially adversely affect its business, results of operations, cash flow, financial condition or prospects. The following is a summary of the principal risk factors facing the Company. The list below is not exhaustive, and the Company faces additional challenges and risks. Investors should carefully consider all of the information set forth in this Quarterly Report on Form 10-Q, including the following risk factors, before deciding to invest in any of the Company's securities.

Risk Factors Summary

Our business is subject to a number of risks and uncertainties, including those risks discussed at length below. These risks include, among others, the following:

- ***We have incurred significant losses since our inception, anticipate that we will incur substantial losses for the foreseeable future, and may never achieve or maintain profitability.***

- ***We may need additional funding to conduct our future clinical trials and to complete development and commercialization of our product candidates. If we are unable to raise capital when needed, we would be forced to delay, reduce, or eliminate our product development programs or commercialization efforts.***

- ***Our operating activities may be restricted as a result of covenants related to the outstanding indebtedness under our loan and security agreement with Hercules and we may be required to repay the outstanding indebtedness in an event of default, which could have a materially adverse effect on our business.***

- ***We have a limited operating history and history of commercializing products, which may make it difficult to evaluate our business and prospects.***

- ***We are substantially dependent on the success of our products and cannot guarantee that any of our product candidates will successfully complete any planned or ongoing clinical trials, receive regulatory approval, or be successfully commercialized.***

- ***If safety and efficacy data for our product candidates, a reference drug, or published literature does not satisfactorily demonstrate safety and efficacy to the FDA, or if the FDA and other regulators do not permit us to rely on the data of a reference drug or published literature, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.***

- ***Although Breakthrough Therapy, Fast Track and other designations are designed to expedite the development and review of drugs, they may not ultimately lead to a faster approval process or faster development of regulatory review and they will not increase the likelihood that our product candidates will receive marketing approval, for example, Breakthrough Therapy designation by the FDA for AXS-05 for the treatment of AD agitation.***

- ***We face significant competition from other pharmaceutical and biotechnology companies, academic institutions, government agencies, and other research organizations. Our operating results will suffer if we fail to compete effectively.***

- ***If we are unable to establish effective marketing, sales and distribution capabilities or enter into agreements with third parties to market, sell and distribute our products, we may be unable to generate substantial product revenues.***

- ***If any of our products do not achieve broad market acceptance, the revenues that we generate from their sales will be limited.***

- ***We rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials, and those third parties may not perform satisfactorily, including by failing to meet deadlines for the completion of such trials or failing to comply with regulatory requirements.***

- ***If the manufacturers upon whom we rely fail to produce our products in the volumes that we require on a timely basis, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the development and commercialization of, or be unable to meet demand for, our products and may lose potential revenues.***

- ***As an NDA applicant and a potential commercial "virtual manufacturer," we may rely in many cases on third parties to perform many essential services for any products that we commercialize, including services related to warehousing and inventory control, distribution, government price reporting, customer service, and adverse event reporting. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to commercialize any of our current or future product candidates will be significantly impacted and we may be subject to regulatory sanctions.***

- ***Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.***

- ***We have licensed and may need to license certain intellectual property from third parties in the future. Such licenses may not be available or may not be available on commercially reasonable terms. Our business may be materially harmed if the licenses are not available or terminated for any reason.***

- ***If we fail to comply with federal, state, and foreign healthcare laws, including fraud and abuse and transparency and health and other data protection, information privacy and security laws, we could face substantial penalties and our business, financial condition, results of operations, and prospects could be adversely affected.***

- ***If the government or third-party payors fail to provide adequate coverage and payment rates for any of our current or future product candidates, or if health maintenance organization (HMOs) or long-term care facilities choose to use therapies that are less expensive, our revenue and prospects for profitability will be limited.***

- ***We have and may continue to significantly increase the size of our organization, and we may experience difficulties in managing growth. If we are unable to implement appropriate controls and procedures to manage our growth, we will not be able to implement our business plan successfully.***

- ***If we fail to maintain an effective system of internal controls 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.***

- ***Our principal stockholders and management own a significant percentage of our stock and may be able to exert significant control over matters subject to stockholder approval.***

- ***The use of our net operating loss carryforwards and research tax credits may be limited.***

RISKS RELATED TO OUR FINANCIAL CONDITION AND CAPITAL REQUIREMENTS

We have incurred significant losses since our inception, anticipate that we will incur substantial losses for the foreseeable future, and may never achieve or maintain profitability.

We are a biopharmaceutical company with a limited operating history. For the last several years, we have focused our efforts primarily on developing CNS product candidates, AXS-05, AXS-07, AXS-12, and AXS-14, with the goal of achieving regulatory approval and commercialization. Since inception, we have incurred significant operating losses. Our net loss was $11.2 million for the three months ended March 31, 2023. As of March 31, 2023, we had an accumulated deficit of $607.6 million. In 2022, we commenced the commercial sale of Auvelity in the United States and Sunosi in the United States and select global markets. Apart from Sunosi and Auvelity, we have no other products which have received regulatory approval.

We expect to continue to incur substantial expenses and operating losses over the next several years, as we continue to develop our current and future product candidates. In addition, we expect to incur significant sales, marketing, and manufacturing expenses related to the commercialization of Sunosi, Auvelity, and any other product candidate which may be approved or which we may in-license. We anticipate that our expenses will increase substantially as we:

- seek regulatory approval for any additional product candidate;

- hire additional commercial, clinical, medical, quality, regulatory, and scientific personnel;

- add operational, financial, and management information systems and personnel;

- expand our sales, marketing, and distribution infrastructure;

- expand external manufacturing capabilities and production to commercialize any additional products for which we may obtain regulatory approval and that we choose not to license to a third-party;

- undertake additional manufacturing activities of our product candidates to satisfy FDA requirements for marketing application submissions;

- conduct our clinical trials with AXS-05 AD agitation;

- conduct our clinical trials with AXS-12 in narcolepsy;

- continue to evaluate, plan for, and conduct, clinical trials for AXS-05 as an aid to smoking cessation treatment and other CNS disorders;

- continue to evaluate, plan for, and conduct, clinical trials for solriamfetol in attention-deficit/hyperactivity disorder (“ADHD”);

- continue to evaluate, plan for, and potentially submit an NDA for AXS-14 in fibromyalgia;
- continue to expand commercial sales of Sunosi and Auvelity;
- develop, in-license, or acquire additional product candidates;
- conduct late-stage clinical trials for any product candidates that successfully complete early-stage clinical trials;
- conduct additional non-clinical studies with any product candidates; and
- maintain, expand, and protect our intellectual property portfolio.

To become and remain profitable, we must succeed in developing (or in-licensing) and commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, which may include completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, potentially entering into collaboration and license agreements, obtaining regulatory approval for product candidates and manufacturing, marketing, and selling any products for which we may obtain regulatory approval, achieving market acceptance of our products, satisfying any post-marketing requirements, maintaining appropriate distribution, setting prices, and obtaining reimbursement for our products from private insurance or government payors. We are only in the preliminary stages of some of these activities with respect to certain products and product candidates. We may never succeed in some of these activities and, even if we do, may never achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we may incur or when, or if, we will be able to achieve profitability. If we are required by the FDA or comparable foreign regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings, continue the commercialization of our products or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We may need additional funding to conduct our future clinical trials and to complete development and commercialization of our product candidates. If we are unable to raise capital when needed, we would be forced to delay, reduce, or eliminate our product development programs or commercialization efforts.

Conducting clinical trials, pursuing regulatory approvals, establishing outsourced manufacturing relationships, and successfully manufacturing and commercializing our product candidates is a time-consuming, expensive, and uncertain process that takes years to complete. We may need to raise additional capital to:

- fund our future clinical trials for our current product candidates, especially if we encounter any unforeseen delays or difficulties in our planned development activities;
- fund our operations and continue to commercialize our products;
- qualify and outsource the commercial-scale manufacturing of our products under current good manufacturing practices, or cGMP;
- develop additional product candidates; and
- in-license other product candidates.

We believe that our current cash, along with the remaining committed capital from the $350.0 million term loan facility, is sufficient to fund anticipated operations into cash flow positivity, based on the current operating plan. Our assumptions may prove to be wrong, and we could spend our available financial resources faster than we currently expect. Further, we may not have sufficient financial resources to meet all of our objectives. Our future funding requirements will depend on many factors, including, but not limited to:

- the rate of progress and costs related to the development of our product candidates, including the costs of preparing filings for regulatory approval;
- the costs associated with conducting additional clinical and non-clinical studies with any of our product candidates;
- the potential for delays in our efforts to seek regulatory approval for our product candidates, and any costs associated with such delays;
- the costs associated with selling, marketing, and distributing our approved products;
- the costs of filing, prosecuting, defending, and enforcing any patent claims and other intellectual property rights associated with our product candidates;
- the cost and timing of manufacturing, or having third parties manufacture, sufficient supplies of our product candidates in preparation for commercialization;
- the effect of competing technological and market developments;
- revenues from commercial sales of our approved products;
- the terms and timing of any collaborative, licensing, co-promotion, or other arrangements that we may establish; and
- the success of the commercialization of any of our current products and, if approved, any of our product candidates.

Future capital requirements will also depend on the extent to which we acquire or invest in additional businesses, products, and technologies. Until we can generate a sufficient amount of product revenue, if ever, we may finance future cash needs through public or private equity offerings, debt financings, royalties, and corporate collaboration and licensing arrangements, as well as through interest income earned on cash and investment balances. We cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our development programs or our commercialization efforts.

Our operating activities may be restricted as a result of covenants related to the outstanding indebtedness under our loan and security agreement with Hercules and we may be required to repay the outstanding indebtedness in an event of default, which could have a materially adverse effect on our business.

In September 2020, we entered into a Loan and Security Agreement, or the Loan Agreement, for a term loan, which we refer to as the 2020 Term Loan, with Hercules Capital, Inc., or Hercules, in its capacity as administrative agent and collateral agent and as a lender, and the other financial institutions that from time to time become parties to the Loan Agreement, collectively referred to as the Lenders, secured by a lien on substantially all of our assets, including intellectual property. In October 2021, we entered into a First Amendment to the Loan Agreement to, among other things, increase the size of the 2020 Term Loan. In March 2022, we entered into a Second Amendment to the Loan Agreement that, among other things, changed the terms of the Term Loan Advances (as defined in the Loan Agreement) upon the consummation of the Acquisition (as defined in the Loan Agreement). In January 2023, we entered into a Third Amendment to the Loan Agreement that amended the terms of the Loan Agreement to, among other things, increase the size of the aggregate principal amount under the 2020 Term Loan from $300.0 million to $350.0 million, reduce the interest rate, and extend the maturity and interest-only period of the Loan Agreement.

The Loan Agreement contains various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things, sell, transfer, lease or dispose of certain assets; incur indebtedness; encumber or permit liens on certain assets; make certain investments; make certain restricted payments, including paying dividends on, or repurchasing or making distributions with respect to, our common stock; and enter into certain transactions with affiliates. Our business may be adversely affected by these restrictions on our ability to operate our business.

The covenants under the Loan Agreement also require maintaining a minimum amount of cash in an account or accounts in which the Lenders have a first priority security interest.

A breach of any of the covenants under the Loan Agreement could result in a default under the 2020 Term Loan. Upon the occurrence of an event of default under the 2020 Term Loan, the Lenders could elect to declare all amounts outstanding, if any, to be immediately due and payable and terminate all commitments to extend further credit. If there are any amounts outstanding that we are unable to repay, the Lenders could proceed against the collateral granted to it to secure such indebtedness.

We have a limited operating history of commercializing products, which may make it difficult to evaluate our business and prospects.

We are an early-stage commercial company. Prior to our commercialization of Auvelity and Sunosi in 2022, we had not obtained marketing approvals for any product candidates, manufactured products on a commercial scale or arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful commercialization. Consequently, predictions about our future success or viability may not be as accurate as they would be if we had a longer history of successfully developing and commercializing products.

We expect our financial condition and operating results to continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. We have transitioned from a company with solely a research and development focus to a company also capable of undertaking commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays, and may not be successful in such a transition.

We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability. Our business, financial condition and results of operations could be materially adversely affected by any negative impact on the global economy and capital markets resulting from geopolitical tensions.

U.S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and the start of the military conflict between Russia and Ukraine. On February 24, 2022, a full-scale military invasion of Ukraine by Russian troops was reported. Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine could lead to market disruptions, including significant volatility in commodity prices, credit and capital markets, as well as supply chain interruptions. We are continuing to monitor the situation in Ukraine and globally and assessing its potential impact on our business.

Additionally, the military conflict in Ukraine has led to sanctions and other penalties being levied by the United States, European Union and other countries against Russia. Additional potential sanctions and penalties have also been proposed and/or threatened. Russian military actions and the resulting sanctions could adversely affect the global economy and financial markets and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds.

Furthermore, because of current geopolitical tensions, the Biden administration has recently signed multiple executive orders regarding China. One particular executive order titled Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy, signed on September 12, 2022, will likely impact the pharmaceutical industry to encourage U.S. domestic manufacturing of pharmaceutical products. Any additional executive orders regarding or potential sanctions on China could materially impact our current manufacturing partners.

Although our business has not been materially impacted by these geopolitical issues to date, it is impossible to predict the extent to which our operations, or those of our suppliers and manufacturers, will be impacted in the short and long term, or the ways in which the conflict may impact our business. The extent and duration of the military action, sanctions and resulting market disruptions are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described herein.

Climate change or legal, regulatory or market measures to address climate change may negatively affect our business, results of operations, cash flows and prospects.

We believe that climate change has the potential to negatively affect our business and results of operations, cash flows and prospects. We are exposed to physical risks (such as extreme weather conditions or rising sea levels), risks in transitioning to a low-carbon economy (such as additional legal or regulatory requirements, changes in technology, market risk and reputational risk) and social and human effects (such as population dislocations and harm to health and well-being) associated with climate change. These risks can be either acute (short-term) or chronic (long-term).

The adverse impacts of climate change include increased frequency and severity of natural disasters and extreme weather events such as hurricanes, tornados, wildfires (exacerbated by drought), flooding, and extreme heat. Extreme weather and sea-level rise pose physical risks to our facilities as well as those of our suppliers. Such risks include losses incurred as a result of physical damage to facilities, loss or spoilage of inventory, and business interruption caused by such natural disasters and extreme weather events. Other potential physical impacts due to climate change include reduced access to high-quality water in certain regions and the loss of biodiversity, which could impact future product development. These risks could disrupt our operations and its supply chain, which may result in increased costs.

New legal or regulatory requirements may be enacted to prevent, mitigate, or adapt to the implications of a changing climate and its effects on the environment. These regulations, which may differ across jurisdictions, could result in us being subject to new or expanded carbon pricing or taxes, increased compliance costs, restrictions on greenhouse gas emissions, investment in new technologies, increased carbon disclosure and transparency, upgrade of facilities to meet new building codes, and the redesign of utility systems, which could increase our operating costs, including the cost of electricity and energy used by us. Our supply chain would likely be subject to these same transitional risks and would likely pass along any increased costs to us.

RISKS RELATED TO OUR BUSINESS AND THE DEVELOPMENT OF OUR PRODUCT CANDIDATES

We are substantially dependent on the success of our products and cannot guarantee that any of our product candidates will successfully complete any planned or ongoing clinical trials, receive regulatory approval, or be successfully commercialized.

We currently have two products approved for commercial distribution. We have invested a significant portion of our efforts and financial resources in the development of our product candidates. Our business, including our ability to generate revenue, depends entirely on the successful commercialization of Sunosi and Auvelity and the successful development and commercialization of our product candidates and/or future in-licensing activities, which may never occur. Furthermore, given the nature of our business, the biopharmaceutical industry in general and the uncertainty and costs associated with developing and commercializing our products within a complicated and costly regulatory regime, our goals, plans and assumptions with respect to our products may evolve or change. For example, we may not continue to emphasize, focus our research and development efforts on or direct resources to certain of our product candidates, and we may shift our focus and resources to our other current or future products. Any such change in our business strategy could harm our business, cause uncertainty or confusion in the marketplace or harm the clinical prospects of our products.

Our product candidates will require additional clinical and non-clinical development, regulatory approval, commercial manufacturing arrangements, significant marketing efforts, and further investment before we generate any revenues from the sale of such product candidates. A Phase 3 trial with AXS-05 in AD agitation and a Phase 3 trial with AXS-12 in narcolepsy are ongoing. As a result of one or more risks discussed in this section, we cannot assure you that we will meet projected timelines related to these trials.

We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Even if our product candidates are approved, they may be subject to limitations on the indicated uses for which they may be marketed, distribution restrictions, or to other conditions of approval, may contain significant safety warnings, including boxed warnings, contraindications, and precautions, may not be approved with label statements necessary or desirable for successful commercialization, or may contain requirements for costly post-market testing and surveillance, or other requirements, including the submission of a risk evaluation and mitigation strategy, or REMS, to monitor the safety or efficacy of the products. If we do not receive regulatory approval for, and successfully commercialize, our product candidates, we will not be able to generate revenue from these product candidates in the foreseeable future, or at all. Any significant delays in obtaining approval for and commercializing our product candidates will have a material adverse impact on our business and financial condition.

Although we submitted NDAs to the FDA for Auvelity (which was approved) and for AXS-07 for the acute treatment of migraines (which received a CRL), we have not otherwise submitted an NDA to the FDA, or similar drug approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that our current or future product candidates will be successful in clinical trials or receive regulatory approval.

Our product candidates are susceptible to the risks of failure inherent at any stage of product development, including the appearance of unexpected adverse events or failure to achieve its primary endpoints in subsequent clinical trials, including our initiated and planned Phase 3 clinical trials. We conducted one interim analysis for the Phase 2/3 trial of AXS-05 in TRD and one interim analysis for the Phase 2/3 trial of AXS-05 for the treatment of AD agitation. We may elect to conduct interim analyses for our other clinical trials. Interim results of a clinical trial do not necessarily predict final results, and interim results may result in early stoppage of our clinical trials for futility or modifications to our clinical trials, including the addition of additional subjects. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials.

If approved for marketing by applicable regulatory authorities, our ability to generate revenues from our product candidates depend on our ability to:

- create market demand for our product candidates through our own marketing and sales activities, and any other arrangements to promote these product candidates that we may otherwise establish;
- receive regulatory approval for claims that are necessary or desirable for successful marketing;
- hire, train, and deploy a sales force to commercialize our product candidates;
- manufacture (or have manufactured by third parties) our product candidates in sufficient quantities and at acceptable quality and manufacturing cost to meet commercial demand at launch and thereafter;
- establish and maintain agreements with wholesalers, distributors, and group purchasing organizations on commercially reasonable terms;
- create partnerships with, or offer licenses to, third parties to promote and sell our product candidates in foreign markets where we receive marketing approval;
- maintain patent and trade secret protection and regulatory exclusivity for our product candidates;
- launch commercial sales of our product candidates, whether alone or in collaboration with others;
- achieve market acceptance of our product candidates by patients, the medical community, and government and private third-party payors;
- achieve appropriate reimbursement for our product candidates;
- effectively compete with other therapies; and
- maintain a continued acceptable safety profile of our product candidates following launch.

Potential conflicts of interest exist with respect to the intellectual property rights that we license from an entity owned by our Chief Executive Officer and Chairman of the Board, and it is possible that our interests and their interests may diverge.

In 2012, we entered into three exclusive license agreements with Antecip Bioventures II LLC, or Antecip, an entity owned by our Chief Executive Officer and Chairman of the Board, Herriot Tabuteau, M.D., in which we were granted exclusive licenses to develop, manufacture, and commercialize Antecip's patents and applications related to the development of certain of the Company's then current product candidates. The patents licensed from Antecip include certain intellectual property pertaining to the Company's Auvelity product / AXS-05 portfolio product. Although Dr. Tabuteau dedicates all of his working time to us, because Antecip is an inactive intellectual property holding company, he may face potential conflicts of interest regarding these licensing transactions as a result of his ownership of Antecip. The license agreements provide that, subject to the reasonable consent of Antecip, we have the right to control the prosecution or defense, as the case may require, of a patent infringement claim involving the licensed intellectual property. Our interests with respect to pleadings and settlements in such cases may be at odds with those of Antecip. If there is a dispute between us and Antecip, Dr. Tabuteau will have a conflict of interest because he may, at the time of a prospective dispute, simultaneously have a financial interest in and owe a fiduciary duty to Antecip and simultaneously have a financial interest in and owe a fiduciary duty to us. For example, if a contractual dispute arises between us and Antecip under any of the license agreements we have with Antecip, Dr. Tabuteau may be in a position where he would benefit if Antecip prevails, to the detriment of our business or our investors, even though he is an officer and director of our company, because he is the sole owner of Antecip. Similarly, if we have a claim of any kind against Antecip, Dr. Tabuteau may be, even as our Chief Executive Officer and Chairman of the Board, reluctant to assert a claim by us against Antecip because of his financial interest in Antecip. We cannot assure you that any conflicts will be resolved in our favor, and as a result, our business could be impeded or materially harmed.

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

Because we have limited financial and managerial resources, we focus on developing product candidates for specific indications that we identify as most likely to succeed, in terms of both its regulatory approval and commercialization. As such, we are currently primarily focused on the development of solriamfetol for ADHD, AXS-05 for the treatment of agitation associated with AD, and smoking cessation, AXS-07 for the acute treatment of migraines, AXS-12 for the treatment of narcolepsy and AXS-14 for the treatment of fibromyalgia. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that may prove to have greater commercial potential. Additionally, as more fully described in "Business—Material License Agreements," we are required to pay to an entity owned by our Chief Executive Officer and Chairman of the Board certain royalty payments related to the sales of the Company's Auvelity product / AXS-05 portfolio product, as well as two product candidates that are not currently in active development. This may influence management's decision concerning which product candidates or indications to pursue and/or the manner in which our products are commercialized. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Our future growth may depend on our ability to identify and develop product candidates and if we do not successfully identify and develop product candidates or integrate them into our operations, we may have limited growth opportunities.

A component of our business strategy is to continue to develop a pipeline of product candidates by developing products that we believe are a strategic fit with our focus on central nervous system, or CNS, therapeutics. However, these business activities may entail numerous operational and financial risks, including:

- difficulty or inability to secure financing to fund business activities for such development;
- disruption of our business and diversion of our management's time and attention;
- higher than expected development costs;
- exposure to unknown liabilities;
- difficulty in managing multiple product development programs; and
- inability to successfully develop new products or clinical failure.

For instance, our prior efforts have resulted in our decision not to further develop certain product candidates that, at one time, appeared to be promising. Likewise, we received a CRL from the FDA relating to the Company's AXS-07 portfolio product in 2022 (we intend to resubmit the NDA for AXS-07). We have limited resources to identify and execute the developments of products. Moreover, we may devote resources to potential development that are never completed, or we may fail to realize the anticipated benefits of such efforts. If we do not successfully develop and commercialize product candidates, we may not be able to obtain product revenues in future periods.

If safety and efficacy data for our product candidates, a reference drug, or published literature does not satisfactorily demonstrate safety and efficacy to the FDA, or if the FDA and other regulators do not permit us to rely on the data of a reference drug or published literature, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

We are not permitted to commercialize, market, promote, or sell any product candidate in the United States without obtaining marketing approval from the FDA. Comparable foreign regulatory authorities, such as the European Medicines Agency, or EMA, impose similar restrictions.

In the United States, we currently plan to, at least initially, seek approval of some of our product candidates using the 505(b)(2) pathway. These 505(b)(2) product candidates include AXS-05 and AXS-07. The FDA interprets Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FDCA, for purposes of approving an NDA, to permit the applicant to rely, in part, upon published literature or the FDA's previous findings of safety and efficacy for an approved product. The FDA, though, requires companies to perform additional clinical trials or preclinical studies to support any deviation from the previously approved product and to support reliance on the FDA's prior findings of safety and efficacy or published literature.

Under the 505(b)(2) pathway, the FDA may approve our product candidates for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought pursuant to the Section 505(b)(2) process. The label, however, may require all or some of the limitations, contraindications, warnings, or precautions included in the reference product's label, including a box warning (commonly referred to as a "black box warning"), or may require additional limitations, contraindications, warnings, or precautions, including class-wide warnings. For instance, antidepressants, including Auvelity, include a class-wide black box warning regarding the increased risk of suicidal thoughts and behavior.

In addition, because we plan to file certain product candidates under an NDA submitted pursuant to 505(b)(2), we will rely, at least in part, upon a reference drug and published literature. For example, we intend to rely on third-party studies in the published literature as well as FDA findings of safety and efficacy for approved drug products containing the same active molecules in AXS-05 and AXS-07. If the FDA disagrees with our conclusions regarding the appropriateness of our reliance on a reference drug or published literature, we could be required to conduct additional clinical trials or other studies to support our NDA, which could lead to unanticipated costs and delays or to the termination of our development program. If we are unable to obtain approval for our pharmaceutical formulations through the 505(b)(2) NDA process, we may be required to pursue the more expensive and time consuming 505(b)(1) approval process, which consists of full reports of investigations of safety and effectiveness conducted by or for the applicant. In addition, because we have submitted NDAs for AXS-05 and AXS-07 pursuant to the 505(b)(2) process, we have not conducted certain additional clinical trials for these product candidates and, as such, we will have less experience with actual testing of these product candidates.

There may also be circumstances under which the FDA would not allow us to pursue a 505(b)(2) application. For instance, should the FDA approve a pharmaceutically equivalent product to our product candidates before we obtain approval, we would no longer be able to use the 505(b)(2) pathway. In that case, it is the FDA's policy that the appropriate submission would be an Abbreviated New Drug Application, or ANDA, for a generic version of the approved product. We may, however, not be able to immediately submit an ANDA or have an ANDA approval made effective, as we could be blocked by others' periods of patent and regulatory exclusivity protection.

Notwithstanding the approval of a number of products by the FDA under 505(b)(2) over the last few years, pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its policies and practices with respect to Section 505(b)(2) regulatory approvals, which could delay or even prevent the FDA from approving any NDA that we submit pursuant to the 505(b)(2) process. Moreover, our inability to pursue a 505(b)(2) application could result in new competitive products reaching the market more quickly than our product candidates, which could hurt our competitive position and our business prospects.

An NDA submitted under Section 505(b)(2) subjects us to the risk that we may be subject to a patent infringement lawsuit or regulatory actions that would delay or prevent the review or approval of our product candidates.

Under the Hatch-Waxman Act, the holder of patents listed in the Orange Book for NDAs that a 505(b)(2) application references may file a patent infringement lawsuit after receiving notice of the paragraph IV certification. Filing of a patent infringement lawsuit against the filer of the 505(b)(2) applicant within 45 days of the patent or NDA owner's receipt of notice triggers a one time, automatic, 30 month stay of the FDA's ability to make the 505(b)(2) NDA approval effective. In such a case, the FDA may not make the 505(b)(2) NDA approval effective until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all. In addition, a 505(b)(2) application approval will not be made effective until any existing non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, or NCE, or exclusivities for changes to NCEs listed in the Orange Book for the referenced product have expired or, if possible, are carved out from the label.

In practice, companies that produce branded reference listed drugs often bring patent litigation against applicants that seek regulatory approval to market generic or reformulated versions of their products. Litigation to enforce or defend intellectual property rights is often complex and often involves significant expense and can delay or prevent introduction or sale of our product candidates. If a court finds patents valid and infringed by our product candidates, we may be required to cease selling, relinquish or destroy existing stock, or pay monetary damages unless we can obtain a license from the patent holder. There may also be situations where we use our business judgment and decide to market and sell our approved products, notwithstanding the fact that allegations of patent infringement have not been finally resolved by the courts, an approach known as an "at risk launch." The risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement may include, among other things, damages measured by the profits lost by the patent owner which may be greater than the profits earned by the infringer. In the case of willful infringement, such damages may be increased up to three times. An adverse decision in patent litigation could have a material adverse effect on our business, financial position, and results of operations and could cause the market value of our common stock to decline.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates as expected, and our ability to generate revenue will be materially impaired.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities and the availability and prioritization of regulatory agency resources. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, and may require us to amend our clinical trial protocols or conduct additional studies that require regulatory or institutional review board, or IRB, approval, or otherwise cause delays in the approval or rejection of an application. To date, we have submitted two NDAs to the FDA and have obtained regulatory approval for one of our product candidates, Auvelity. It is possible that none of our other existing product candidates, or any product candidates we may seek to develop in the future, will ever obtain regulatory approval. Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability or that of any of our collaborators to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price.

Our products and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States, and by the EMA, in Europe, and similar regulatory authorities outside the United States and Europe. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have limited experience in filing and supporting the applications necessary to gain marketing approvals and rely on third-party contract research organizations, or CROs, and consultants to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy for that indication and the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by, the regulatory authorities.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies; our product candidates' mechanism of action; studies conducted by third parties in different patient populations, using different products, or using different study designs; and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Preclinical studies may also reveal unfavorable product candidate characteristics, including safety concerns. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be successful. Moreover, should there be a flaw in a clinical trial, it may not become apparent until the clinical trial is well advanced.

We may also experience numerous unforeseen events during, or as a result of, clinical trials and in the course of our preparation, submission, and review of NDA filings that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or IRBs may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or amend trial protocols;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and our CROs;
- clinical trials of our product candidates may produce negative or inconclusive results, or our studies may fail to reach the necessary level of statistical or clinical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- interim analyses may result in our clinical trials being discontinued for safety or futility reasons or may result in modifications to our clinical trials that prolong the trials or make them difficult and more expensive to complete, such as increases in the number of subjects;

- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or the clinical trial protocol, or meet their contractual obligations to us in a timely manner, or at all, or we may be required to engage in additional clinical trial site monitoring;
- we, the regulators, or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks, undesirable side effects, or other unexpected characteristics of the product candidate, or due to findings of undesirable effects caused by a chemically or mechanistically similar drug or drug candidate. We may also discontinue clinical research and programs due to changing business priorities;
- changes in marketing approval policies during the development period rendering our data insufficient to obtain marketing approval;
- changes in or the enactment of additional statutes or regulations;
- changes in regulatory review for each submitted product application;
- the cost of clinical trials of our product candidates may be greater than we anticipate, or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA upon the filing of an NDA;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- we may decide, or regulators may require us, to conduct additional clinical trials, analyses, reports, data, or preclinical/nonclinical studies than we currently plan, or we may abandon product development programs. For instance, although we believe that we are able to rely on the Phase 2 CONCERT trial and ongoing SYMPHONY trial to support an NDA for AXS-12 for the treatment of cataplexy and narcolepsy and the completed Phase 2 trial and Phase 3 trial to support an NDA for AXS-14 for the management of fibromyalgia, the FDA could still require additional studies to support the approval of an NDA for these product candidates. The outcome of our studies may further necessitate additional clinical or preclinical work;
- we may fail to reach an agreement with regulators regarding the scope or design of our clinical trials;
- we may have delays in adding new investigators or clinical trial sites, or we may experience a withdrawal of clinical trial sites;
- we may experience delays in our clinical trials due to the ongoing COVID-19 pandemic;
- patients that enroll in our studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the study or clinical trial, increase the needed enrollment size for the study or clinical trial, or extend the study's or clinical trial's duration;
- there may be regulatory questions regarding interpretations of data and results, or new information may emerge regarding our product candidates;
- the FDA or comparable foreign regulatory authorities may disagree with our study design or our interpretation of data from preclinical studies and clinical trials or find that a product candidate's benefits do not outweigh its safety risks. For instance, in our communications with the FDA, the FDA has raised questions and had comments regarding our preclinical studies and clinical trials, such as comments on the acceptability of the proposed trial designs for our product candidates, the number of patients planned for our studies, our data analysis plans, the species and doses used in our preclinical studies, and the results of our preclinical studies;

- the FDA or comparable foreign regulatory authorities may disagree with our belief that certain product attributes are advantageous or may require further study of product attributes that are different than our reference listed drugs. Pharmacokinetic differences between our product candidates and the reference listed drugs, may also make bridging studies more difficult or may prevent us from using the 505(b)(2) pathway. If we are prevented from using the 505(b)(2) pathway, we will need to use the more time consuming and expensive NDA pathway to receive product approval;

- the FDA or comparable foreign regulatory authorities may not accept data from studies with clinical trial sites in foreign countries;

- the FDA or comparable foreign regulatory authorities may disagree with our intended indications;

- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or our manufacturing facilities for clinical and future commercial supplies;

- in connection with the chemistry, manufacturing, and controls (CMC) data necessary for our NDA filing and approval, we will need to conduct stability studies and provide stability data to establish appropriate retest or expiration dating periods applicable to all future drug substance and drug product batches manufactured, packaged, and stored under similar circumstances, to establish the long-term storage conditions, and to provide evidence of the effect of various environmental conditions on the quality of the drug substance and drug product -- our product candidates may not demonstrate sufficient long-term stability to support an NDA filing or obtain approval, or the product shelf life may be limited by stability results;

- there may be delays in the FDA's ability to conduct necessary Pre-Approval Inspections, or PAIs, due to the COVID-19 pandemic or for other reasons, and more generally the FDA or comparable foreign regulatory authorities may take longer than we anticipate to make a decision on our product candidates; and

- we may not be able to demonstrate that a product candidate provides an advantage over current standards of care or current or future competitive therapies in development.

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

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

- not obtain marketing approval at all;

- obtain approval for indications or patient populations that are not as broad as intended or desired or are not covered by our intellectual property;

- obtain approval with labeling that includes significant use or distribution restrictions, including restrictions on the intended patient population, or safety warnings, including boxed warnings, contraindications, and precautions, or may not include label statements necessary or desirable for successful commercialization;

- be subject to additional post-marketing testing and surveillance requirements, including REMS; or

- have the product removed from the market after obtaining marketing approval.

Our product candidate development costs will also increase if we experience delays in testing or approvals and we may not have sufficient funding to complete the testing and approval process for any of our product candidates. We may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of our product candidates. We do not know whether any additional preclinical tests or clinical trials will be required, will begin as planned, will need to be restructured, or will be completed on schedule, or at all. Significant delays relating to any preclinical studies or clinical trials also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors, or the competitors of our collaborators, to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. In addition, many of the factors that cause, or lead to, such delays may ultimately lead to the denial of marketing approval of any of our product candidates. If any of this occurs, our business, financial condition, results of operations, and prospects may be materially harmed.

Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical studies, clinical trials, or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. During the course of review, the FDA may also request or require additional CMC, or other data and information, and the development and provision of these data and information may be time consuming and expensive. For example, in the CRL with respect to our NDA for AXS-07, the FDA noted the need for additional CMC data.

If we experience delays in obtaining approval, if we fail to obtain approval of a product candidate or if the label for a product candidate does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate, the commercial prospects for such product candidate may be harmed and our ability to generate revenues from that product candidate will be materially impaired.

If we cannot demonstrate an acceptable safety and toxicity profile for our product candidates, we will not be able to continue our clinical trials of or obtain approval for those product candidates.

In order to obtain approval of a product candidate we must demonstrate safety in various nonclinical tests (including, for example, carcinogenicity studies, drug-drug interaction studies, and toxicity studies), in addition to human clinical trials. At the time of initiating human clinical trials, we may not have conducted or may not conduct all the types of nonclinical testing ultimately required by regulatory authorities, or future nonclinical tests may indicate safety concerns regarding our product candidates. Nonclinical testing and clinical testing are both expensive and time-consuming and have uncertain outcomes. Even if initial tests appear favorable, later testing may have unfavorable results. We may experience numerous unforeseen events during, or as a result of, the testing process, which could delay or prevent our ability to develop or commercialize our product candidates, including:

- our preclinical or nonclinical testing may produce inconclusive or negative safety results, which may require us to conduct additional nonclinical testing or to abandon product candidates;
- our product candidates may have unfavorable pharmacology or toxicity characteristics or suggest possible drug-drug interaction;
- our product candidates may cause undesirable side effects; and
- the FDA or other regulatory authorities may determine that additional safety testing is required.

Any such events would increase our costs and could delay or prevent our ability to commercialize our product candidates, which could adversely impact our business, financial condition and results of operation.

The FDA may determine that any of our current or future product candidates have undesirable side effects that could delay or prevent their regulatory approval or commercialization.

Undesirable side effects caused by our product candidates could cause us, IRBs, and other reviewing entities or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. For example, if concerns are raised regarding the safety of a new drug as a result of undesirable side effects identified during clinical or preclinical testing, the FDA may order us to cease further development, decline to approve the drug, or issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve the drug.

The number of requests for additional data or information issued by the FDA in recent years has increased and resulted in substantial delays in the approval of several new drugs. Undesirable side effects caused by any of our current or future product candidates could also result in denial of regulatory approval by the FDA or other comparable foreign authorities for any or all targeted indications or the inclusion of unfavorable information in our product labeling, such as limitations on the indicated uses for which the products may be marketed or distributed, a label with significant safety warnings, including boxed warnings, contraindications, and precautions, a label without statements necessary or desirable for successful commercialization, or may result in requirements for costly post-marketing testing and surveillance, or other requirements, including REMS, to monitor the safety or efficacy of the products, and in turn prevent us from commercializing and generating revenues from the sale of any of our current or future product candidates.

Based on the side effects disclosed in FDA product labeling for marketed drugs that contain the same active molecules as our product candidate, AXS-07 may result in fatigue, confusion, dry mouth, diarrhea, nausea, insomnia, anemia, increased appetite, anxiety, sweating, dizziness, palpitations, arrythmia, tachycardia, abnormal vision, syncope, seizure, tremor, tinnitus, dizziness, somnolence, paresthesia, dysgeusia, dyspepsia, constipation, weight increase or decrease, gastritis, hematuria, flatulence, esophagitis, gastric ulcers, gastroesophageal reflux, gastrointestinal hemorrhages, colitis, rash, pain or tightness in the chest, neck, throat or jaw, upper respiratory tract infections, influenza-like symptoms, or other adverse events or potential adverse events reported or discussed in the product labels for meloxicam-containing or rizatriptan-containing products including Anjeso, Vivlodex, Mobic, and Maxalt.

Based on the side effects disclosed in the EMA required product label for marketed drugs that contain the same active molecule as our product candidate, AXS-12 and AXS-14 may result in decreased appetite, insomnia, agitation, anxiety, dizziness, headache, paresthesia, akathisia, dysgeusia, accommodation disorder, mydriasis, glaucoma, vertigo, tachycardia, palpitations, vasodilation, hypotension, hypertension, dry mouth, vomiting, hyperhidrosis, rash, sensation of incomplete bladder emptying, urinary tract infection, dysuria, urinary retention, erectile dysfunction, ejaculatory pain, ejaculatory delay, chills, or other adverse events or potential adverse events reported or discussed in the product labels for reboxetine containing products including Edronax.

Known side effects for Auvelity and Sunosi are described on the approved labels for those products. In relation to further development efforts with respect to these compounds, different patient populations may react to these compounds differently. For example, AD agitation patients in the case of AXS-05 or ADHD patients in the case of solriamfetol may experience different side effects than patients taking these products for their currently approved indications. This is particularly true where different dosing, formulations or methods of administration are implicated.

If any of our other product candidates are associated with serious adverse events or undesirable side effects or have properties that are unexpected, we may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk-benefit perspective. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may significantly harm our business, financial condition, results of operations, and prospects.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue conducting clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Patient enrollment is affected by other factors including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the eligibility criteria for, and design of, the clinical trial in question, including factors such as frequency of required assessments, length of the study, and ongoing monitoring requirements;
- the perceived risks and benefits of the product candidate under study, including the potential advantages or disadvantages of the product candidate being studied in relation to other available therapies;
- competition in recruiting and enrolling patients in clinical trials;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- effectiveness of publicity created by clinical trial sites regarding the trial;
- patients' ability to comply with the specific instructions related to the trial protocol, proper documentation, and use of the drug product;

- inability to obtain or maintain patient informed consents;
- risk that enrolled patients will drop out before completion;
- the ability to identify patients for enrollment and maintain a sufficient level of patient participants in our clinical studies due to the ongoing COVID-19 pandemic;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays which would cause us to miss our projected timelines and could require us to abandon one or more clinical trials altogether. For instance, because we are seeking regulatory approval for certain indications that may have a narrow or small patient population, it may be difficult to find patients eligible to participate in our clinical studies at a sufficient rate or in a sufficient quantity. We may be required by the FDA to modify the entry criteria for our planned Phase 3 clinical trials and these changes may make it more difficult to enroll patients in our clinical trials. Moreover, patients in our clinical trials, especially patients in our control groups, may be at risk for dropping out of our studies if they are not experiencing relief of their symptoms. A significant number of withdrawn patients would compromise the quality of our data.

Enrollment delays or slower periods of enrollment in our clinical trials may result in increased development costs for our product candidates, or the inability to complete development of our product candidates, which would cause the value of our company to decline, limit our ability to obtain additional financing, and materially impair our ability to generate revenues.

Development of combination product candidates may present more or different challenges than development of single agent product candidates.

Certain product candidates of ours, including AXS-05 and AXS-07, are combination therapies. A combination therapy is a single drug product that consists of two or more active ingredients, with each component making a contribution to the claimed effect of the drug. The development of combination drugs may be more complex than the development of single agent products and generally requires that sponsors demonstrate the contribution of each component to the claimed effect and the safety and efficacy of the product as a whole. This requirement may make the design and conduct of clinical trials more complex, requiring more clinical trial subjects. We also may not be able to meet the FDA's approval standards required for combination products. The FDA's requirements concerning combination products may change in the future. Moreover, the applicable requirements for approval may differ from country to country.

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

As product candidates are developed through preclinical studies to late stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. For instance, as we begin scale-up efforts for commercial-size manufacturing batches, formulation changes may be necessary to improve tablet robustness. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification, or FDA approval. This could delay completion of clinical trials; require the conduct of bridging clinical trials or studies, or the repetition of one or more clinical trials; increase clinical trial costs; delay approval of our product candidates; and jeopardize our ability to commence product sales and generate revenue.

Failure to obtain marketing approval in international jurisdictions would prevent our products from being marketed abroad.

In order to market and sell our products in the European Union, or EU, and many other jurisdictions, we or our third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or these third parties may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, the failure to obtain approval in one jurisdiction may compromise our ability to obtain approval elsewhere. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

Although Breakthrough Therapy, Fast Track, and other designations are designed to expedite the development and review of drugs, they may not ultimately lead to a faster approval process or faster development of regulatory review and they will not increase the likelihood that our product candidates will receive marketing approval, for example, Breakthrough Therapy designation by the FDA for AXS-05 for the treatment of AD agitation.

We have received a Fast Track product designation for AXS-05 for both the treatment of TRD as well as for the treatment of AD agitation, and we may seek Fast Track designation for other of our current or future product candidates. The FDA may designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with the FDA, and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information, and the sponsor must pay applicable user fees.

We also received Breakthrough Therapy designation for AXS-05 for both the treatment of MDD and the treatment of AD agitation, and we may seek Breakthrough Therapy designation for other current or future product candidates. A Breakthrough Therapy is defined as a product candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Breakthrough Therapy designation also allows the sponsor to request a Priority Review or file sections of the NDA on an ongoing basis for rolling review where the FDA may consider beginning review portions of a marketing application before the full submission is complete. Product candidates designated as Breakthrough Therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the NDA.

Breakthrough Therapy or Fast Track designation is within the discretion of the FDA. The receipt of a Breakthrough Therapy or Fast Track designation for a product candidate may not ultimately result in a faster development process or review, and it does not in any way assure approval of product candidates by the FDA. In addition, the FDA may later decide to rescind the Breakthrough Therapy or Fast Track designation for one or more of our applicable product candidates if such product candidates no longer meet the conditions for qualification of this program. For example, we were initially granted Breakthrough Therapy designation for AXS-12 for the treatment of cataplexy in patients with narcolepsy in August 2020. In July 2021, the FDA rescinded our Breakthrough Therapy designation due to the FDA approving an additional drug product for the treatment of cataplexy in narcolepsy.

Regulatory approval is limited by the FDA or comparable foreign regulatory authorities to those specific indications and conditions for which clinical safety and efficacy have been demonstrated, and we may be subject to fines, penalties, injunctions, or other enforcement actions if we are determined to be promoting the use of our products for unapproved or "off-label" uses, resulting in damage to our reputation and business.

We, and any of our collaborators, must comply with requirements concerning advertising and promotion for any of our products for which we or they obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and continuing review by the FDA, Department of Justice, Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress, and the public. When the FDA or comparable foreign regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product is approved. If we are not able to obtain FDA approval for any desired uses or indications for our products and product candidates, we may not market or promote our products for those indications and uses, referred to as off-label uses, and our business may be adversely affected. We further must be able to sufficiently substantiate any claims that we make for our products including claims comparing our products to other companies' products.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, we are prohibited from marketing and promoting the products for indications and uses that are not specifically approved by the FDA or comparable foreign regulatory authorities. These off-label uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States and in many other major markets do not generally restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by pharmaceutical companies concerning off-label use.

If we are found to have impermissibly promoted any of our products, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations regarding product promotion, particularly those prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted a product may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed. Thus, we and any of our collaborators will not be able to promote any products we develop for indications or uses for which they are not approved.

In the United States, engaging in the impermissible promotion of our products, following approval, for off-label uses can also subject us to false claims and other litigation under federal and state statutes, including fraud and abuse and consumer protection laws, which can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which we promote or distribute drug products and do business through, for example, corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, and debarment from government contracts and refusal of future orders under existing contracts. Recent court decisions have impacted the FDA's enforcement activity regarding off-label promotion in light of First Amendment considerations; however, there are still significant risks in this area in part due to the potential False Claims Act exposure. The False Claims Act 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 others to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the qui tam lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. Under the False Claims Act, a penalty may be imposed for each false claim, for example, a claim for payment for each prescription for the product, and, when aggregated, these penalties often total millions of dollars and incentivize qui tam lawsuits. These False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements, up to $3.0 billion, pertaining to certain sales practices and promoting off-label drug uses. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action; pay settlement fines or restitution, as well as criminal and civil penalties; agree to comply with burdensome reporting and compliance obligations; and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If we or our collaborators do not lawfully promote our approved products, if any, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations, and prospects.

In the United States, the distribution of product samples to physicians must further comply with the requirements of the U.S. Prescription Drug Marketing Act. If the FDA determines that our promotional materials or activities violate its regulations and policies pertaining to product promotion, it could request that we modify our promotional materials or activities or subject us to regulatory or other enforcement actions, including issuance of warning letters or untitled letters, suspension or withdrawal of an approved product from the market, requests for recalls, payment of civil fines, disgorgement of money, imposition of operating restrictions, injunctions, or criminal prosecution. These regulatory and enforcement actions could significantly harm our business, financial condition, results of operations, and prospects.

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

Our product(s) are subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities, including requirements related to the manufacturing processes, post approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising, marketing, and promotional activities for such product. These requirements further include submissions of safety and other post-marketing information, including manufacturing deviations and reports; registration and listing requirements; the payment of annual program fees for our products; continued compliance with cGMP requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents; requirements regarding the distribution of samples to physicians and recordkeeping; and GCP, for any clinical trials that we conduct post approval.

We and any of our collaborators, including our contract manufacturers, could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMP and GCP. Application holders must further notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product and manufacturing changes. Application fees may apply to certain changes.

In addition, later discovery of previously unknown adverse events or that the drug is less effective than previously thought or other problems with our products, manufacturers, or manufacturing processes, or failure to comply with regulatory requirements both before and after approval, may yield various results, including:

- restrictions on manufacturing or distribution, or marketing of such products;
- restrictions on the labeling, including required additional warnings, such as black box warnings, contraindications, precautions, and restrictions on the approved indication or use;
- modifications to promotional pieces;
- requirements to conduct post-marketing studies or clinical trials; clinical holds or termination of clinical trials;
- requirements to establish or modify a REMS or a comparable foreign authority may require that we establish or modify a similar strategy, that may, for instance, require us to create or modify a medication guide outlining the risks of the previously unidentified side effects for distribution to patients, or restrict distribution of the product, if and when approved, and impose burdensome implementation requirements on us;
- changes to the way the drug is administered;
- liability for harm caused to patients or subjects;
- reputational harm;
- the drug becoming less competitive;
- warning or untitled letters;
- suspension of marketing or withdrawal of the products from the market;
- regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the drug;

- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, damages, restitution, or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure or detention;
- FDA debarment, debarment from government contracts, and refusal of future orders under existing contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements; or
- injunctions or the imposition of civil or criminal penalties, including imprisonment.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular products, or could substantially increase the costs and expenses of commercializing such product, which in turn could delay or prevent us from generating significant revenues from its sale. Any of these events could further have other material and adverse effects on our operations and business and could adversely impact our stock price and could significantly harm our business, financial condition, results of operations, and prospects.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates or that could impose additional regulatory obligations on our products. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and be subject to regulatory enforcement action.

Should any of the above actions take place, they could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Timelines for the review of our regulatory submissions by the FDA and other regulatory agencies are subject to change and uncertainty, which may delay the potential approval of any product candidates we seek to develop or commercialize.

We cannot predict the timeline for review of submissions to any regulatory authorities or when any of our product candidates will receive marketing approval, if at all. The timeline for regulatory approval can be affected by a variety of factors, including disruptive effects of the COVID-19 pandemic, budget and funding levels, agency staffing, and statutory, regulatory and policy changes. Delays or uncertainty in the timing of regulatory action in response to our submissions could adversely impact our development and commercialization efforts and our business prospects.

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

We are, and may become party to further agreements, pursuant to which we out-license our products outside of the United States. The Company also currently markets Sunosi in Canada. We expect that we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for approval of drugs in foreign countries;
- the potential for so-called parallel importing, particularly within Europe, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally with EU laws supporting such "free movement of goods" within the EU;
- stricter harmonized EU rules on data privacy particularly in relation to health data than is the case in the United States which are being further toughened with the EU General Data Protection Regulation, or the GDPR, which became enforceable beginning May 25, 2018;

- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- unexpected changes in tariffs, trade barriers, and regulatory requirements and in the health care policies of foreign jurisdictions;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States and worker rights tend to be stronger;
- costs of compliance with U.S. laws and regulations for foreign operations, including the Foreign Corrupt Practices Act or comparable foreign regulations, and the risks and costs of noncompliance;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods, and fires.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

We will need to obtain FDA approval (and that of comparable foreign regulatory authorities) of any proposed product names, and any failure or delay associated with such approval may adversely affect our business.

Any name we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or USPTO. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. If the FDA objects to any of our proposed product names, we may be required to adopt alternative names for our product candidates. If we adopt alternative names, we would lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

RISKS RELATED TO THE COMMERCIALIZATION OF OUR PRODUCTS

We face significant competition from other pharmaceutical and biotechnology companies, academic institutions, government agencies, and other research organizations. Our operating results will suffer if we fail to compete effectively.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of CNS disorders. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

Specifically, there are a large number of companies developing or marketing therapies for CNS disorders, including many major pharmaceutical and biotechnology companies. Among the companies that currently market or are developing therapies that, if approved, our product candidates would potentially compete with include: AbbVie Inc.; Amgen Inc.; Avadel Pharmaceuticals plc; Biogen Inc.; Eli Lilly and Company; H. Lundbeck A/S; Harmony Biosciences; Intra-Cellular Therapies, Inc.; Janssen; Jazz Pharmaceuticals plc; Otsuka Pharmaceutical Co. Ltd.; Pfizer Inc.; Relmada Therapeutics Inc.; Sage Therapeutics, Inc.; and Takeda Pharmaceutical Company Limited.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, are more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products or therapeutically similar lower cost brands. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic products, which would further impact our commercialization efforts.

Generic forms of the active ingredients of our product candidates, including dextromethorphan, bupropion, meloxicam, rizatriptan, and reboxetine, are available in the United States and abroad and could be used off-label. Any such off-label use could adversely affect our profitability and have a negative effect on our operating results and financial condition. For example, even though meloxicam is not currently approved for the treatment of acute migraine, we would not be able to prevent a physician from prescribing it for such treatment. Nor could we prevent a payor from offering favorable coverage for such product and disadvantaging our product candidates, even if the generics would be used off-label.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with, or acquisition by large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If the FDA or comparable foreign regulatory authorities approve generic or similar versions of any of our products that receive marketing approval, or such authorities do not grant our products appropriate periods of exclusivity before approving generic or similar versions of our products, the sales of our products could be adversely affected.

Once an NDA is approved, the covered product becomes a “reference listed drug” in the FDA’s Orange Book. Manufacturers may seek approval of generic versions of reference listed drugs through submission of ANDAs in the United States. In support of an ANDA, a generic manufacturer need not conduct full clinical studies. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use or labeling, among other commonalities, as the reference listed drug and that the generic version is bioequivalent to the reference listed drug, meaning it is absorbed in the body at the same rate and to the same extent. For example, in February 2023, we received a paragraph IV certification notice letter from Teva Pharmaceuticals, Inc., or Teva, providing notification to the Company that Teva has submitted an ANDA to the FDA seeking approval to manufacture, use, or sell a generic version of Auvelity.

Recently, the FDA and Congress have also taken steps to encourage increased generic drug competition in the market. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices, and are generally preferred by third-party payors. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug is typically lost to the generic product.

Moreover, in addition to generic competition, we could face competition from other companies seeking approval of drug products that are similar to ours using the 505(b)(2) pathway. Such applicants may be able to rely on our products, or other approved drug products or published literature to develop drug products that are similar to ours. The introduction of a drug product similar to our product candidates could expose us to increased competition.

Further, if we do not file a patent infringement lawsuit against a generic manufacturer within 45 days of receiving notice of its paragraph IV certification, the ANDA or 505(b)(2) applicant may not be subject to a 30-month stay. Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be expensive and time consuming, may divert our management's attention from our core business, and may result in unfavorable results that could adversely impact our ability to prevent third parties from competing with our products. Accordingly, we may be subject to generic competition or competition from similar products, or may need to commence patent infringement proceedings, which would divert our resources.

Competition that our products may face from generic or similar versions of our products could materially and adversely impact our future revenue, profitability, and cash flows and substantially limit our ability to obtain a return on the investments we have made in our product candidates.

AXS-12 received Orphan Drug Designation from the FDA. However, there is no guarantee that we will receive this designation for any of our other product candidates or receive or maintain any corresponding benefits for any of our other product candidates that may receive Orphan Drug Designation in the future, including periods of exclusivity.

AXS-12 received Orphan Drug Designation from FDA for the treatment of narcolepsy. We may also seek Orphan Drug Designation for our other products, as appropriate.

Orphan Drug Designation, however, may be lost if the indications for which we develop any of our future product candidates do not meet the orphan drug criteria. Moreover, following product approval, orphan drug exclusivity may be lost if the FDA determines, among other reasons, that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition. Even if we obtain orphan drug exclusivity for any of our current or future product candidates, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. Even after an orphan product is approved, the FDA can subsequently approve a product containing the same principal molecular features for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer or more effective or makes a major contribution to patient care.

The FDA or the EMA may grant orphan exclusivity to two different sponsors for the same compound or active molecule and for the same indication. For example, if another sponsor receives FDA approval for a reboxetine containing product for the treatment of narcolepsy before we obtain FDA approval for AXS-12 for the treatment of narcolepsy, we would be prevented from launching our product in the United States for this indication for a period of at least 7 years. If another sponsor receives EMA approval for a reboxetine containing product for the treatment of narcolepsy before we obtain EMA approval for AXS-12 for the treatment of narcolepsy, we would be prevented from launching our product in the EU for this indication for a period of at least 10 to 12 years.

The FDA may undertake a reevaluation of aspects of its orphan drug regulations and policies at any time and may possibly do so in response to a recent court decision regarding the plain meaning of the exclusivity provision of the Orphan Drug Act. We do not know if, when, or how the FDA may change the orphan drug regulations and policies, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business, financial condition, results of operations, and prospects could be harmed.

If we are unable to establish effective marketing, sales and distribution capabilities or enter into agreements with third parties to market, sell and distribute our products, we may be unable to generate substantial product revenues.

We recently expanded our commercial infrastructure for the marketing, sale, and distribution of pharmaceutical products, which included the creation of a sales force to launch our commercial stage products throughout the United States. This requires additional compliance with a range of federal and state laws. Additionally, we currently commercialize Sunosi outside the United States. Each global market we commercialize Sunosi in has its own set of applicable laws.

We have limited experience in the marketing, sale, and distribution of pharmaceutical products, and there are significant risks involved in the building and managing of a commercial infrastructure. We have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, manage, and retain marketing and sales personnel. In the event we are unable to maintain our marketing and sales infrastructure, we may not be able to successfully commercialize any of our existing commercial stage products or future product candidates, which would limit our ability to generate revenue. Factors that may inhibit our efforts to commercialize any of our products on our own include:

- our inability to recruit, train, manage, and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any of our current or future product candidates;
- our inability to effectively oversee a geographically dispersed sales and marketing team;
- the application of federal and state drug distribution and supply chain requirements to our business;
- the costs associated with training sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions;
- an inability to secure adequate coverage and reimbursement by government and private health plans;
- the clinical indications and labeled claims for which the product is approved;
- limitations or warnings, including distribution or use restrictions, contained in the product's approved labeling;
- any distribution and use restrictions imposed by the FDA or to which we agree as part of a mandatory REMS or voluntary risk management plan;
- liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization or engaging a contract sales organization.

If additional product candidates are approved, we may incur expenses prior to product launch in expanding our sales force and compliant marketing and sales infrastructure. If a commercial launch is delayed as a result of FDA requirements or other reasons, we may incur these expenses prior to being able to realize any revenue from sales of such product candidate(s). Furthermore, our sales force and marketing teams may not be successful in commercializing any of our current or future product candidates.

If any of our products do not achieve broad market acceptance, the revenues that we generate from their sales will be limited.

Our products, and, if approved, our product candidates, may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If any of our products or product candidates, for which we obtain regulatory approval, do not gain an adequate level of market acceptance, we may not generate significant product revenues or become profitable. Market acceptance of any of our products by the medical community, patients, and third-party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to the therapy that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch therapies due to lack of reimbursement for existing therapies. Even if physicians prescribe our products, third-party payors may not consider them cost effective without a significant price concession, which could negatively impact our revenue. Third-party payors may also implement onerous access controls, which could further impede our efforts to effectively transition eligible patients to our therapies.

Efforts to educate the medical community and third-party payors on the benefits of our products may require significant resources and may not be successful. If any of our product candidates is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of any of our products will depend on a number of factors, including:

- the efficacy of our products;
- the prevalence and severity of adverse events associated with such product;
- the clinical indications for which the product is approved and the approved claims that we may make for the product;
- limitations or warnings contained in the product's FDA-approved labeling, including potential limitations or warnings for such product candidate, that may be more restrictive than other competitive products;
- changes in the standard of care for the targeted indications for such product candidate, which could reduce the marketing impact of any claims that we could make following FDA approval, if obtained;
- the relative convenience and ease of administration of such product;
- cost of treatment versus economic and clinical benefit in relation to alternative treatments or therapies;
- the availability of adequate coverage or reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;
- the willingness of third-party payors to prefer similar but less expensive products even if not approved for our product's indication;
- the extent and strength of our marketing and distribution of such product;
- the safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used or that may later be approved for any of our intended indications;
- distribution and use restrictions imposed by the FDA with respect to such product or to which we agree as part of a mandatory risk evaluation and mitigation strategy or voluntary risk management plan;
- the timing of market introduction of such product, as well as competitive products;
- our ability to offer such product candidate for sale at competitive prices, including prices that are competitive with generic products;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the extent and strength of our third-party manufacturer and supplier support;

- the approval of other new products for the same indications;
- adverse publicity about the product or favorable publicity about competitive products; and
- potential product liability claims.

Our efforts to educate the medical community and third-party payors on the benefits of our products may require significant resources and may never be successful. Even if the medical community accepts that one of our product candidates is safe and effective for its approved indications, physicians and patients may not immediately be receptive to such product candidate and may be slow to adopt it as an accepted treatment of the approved indication. It is unlikely that any labeling approved by the FDA will contain claims that one of our product candidates is safer or more effective than competitive products or will permit us to promote such product candidate as being superior to competing products. Further, the availability of inexpensive generic forms of pain management products for acute pain may also limit acceptance of certain of our product candidates among physicians, patients, and third-party payors.

The potential market opportunities for our products and/or product candidates are difficult to precisely estimate. Our estimates of the potential market opportunities are predicated on many assumptions including industry knowledge and publications, third-party research reports, and other surveys. While we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management and are inherently uncertain, and the reasonableness of these assumptions has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability and may have to limit our products' commercialization.

The use of any of our current or future product candidates in clinical trials, and the sale of any of our products exposes us to the risk of product liability claims. We face inherent risk of product liability related to the testing of our product candidates in human clinical trials and face an even greater risk for our commercialized products. For example, we may be sued if any products we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. Product liability claims might be brought against us by consumers, healthcare providers, or others using, administering, or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities or be required to limit commercialization of our products. Even successful defense would require significant financial and management resources. Regardless of merit or eventual outcome, liability claims may result in loss of revenue from including from:

- decreased demand for our products;
- impairment of our business reputation or financial stability;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- diversion of management attention;
- loss of revenues;
- withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs;
- the inability to commercialize our product candidates;
- significant negative media attention;
- decrease in our stock price;

- initiation of investigations and enforcement actions by regulators; and

- product recalls, withdrawals, or labeling, marketing, or promotional restrictions.

We have obtained limited product liability insurance coverage for our products and our clinical trials with a $10.0 million annual aggregate coverage limit. We have also obtained local policies in those foreign jurisdictions where it was appropriate. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business and our prospects.

Sunosi is a controlled substance and may be subject to U.S. federal and state controlled substance laws and regulations, and our failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, could materially and adversely affect our business, results of operations, financial condition and growth prospects.

Sunosi contains controlled substances as defined in the Federal Controlled Substances Act, or CSA. Controlled substances are subject to a number of requirements and restrictions under the CSA and implementing regulations, including certain registration, security, recordkeeping, reporting, import, export and other requirements administered by the U.S. Drug Enforcement Administration, or DEA. The DEA classifies controlled substances into five schedules: Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse, no currently “accepted medical use” in the U.S., lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the U.S. Pharmaceutical products approved for use in the U.S. which contain a controlled substance are listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, heightened security requirements and additional criteria for importation. In addition, dispensing of Schedule II drugs is further restricted. For example, they may not be refilled without a new prescription. Sunosi is a Schedule IV controlled substance.

Individual states have also established controlled substance laws and regulations. Though state-controlled substances laws often mirror federal law, they may separately schedule our products or our product candidates as well. We or our partners may also be required to obtain separate state registrations, permits or licenses in order to be able to manufacture, distribute, administer or prescribe controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

U.S facilities conducting research, manufacturing, distributing, importing or exporting, or dispensing controlled substances must be registered (licensed) to perform these activities and must comply with the security, control, recordkeeping and reporting obligations under the CSA, DEA regulations and corresponding state requirements. DEA and state regulatory bodies conduct periodic inspections of certain registered establishments that handle controlled substances. Obtaining and maintaining the necessary registrations and complying with the regulatory obligations may result in delay of the importation, manufacturing, distribution or clinical research of our products and products candidates. Furthermore, failure to maintain compliance with the CSA and DEA and state regulations by us or any of our contractors, distributors or pharmacies can result in regulatory action that could have a material adverse effect on our business, financial condition and results of operations. DEA and state regulatory bodies may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal penalties. Any penalties imposed by the DEA to us or our third-party manufacturers which could have a material adverse effect on our business, results of operations, financial condition and growth prospects.

RISKS RELATED TO OUR DEPENDENCE ON THIRD PARTIES

We rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials, and those third parties may not perform satisfactorily, including by failing to meet deadlines for the completion of such trials or failing to comply with regulatory requirements.

We rely on third-parties to conduct, supervise, and monitor our preclinical studies and certain clinical trials for our product candidates and do not currently plan to independently conduct preclinical studies or clinical trials of any other potential product candidates. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our preclinical studies and clinical trials. While we have agreements governing their activities, we have limited influence over their actual performance and control only certain aspects of their activities. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may not obtain marketing approval for or commercialize our product candidates in a timely manner or at all. Moreover, these agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that could delay our product development activities and adversely affect our business.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial and for ensuring that our preclinical trials are conducted in accordance with good laboratory practice, or GLP, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with standards, such as GCP for conducting, monitoring, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. As a clinical trial sponsor, we also have regulatory requirements that directly apply to us. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators, and trial sites. If we or any of the third parties we engage fail to comply with applicable GCP, we or those third parties may be subject to enforcement or other legal actions, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials.

In addition, when we submit an NDA for review, we are required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA and comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who previously served or currently serve as scientific advisors or consultants to us from time to time and receive cash compensation in connection with such services or otherwise receive compensation from us that could be deemed to impact study outcome, proprietary interests in a product candidate, certain company equity interests, or significant payments of other sorts.

We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product candidates that were produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of certain completed clinical trials on a government sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so or to meet the related submission requirements can result in enforcement actions, including civil monetary penalties and adverse publicity.

Third parties we engage to conduct research may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. In addition, these third parties are not our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, non clinical, and preclinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, 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 or regulatory requirements or for other reasons, our clinical trials may be extended, delayed, or terminated and we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates, or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third party service providers in the future, our business may be materially and adversely affected.

If any of our relationships with these third parties terminates, we may not be able to enter into arrangements with alternative resources or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. Though we carefully manage our relationships with these third party vendors, 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, and results of operations.

If the manufacturers upon whom we rely fail to produce our products in the volumes that we require on a timely basis, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the development and commercialization of, or be unable to meet demand for, our products and may lose potential revenues.

We do not manufacture any of our products, and we do not currently plan to develop any capacity to do so. We currently outsource all manufacturing of our products to third parties typically without any guarantee that there will be sufficient supplies to fulfill our requirements or that we may obtain such supplies on acceptable terms. Any delays in obtaining adequate supplies with respect to our products may delay the development or commercialization of our products. Moreover, we do not yet in all cases have agreements established regarding commercial supply of our product candidates, and we may not be able to establish or maintain commercial manufacturing arrangements on commercially reasonable terms for any of our current or future product candidates for which we obtain approval in the future.

We may not succeed in our efforts to establish manufacturing relationships or other alternative arrangements for any of our existing or future products and programs. Our products may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing for us and willing to do so. If our existing third-party manufacturers, or the third parties that we engage in the future to manufacture a product for commercial sale or for our clinical trials, should cease to continue to do so for any reason, we likely would experience delays in obtaining sufficient quantities of our product for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers. If for any reason we are unable to obtain adequate supplies of our products or the drug substances used to manufacture them, it will be more difficult for us to develop our products and compete effectively. Further, even if we do establish such collaborations or arrangements, our third-party manufacturers may breach, terminate, or not renew these agreements.

Any problems or delays we experience in preparing for commercial-scale manufacturing of a product candidate may result in a delay in FDA approval of the product candidate or may impair our ability to manufacture commercial quantities or such quantities at an acceptable cost, which could result in the delay, prevention, or impairment of clinical development and commercialization of our product candidates and could adversely affect our business. For example, our manufacturers will need to produce specific batches of our product candidates to demonstrate acceptable stability under various conditions and for commercially viable lengths of time. We and our contract manufacturers will need to demonstrate to the FDA and other regulatory authorities that this is acceptable stability data for our product candidates, as well as validate methods and manufacturing processes, in order to receive regulatory approval to commercialize any of our current or future product candidates. Furthermore, if our commercial manufacturers fail to deliver the required commercial quantities of bulk drug substance or finished product on a timely basis and at commercially reasonable prices, we would likely be unable to meet demand for our products and we would lose potential revenues.

We have a limited number of contract manufacturers for our products. At times we may have only one manufacturer for a product. In addition, we do not have any long-term commitments from our suppliers of clinical trial material or guaranteed prices for our product candidates. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields; quality control, including stability of the product candidate and quality assurance testing; shortages of qualified personnel; and compliance with strictly enforced federal, state, and foreign regulations. Our manufacturers may not perform as agreed. If our manufacturers were to encounter any of these difficulties, our ability to provide product candidates to patients in our clinical trials and for commercial use, if approved, would be jeopardized.

In addition, all manufacturers of our products must comply with cGMP requirements enforced by the FDA and comparable foreign regulatory authorities that are applicable to both finished drug products and active pharmaceutical ingredients used both for clinical and commercial supply, through its facilities inspection program. The FDA must verify our contract manufacturers' compliance with cGMP requirements and comparable foreign regulatory authorities will similarly inspect our contract manufacturers' facilities after we submit our marketing applications to the agency and comparable foreign regulatory authorities. The cGMP requirements include quality control, quality assurance, and the maintenance of records and documentation. Manufacturers of our products may be unable to comply with our specifications, these cGMP requirements and with other FDA, state, and foreign regulatory requirements. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. While we are ultimately responsible for the manufacture of our products, other than through our contractual arrangements, we have little control over our manufacturers' compliance with these regulations and standards. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our products or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop or market our products, or obtain regulatory approval for, our product candidates. A failure to comply with these requirements may result in regulatory enforcement actions against our manufacturers or us, including fines and civil and criminal penalties, including imprisonment; suspension or restrictions of production; suspension, delay, or denial of product approval or supplements to approved products; clinical holds or termination of clinical studies; warning or untitled letters; regulatory authority communications warning the public about safety issues with the drug; refusal to permit the import or export of the products; product seizure, detention, or recall; suits under the civil False Claims Act; corporate integrity agreements; consent decrees; or withdrawal of product approval. If the safety of any quantities supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for our product candidates or successfully commercialize our products.

Any failure or refusal to supply our products or components for our current or future product candidates that we may develop could delay, prevent, or impair our clinical development or commercialization efforts. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

As an NDA applicant and a potential commercial "virtual manufacturer," we may rely in many cases on third parties to perform many essential services for any products that we commercialize, including services related to warehousing and inventory control, distribution, government price reporting, customer service, and adverse event reporting. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to commercialize any of our current or future product candidates will be significantly impacted and we may be subject to regulatory sanctions.

We have retained third-party service providers to perform a variety of functions related to the sale and distribution of our products, key aspects of which are out of our direct control. These service providers provide key services related to warehousing and inventory control, distribution, government price reporting, and customer service and, as a result, much of our inventory is stored at a single warehouse maintained by one such service provider. We substantially rely on this service provider as well as other third-party providers that perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter physical or natural damage at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired and we may be subject to regulatory enforcement action.

In addition, we may engage third parties to perform various other services for us relating to adverse event reporting, safety database management, fulfillment of requests for medical information regarding our products and related services. If the quality or accuracy of the data maintained by these service providers is insufficient, or these third parties otherwise fail to comply with regulatory requirements related to adverse event reporting, we could be subject to regulatory sanctions.

Additionally, if a third-party errs in calculating government pricing information from transactional data in our financial records, it could impact our discount and rebate liability and potentially cause government programs to overpay providers for our products, which could expose us to significant False Claims Act liability and other civil monetary penalties.

Any collaboration arrangements that we are a party to or may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.

Our business model is to commercialize our product candidates in the United States, and we may either commercialize products outside the United States ourselves or collaborate with pharmaceutical or biotechnology companies, or academic institutions, for the development or commercialization of our product candidates in the rest of the world. For example, we currently commercialize Sunosi in Canada. In February 2023, we announced a licensing transaction with Pharmanovia to market Sunosi in Europe and certain countries in the Middle East / North Africa. Our current and future collaboration arrangements may not be successful, and the success of them will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaboration arrangements. For clinical trials of our product candidates being conducted by our collaborators, for example, the Phase 2 clinical trial of AXS-05 for smoking cessation in collaboration with Duke University, we relied on timeline estimates provided by our collaborators for these trials. Such timeline estimates may differ materially from actual trial completion dates. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority.

We may license the right to market and sell our product candidates under our collaborators' labeler codes. Alternatively, we may enter into agreements with collaborators to market and sell our product candidates under our own labeler code, in which case errors and omissions by collaborators in capturing and transmitting transactional data may impact the accuracy of our government price reporting.

Collaborations with pharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation. Any future collaborations we might enter into may pose a number of risks, including:

- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates which achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could fail to make timely regulatory submissions for a product candidate;
- collaborators may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates 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;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product candidate or product;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation, or the preferred course of development, might cause delays or termination of the research, development, or commercialization of product candidates, lead to additional responsibilities for us with respect to product candidates, or result in litigation or arbitration, any of which would be time consuming and expensive;

- 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 intellectual property or proprietary information or expose us to potential litigation; and

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability.

If any collaborations we might enter into in the future do not result in the successful development and commercialization of products or if one of our collaborators subsequently terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under the agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates and our product platform.

Additionally, if any future collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our reputation in the business and financial communities could be adversely affected.

We may in the future determine to collaborate with additional pharmaceutical and biotechnology companies and academic institutions for the development and potential commercialization of any of our current or future product candidates. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for collaboration will depend upon, among other things, our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform and our business may be materially and adversely affected.

RISKS RELATED TO INTELLECTUAL PROPERTY

It is difficult and costly to protect our proprietary rights, and, as a result, we may not be able to ensure their protection. In addition, patents have a limited lifespan and will eventually expire.

Market exclusivity awarded by the FDA upon the approval of an NDA is limited in scope and duration. For example, our New Chemical Entity exclusivity for Sunosi expires on June 17, 2024 with an Orphan Drug Exclusivity relating to the product's narcolepsy indication expiring on June 17, 2026. For Auvelity, the New Product Exclusivity expires on August 18, 2025. Neither of these expiry dates take into account the effect of the statutory 30-month stay should we timely commence litigation against any generic filer. A generic filler may be permitted to launch a generic version of either of our products following expiry of these exclusivities if our patents do not preclude a generic launch. Patent litigation is inherently uncertain, and we cannot guarantee the outcome of any such proceedings or that we would succeed in stopping the "at risk" launch of a generic version of either of our currently commercialized products during the pendency of litigation following expiry of the 30-month stay. Such a generic launch could materially impact our commercial success.

We seek to protect intellectual property relating to our products and portfolio products by prosecuting patents in the United States and elsewhere. The patent prosecution process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, should we enter into additional collaborations we may be required to consult with or cede control to collaborators regarding the prosecution, maintenance, and enforcement of our patent applications and patents. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical or biotechnology patents has emerged to date in the United States. The patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents and patent applications or in third-party patents and patent applications. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. Moreover, the patent application process is also subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting any of our current or future product candidates that we may develop, license, or acquire by obtaining and defending patents. For example:

- we may not have been the first to conceive of and reduce to practice the inventions covered by each of our pending patent applications and issued patents;
- we may not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our product candidates or technologies;
- it is possible that none of the pending patent applications will result in issued patents;

- the issued patents may not cover commercially viable active products, may not provide us with any competitive advantages, or may be successfully challenged by third parties;
- we may not develop additional proprietary technologies that are patentable;
- patents of others may have an adverse effect on our business;
- noncompliance with requirements of governmental patent agencies can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction, potentially allowing competitors to enter the market earlier than would otherwise have been the case;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential product candidates; or
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of available patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns.

Patents have a limited lifespan. In most countries, including the United States, the expiration of a patent is typically 20 years from the date that the application for the patent is filed. Various extensions of patent term may be available in particular countries; however, in all circumstances the life of a patent, and the protection it affords, has a limited term. If we encounter delays in obtaining regulatory approvals, the period of time during which we could market a product under patent protection could be reduced. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. Such possible extensions include those permitted under the Drug Price Competition and Patent Term Restoration Act of 1984 in the United States, which permits a patent term extension of up to five years to cover an FDA-approved product. The actual length of the extension will depend on the amount of patent term lost while the product was in clinical trials. However, the applicable authorities, including the U.S. Patent and Trademark Office, or USPTO and the FDA in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data, and then may be able to launch their product earlier than might otherwise be the case.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO and may become involved in post-grant proceedings including reexamination, post-grant review, inter-partes review, or derivation or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding, or litigation could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent prosecution process. Periodic maintenance fees, renewal fees, annuity fees, and various other governmental fees on patents or patent applications will be due to be paid to the USPTO and various patent agencies outside of the United States in several stages over the lifetime of the patents and applications. We have systems in place to remind us to pay these fees, and we employ and rely on reputable law firms and other professionals to effect payment of these fees to the USPTO and non-U.S. patent agencies for the patents and patent applications we own and those that we in-license. We also employ reputable law firms and other professionals to help us comply with the various documentary and other procedural requirements with respect to the patents and patent applications that we own and those that we in-license. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

If we or any future collaboration partner are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in any litigation would harm our business.

Our ability to develop, manufacture, market, and sell any of our current and future products depends upon our ability to avoid infringing the proprietary rights of third parties, and our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market, and sell our products and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties, exist in the general field of treatment and management of CNS disorders and cover the use of numerous compounds and formulations in our targeted markets. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we and our licensors may not be successful in defending intellectual property claims by third parties, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Regardless of the outcome of any litigation, defending against litigation may be expensive, time consuming, and distracting to management. In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that any of our current or future products may infringe. There could also be existing patents of which we are not aware that any of our current or future products may inadvertently infringe.

If a third-party claims that we infringe their intellectual property rights, we could face a number of issues, including:

- infringement and other intellectual property claims which, whether meritorious or not, can be expensive and time consuming to litigate and can divert management’s attention from our core business;
- substantial damages for past infringement which we may have to pay if a court decides that our product infringes on a competitor’s patent;
- a court prohibiting us from selling or licensing our product unless the patent holder licenses the patent to us, which it would not be required to do;
- if a license is available from a patent holder, we may have to pay substantial royalties or grant cross licenses to our patents; and
- redesigning our products and processes so they do not infringe, which may not be possible or could require substantial funds and time.

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 and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, 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, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations, and prospects.

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

Competitors may infringe our issued patents, our in-licensed patents, or other intellectual property that we own or in-license. Under the terms of our license agreements with Antecip, if we believe a third-party is infringing on the patents subject to the licenses, we are obligated, at our own expense, to initiate suit against those third parties. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part; construe the patent's claims narrowly; or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

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

We have licensed and may need to license certain intellectual property from third parties in the future. Such licenses may not be available or may not be available on commercially reasonable terms. Our business may be materially harmed if the licenses are not available or terminated for any reason.

We are a party to certain license agreements under which we are granted rights to intellectual property, including patent rights that are important to our business. We expect that we may need to enter into additional license agreements in the future to commercialize our products, in which case we would be required to obtain a license from additional third parties. Such licenses may not be available on commercially reasonable terms, or at all, which could materially harm our business, financial condition, results of operations, and prospects. We rely on these licenses to use intellectual property that may be material to our business and important or necessary to the development or commercialization of our products. Our existing license agreements impose, and we expect that future license agreements will impose on us, various exclusivity obligations. If we fail to comply with our obligations under these agreements, the applicable licensor may have the right to terminate our license, in which case we may not be able to develop or commercialize the products covered by such license.

In January 2020, we entered into an agreement with Pfizer Inc., or Pfizer, for an exclusive U.S. license to Pfizer's clinical and nonclinical data, and intellectual property for reboxetine, the active pharmaceutical ingredient in AXS-12 which Axsome is developing for the treatment of narcolepsy. The agreement also provides Axsome exclusive rights to develop and commercialize esreboxetine, a new late-stage product candidate now referred to as AXS-14, in the U.S. for the treatment of fibromyalgia. Under the terms of the agreement, we received from Pfizer an exclusive U.S. license to Pfizer data for reboxetine and esreboxetine encompassing a full range of nonclinical studies, and short-term and long-term clinical trials involving more than five thousand patients. The licensed data includes results of a positive Phase 3 trial and a positive Phase 2 trial of esreboxetine in the treatment of fibromyalgia. We will have the exclusive right and sole responsibility of developing AXS-14 (esreboxetine) in the U.S. for the treatment of fibromyalgia and for other indications. Pfizer received 82,019 shares of our common stock having a value of $8.0 million, based on the average closing price of our common stock for the 10 prior trading days of $97.538, in consideration for the license and rights. Pfizer also received an upfront cash payment of $3.0 million and will receive up to $323 million in regulatory and sales milestones, and tiered mid-single to low double-digit royalties on future sales. Pfizer will also have a right of first negotiation on any potential future strategic transactions involving AXS-12 and AXS-14. Under the agreement, we are obligated to use commercially reasonable efforts to develop, manufacture and commercialize the compounds and products in the United States and to seek and maintain regulatory approvals for the compounds and products. The agreement will expire on a product-by-product basis upon expiration of the last-to-expire royalty term for such product. On expiration (but not earlier termination), we will have a perpetual, non-exclusive, fully paid, royalty-free and irrevocable license under the licensed patent rights and related data to develop, manufacture, use, commercialize and otherwise exploit the compounds. Either party may terminate the agreement for the other party's material breach following a cure period. Pfizer may immediately terminate the agreement upon certain insolvency events relating to us. We may terminate the agreement for any reason upon ninety days written notice to Pfizer at any time after the first anniversary of the agreement. If the license agreement with Pfizer is terminated for any reason, our business, financial condition, results of operations, and prospects will be materially harmed.

In 2012, we entered into three exclusive license agreements with Antecip Bioventures II LLC, or Antecip, an entity owned by our Chief Executive Officer and Chairman of the Board, Herriot Tabuteau, M.D., in which we were granted exclusive licenses to develop, manufacture, and commercialize Antecip's patents and applications related to the development of AXS-05, as well as two product candidates that are not currently in development, anywhere in the world for human therapeutic, veterinary, and diagnostic use. The agreements were amended in August 2015 to update the schedule of patents and applications subject to the license agreements. Pursuant to the agreements, we are required to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize AXS-05. Under the terms of the agreements, we are required to pay to Antecip a royalty equal to 3.0% for AXS-05, of net sales of products containing the licensed technology by us, our affiliates, or permitted sublicensees. These royalty payments are subject to reduction by an amount up to 50.0% of any required payments to third parties. Unless earlier terminated by a party for cause or by us for convenience, the agreements remain in effect on a product-by-product and country-by-country basis until the later to occur of (1) the applicable product is no longer covered by a valid claim in that country or (2) 10 years from the first commercial sale of the applicable product in that country. Upon expiration of the agreements with respect to a product in a country, our license grant for that product in that country will become a fully paid up, royalty free, perpetual non-exclusive license. If Antecip terminates any of the agreements for cause, or if we exercise our right to terminate any of the agreements for convenience, the rights granted to us under such terminated agreement will revert to Antecip. We are dependent upon the license agreements with Antecip and if any of the license agreements with Antecip are terminated for any reason, our business, financial condition, results of operations, and prospects will be materially harmed.

In connection with the acquisition of Sunosi, in addition to the upfront purchase price, we assumed certain liabilities in connection with the acquisition and agreed to make non-refundable, non-creditable royalty payments to Jazz on U.S. net sales. There are no royalty payments due to Jazz for net sales outside of the U.S. In addition, we assumed all of the commitments of Jazz to SK and Aerial. The assumed commitments to SK and Aerial include single-digit tiered royalties and certain sales and development milestones. We are dependent on these agreements, and if we breach these agreements, our business, financial condition, results of operations, and prospects will be materially harmed.

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

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

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We rely on trade secrets to protect our proprietary technological advances and know-how, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, contractors, outside scientific collaborators, sponsored researchers, and other advisors, including the third parties we rely on to manufacture our products, to protect our trade secrets and other proprietary information. However, any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets. Accordingly, these agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. In addition, others may independently discover our trade secrets and proprietary information. Further, the FDA, as part of its Transparency Initiative, a proposal to increase disclosure and make data more accessible to the public, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects upon our competitive business position and financial results.

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

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

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

RISKS RELATED TO LEGAL AND COMPLIANCE MATTERS

If we fail to comply with federal, state, and foreign healthcare laws, including fraud and abuse and transparency and health and other data protection, information privacy and security laws, we could face substantial penalties and our business, financial condition, results of operations, and prospects could be adversely affected.

As a pharmaceutical company, we are subject to many federal and state healthcare laws, including those described in the "Business—Government Regulation and Product Approval" section of the filed Annual Report on Form 10-K, such as the federal Anti-Kickback Statute, the federal civil and criminal False Claims Act, the civil monetary penalties statute, the Medicaid Drug Rebate statute and other price reporting requirements, the Veterans Health Care Act of 1992, the Physician Payments Sunshine Act, the Foreign Corrupt Practices Act of 1977, the Patient Protection and Affordable Care Act of 2010, and similar state and foreign laws. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid, or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We are subject to healthcare fraud and abuse laws by both the federal government and the states in which we conduct our business.

There are numerous other laws and legislative and regulatory initiatives at the federal and state levels addressing privacy and security concerns, and some state privacy and security laws apply more broadly than the Health Insurance Portability and Accountability Act (HIPAA) and its implementing regulations. For example, California enacted legislation – the California Consumer Privacy Act, or CCPA – which went into effect in January 2020. The CCPA, among other things, creates data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Further, many data privacy and security laws within the U.S. have concurrent jurisdiction, which could subject us to enforcement by multiple agencies under multiple statutes for the same conduct (e.g., FTC enforcement under Section 5, HHS-Office for Civil Rights enforcement under HIPAA, and actions by state Attorneys General for violation of applicable state laws).

In addition, EU member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. Moreover, the collection and use of personal health data in the EU, which was formerly governed by the provisions of the EU Data Protection Directive, was replaced with the EU General Data Protection Regulation, or the GDPR, in May 2018. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU to the U.S., provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. The GDPR requirements apply not only to third-party transactions, but also to transfers of information between us and our subsidiaries, including employee information. The recent implementation of the GDPR has increased our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business. Moreover, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EU and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

If we or our operations are found to be in violation of any federal or state healthcare, data or information privacy law, or any other governmental regulations that apply to us, we may be subject to penalties, including civil, criminal, and administrative penalties, damages, fines, disgorgement, debarment from government contracts, refusal of orders under existing contracts, exclusion from participation in U.S. federal or state health care programs, corporate integrity agreements, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, it may be subject to criminal, civil, or administrative sanctions, including but not limited to, exclusions from participation in government healthcare programs, which could also materially affect our business.

Although an effective compliance program can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with applicable federal and state fraud laws may prove costly. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

If the government or third-party payors fail to provide adequate coverage and payment rates for any of our current or future product candidates, or if health maintenance organization (HMOs) or long-term care facilities choose to use therapies that are less expensive, our revenue and prospects for profitability will be limited.

In both domestic and foreign markets, sales of our products depend in part upon the availability of coverage and reimbursement from third-party payors. Such third-party payors include government health programs such as Medicare and Medicaid, managed care providers, private health insurers, and other organizations. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Many private payors employ "new-to-market blocks" for newly launched medications and other products until the payors have had the opportunity to make a coverage decision based upon their internal review of such products. When a medication or other product is not covered, the patient is responsible to pay the full price, which can significantly limit utilization. If reimbursement is not available, or is available only to limited levels, our product candidates may be competitively disadvantaged, and we, or our collaborators, may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us, or our collaborators, to establish or maintain a market share sufficient to realize a sufficient return on our or their investments. Alternatively, securing favorable reimbursement terms may require us to compromise pricing and prevent us from realizing an adequate margin over cost.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved drugs. Marketing approvals, pricing, and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the product in that country. Additionally, drug pricing is a key state and federal issue within the U.S., with recent legislation and additional proposals designed to bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare and Medicaid, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. We expect continued focus and pressure on drug pricing going forward. Adverse pricing limitations may hinder our ability or the ability of our collaborators to recoup our or their investment in one or more of our products or product candidates. Our ability, and the ability of our collaborators, to commercialize our product candidates will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. Regulatory authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will cover and establish reimbursement levels. The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Several third-party payors are requiring that drug companies provide them with predetermined discounts from list prices, are using preferred drug lists to leverage greater discounts in competitive classes, are disregarding therapeutic differentiators within classes, and are challenging the prices charged for drugs. Brand drugs without generic equivalents are often included in therapeutic classes with other brands that have generic versions and may be similarly disadvantaged by the availability of low-cost alternatives within the class, particularly if a generic version of the same agent is available in another form.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for our products or product candidates for which we receive regulatory approval may not be available or adequate in either the United States or international markets, which could have a negative effect on our business, financial condition, results of operations, and prospects.

Assuming coverage is approved, the resulting reimbursement payment rates might not be adequate. If payors subject our products to maximum payment amounts or impose limitations that make it difficult to obtain reimbursement, providers may choose to use therapies which are less expensive or have fewer access restrictions when compared to our product candidates. Additionally, if payors require high copayments, beneficiaries may decline prescriptions and seek alternative therapies. We may need to conduct post-marketing studies in order to demonstrate the cost effectiveness of any our products to the satisfaction of hospitals and other target customers and their third-party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Our products might not ultimately be considered cost effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

In addition, federal programs impose penalties on manufacturers of drugs marketed under an NDA, including 505(b)(2) drugs, in the form of mandatory additional rebates and/or discounts if commercial prices increase at a rate greater than the Consumer Price Index Urban, and these rebates and/or discounts, which can be substantial, may impact our ability to raise commercial prices. Regulatory authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability or that of our collaborators to sell our product candidates profitably. These payors may not view our products, if any, as cost effective, and coverage and reimbursement may not be available to our customers, or those of our collaborators, or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. Cost control initiatives could cause us, or our collaborators, to decrease, discount, or rebate a portion of the price we, or they, might establish for products, which could result in lower than anticipated product revenues. If the realized prices for our products, if any, decrease or if governmental and other third-party payors do not provide adequate coverage or reimbursement, our prospects for revenue and profitability will suffer.

There may also be delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for 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, by way of example, according to the use of the drug and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost drugs or may be incorporated into existing payments for other services.

Prices paid for a drug also vary depending on the class of trade. Prices charged to government customers are subject to price controls, including ceilings, and private institutions obtain discounts through group purchasing organizations. Net prices for drugs may be further reduced by mandatory discounts or rebates required by government healthcare programs and demanded by private payors. Drugs approved under NDAs, including 505(b)(2) drugs, are subject to greater discounts and reporting obligations under federal programs than drugs approved under ANDAs, and the inflation penalty applicable to these products can equal the selling price. It is also not uncommon for market conditions to warrant multiple discounts to different customers on the same unit, such as purchase discounts to institutional care providers and rebates to the health plans that pay them, which reduces the net realization on the original sale.

In addition, increasingly, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. We, and our collaborators, cannot be sure that coverage will be available for any product that we, or they, commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. An inability to promptly obtain coverage and adequate payment rates from both government funded and private payors for any our product candidates for which we obtain marketing approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

We are subject to new legislation, regulatory proposals, and healthcare payor initiatives that may increase our costs of compliance, and adversely affect our ability to market our products, obtain collaborators, and raise capital.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, and affect our ability, or the ability of our collaborators, to profitably sell any products for which we obtain marketing approval. It is unclear what impact these various efforts have and will have on our business operations and resulting financial condition. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or our collaborators, may receive for any approved products.

It is unclear how regulations and sub-regulatory policy, which fluctuate continually, may affect interpretation and further implementation of the Patient Protection and Affordable Care Act, or the ACA and its practical effects on our business. We are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare, including drugs and biologics. Any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations. Furthermore, we anticipate that the Biden administration will issue a number of Executive Orders, which may alter the policies of the previous administration. Additionally, certain agency rules and policy statements of the prior four years may be rescinded. Further, the Biden administration may propose substantial changes to the U.S. healthcare system, including expanding government-funded health insurance options. We are uncertain of the impact or outcome of these potential Executive Orders, rescission of rules and policy statements, or new legislation, especially any relative impact on the healthcare regulatory and policy landscape, or the impact they may have on our business.

While the full effect that the ACA may have on our business continues to evolve, we expect that the ACA, as well as other federal and state healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria, increased regulatory burdens and operating costs, decreased net revenue from our pharmaceutical products, decreased potential returns from our development efforts, and additional downward pressure on the price that we receive for any approved drug. There is also an increasing focus on the price of drugs, both at the state and federal levels, and it is likely that additional pricing controls will be enacted and could harm our business, financial condition and results of operations. For instance, states such as California have begun enacting transparency laws aimed at curbing drug price increases and with the change in administration it is possible that President Biden may issue Executive Orders with the potential to change a number of prior executive branch actions on drug pricing. We continue to monitor the potential impact of proposals and recently enacted legislation to lower prescription drug costs at the federal and state level. For example, the Inflation Reduction Act, or the IRA, was recently signed into law by President Biden, which makes significant changes to how drugs are covered and paid for under the Medicare program, including the creation of financial penalties for drugs whose prices rise faster than the rate of inflation, redesign of the Medicare Part D program to require manufacturers to bear more of the liability for certain drug benefits, and government price-setting for certain Medicare Part D drugs, starting in 2026, and Medicare Part B drugs starting in 2028. We are evaluating what effect, if any, the IRA may have on our business. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

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

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the pharmaceutical industry. For instance, the enacted Drug Supply Chain Security Act, or DSCSA imposes obligations on manufacturers of prescription drug products for commercial distribution, regulating the distribution of the products at the federal level, and sets certain standards for federal or state registration and compliance of entities in the supply chain (manufacturers and repackagers, wholesale distributors, third-party logistics providers, and dispensers). The DSCSA preempts certain previously enacted state pedigree laws and the pedigree requirements of the Prescription Drug Marketing Act, or PDMA. Trading partners within the drug supply chain must now ensure certain product tracing requirements are met that they are doing business with other authorized trading partners; and they are required to exchange transaction information, transaction history, and transaction statements. Product identifier information (an aspect of the product tracing scheme) is also now required. The DSCSA requirements, development of standards, and the system for product tracing have been and will continue to be phased in over a period of years, with the FDA indicating it would permit certain exemptions and exclusions, and enforcement discretion on certain aspects due to the COVID-19 pandemic, although this situation may continue to evolve. The distribution of product samples continues to be regulated under the PDMA, and some states also impose regulations on drug sample distribution.

Compliance with the federal track and trace requirements may increase our operational expenses and impose significant administrative burdens. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits, or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition, and results of operations.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In international markets, reimbursement and health care payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some countries, particularly the countries of the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. There can be no assurance that our products will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be available, or that the third-party payors' reimbursement policies will not adversely affect our ability to sell our products profitably. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

Our employees, independent contractors, consultants, commercial partners, principal investigators, or CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, independent contractors, consultants, commercial partners, principal investigators, or CROs could include intentional, reckless, negligent, or unintentional failures to comply with FDA regulations, comply with applicable fraud and abuse laws, provide accurate information to the FDA, report financial information or data accurately, or disclose unauthorized activities to us. This misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter this type of misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance 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 significant impact on our business, financial condition, and results of operations, including the imposition of significant fines or other sanctions. Further, even if we are successful in mounting a defense, we may incur substantial costs in preparing and maintaining our defense and any such action would be time- and resource-intensive and potentially divert management's attention from the business, which could adversely affect our ability to operate our business and our results of operations.

Our third-party manufacturers may use hazardous materials in the production of our products and if so, they must comply with environmental laws and regulations, which can be expensive and restrict how we or they do business.

Manufacturing activities for the production of our products involve the controlled storage, use, and disposal of hazardous materials, including the components of our products, and other hazardous compounds. Our third-party manufacturers and we are subject to federal, state, and local laws and regulations governing the use, manufacture, storage, handling, release, and disposal of, and exposure to, these hazardous materials. Violation of these laws and regulations could lead to substantial fines and penalties. Although we believe that our safety procedures, and those of our third-party manufacturers, for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, state or federal authorities may curtail our use of these materials and interrupt our business operations. In addition, we could become subject to potentially material liabilities relating to the investigation and cleanup of any contamination, whether currently unknown or caused by future releases.

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

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations. These current or future laws and regulations may impair our research, development, or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties, or other sanctions.

RISKS RELATED TO OUR BUSINESS OPERATIONS

We have and may continue to significantly increase the size of our organization, and we may experience difficulties in managing growth. If we are unable to implement appropriate controls and procedures to manage our growth, we will not be able to implement our business plan successfully.

As of May 1, 2023, we had 393 full-time employees. Our management, personnel, systems, and facilities currently in place may not be adequate to support future growth. In addition, we may not be able to recruit and retain qualified personnel in the future, particularly for sales and marketing positions, due to competition for personnel among pharmaceutical businesses, and the failure to do so could have a significant negative impact on our future product revenues and business results. Further, the value to employees of stock options or restricted stock units that vest over time is significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Our need to effectively manage our operations, growth and various projects requires that we:

- continue the hiring and training of personnel for an effective commercial organization, and establish appropriate systems, policies and infrastructure to support that organization;
- ensure that our consultants and other service providers successfully carry out their contractual obligations, provide high quality results, and meet expected deadlines;
- continue to carry out our own contractual obligations to our licensors and other third parties; and
- continue to improve our operational, financial, and management controls, reporting systems, and procedures.

We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our development and commercialization goals.

Our continued growth could strain our personnel resources and infrastructure, and if we are unable to implement appropriate controls and procedures to manage our growth, we will not be able to implement our business plan successfully.

As we continue to complete our clinical trials and commercialize our product candidates, and as our company continues to grow, we may experience significant strains on our resources, including to our administrative, operational and financial infrastructure, which will result in additional burdens on management. Our success will depend in part upon the ability of our senior management to manage this growth effectively. To do so, we must continue to hire, train and manage new employees as needed. If our new hires perform poorly, or if we are unsuccessful in hiring, training, managing and integrating these new employees, or if we are not successful in retaining our existing employees, our business would be harmed. To manage the expected growth of our operations and personnel, we will need to continue to improve our operational, financial and management controls and our reporting systems and procedures.

We may acquire businesses or products, or form strategic alliances in the future, and we may not realize the benefits of such acquisitions or alliances.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing, and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

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

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the skills and leadership of our management team, including Dr. Herriot Tabuteau, our Chief Executive Officer and Chairman of the Board. We do not have formal employment agreements with any of our management team. However, we typically enter into offer letters with our executive officers and key personnel. Our senior management may terminate their employment with us at any time. If we lose one or more members of our senior management team, our ability to successfully implement our business strategy could be seriously harmed. Replacing these employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of, and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain, or motivate additional key personnel. We do not maintain “key person” insurance for any of our executives or other employees.

If we fail to maintain an effective system of internal controls 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.

As a public company, we continue to incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and the Nasdaq Global Market, impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure controls and internal control over financial reporting and changes in corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and have made some activities more time-consuming and costly.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. Under Section 404(a) of the Sarbanes-Oxley Act, we are required to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This report must include disclosure of any material weaknesses identified by our management during its periodic assessment of our internal control over financial reporting. A material weakness is a deficiency, or combination of 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(b) of the Sarbanes-Oxley Act also requires our independent auditors to attest to, and report on, this management assessment. Ensuring that we have adequate internal controls in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort. If we are not able to comply with the requirements of Section 404 or if we or our independent registered public accounting firm are unable to attest to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities, which would require additional financial and management resources.

During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we would be required to implement remediation procedures aimed at mitigating the control weakness or weaknesses. Until such remediation procedures succeed in mitigating the control weakness or weaknesses, we would be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses 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 timely and accurately report our financial condition, results of operations or cash flows. The cost of compliance with Section 404 requires us to incur substantial accounting expense and expend significant management time on compliance related issues as we implement additional corporate governance practices and comply with reporting requirements. Although we currently use the services of a third-party accounting firm to assist us with internal controls, we currently do not have an internal audit group, and we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge.

Moreover, if we are not able to comply with these requirements in a timely manner or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline, we could lose investor confidence in the accuracy and completeness of our financial reports, and we could be subject to sanctions or investigations by the Nasdaq Global Market, the SEC or other regulatory authorities, which would require additional financial and management resources. 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 Securities Exchange Act of 1934, as amended, or 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 or internal 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.

In addition, as discussed above, the Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In particular, Section 404 of the Sarbanes-Oxley Act requires us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on, and our independent registered public accounting firm to attest to, the effectiveness of our internal control over financial reporting. Pursuant to Section 404, we are required to provide an annual management report on the effectiveness of our internal control over financial reporting and we will also be required to include with such annual report an attestation report on internal controls over financial reporting issued by our independent registered public accounting firm. In the future, our independent registered public accounting firm may issue a report that is adverse in the event that we have not maintained effective internal controls over financial reporting, in all material respects. Any failure to maintain effective disclosure controls and internal control over financial reporting could have a material and adverse effect on our business, results of operations and financial condition and could cause a decline in the trading price of our common stock.

These inherent limitations include the realities that judgments in decision-making 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 or insufficient disclosures due to error or fraud may occur and not be detected.

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

Despite our implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product candidate development programs. For example, the loss of clinical trial data from completed, ongoing, or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential, or proprietary information, we could incur liability and the further development of any of our product candidates could be delayed.

Environmental, social and governance matters may impact our business and reputation.

Governmental authorities, non-governmental organizations, customers, investors, external stakeholders and employees are increasingly sensitive to environmental, social and governance, or ESG, concerns, such as diversity and inclusion, climate change, water use, recyclability or recoverability of packaging, and plastic waste. This focus on ESG concerns may lead to new requirements that could result in increased costs associated with developing, manufacturing and distributing our products. Our ability to compete could also be affected by changing customer preferences and requirements, such as growing demand for more environmentally friendly products, packaging or supplier practices, or by failure to meet such customer expectations or demand. While we strive to improve its ESG performance, we risk negative stockholder reaction, including from proxy advisory services, as well as damage to its brand and reputation, if we do not act responsibly, or if we are perceived to not be acting responsibly in key ESG areas, including equitable access to medicines and vaccines, product quality and safety, diversity and inclusion, environmental stewardship, support for local communities, corporate governance and transparency, and addressing human capital factors in our operations. If we do not meet the ESG expectations of its investors, customers and other stakeholders, we could experience reduced demand for its products, loss of customers, and other negative impacts on our business and results of operations.

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

An active trading market for our common stock may not be sustained.

In November 2015, we closed our initial public offering. Prior to our initial public offering, there was no public market for shares of our common stock. Although we have completed our initial public offering and shares of our common stock are listed and trading on The Nasdaq Global Market, an active trading market for our shares may not be sustained. If an active market for our common stock does not continue, it may be difficult for our stockholders to sell their shares without depressing the market price for the shares or sell their shares at or above the prices at which they acquired their shares or sell their shares at the time they would like to sell. Any inactive trading market for our common stock may also impair our ability to raise capital to continue to fund our operations by selling shares.

The market price of our common stock may be highly volatile.

The trading price of our common stock is likely to be highly volatile. For example, in 2019, we experienced an extraordinary level of appreciation in our stock price. Such levels of gain are unlikely to continue in the future. Throughout the course of fiscal years 2020, 2021, and 2022, we saw both significant appreciations and depreciations in our stock price. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- the commercial success of our products;
- delays in the commencement, enrollment, and ultimate completion, of our planned and ongoing Phase 3 clinical trials for our product candidates;
- any delay or refusal on the part of the FDA in approving an NDA for any of our current and future product candidates;
- operating and stock price performance of other companies that investors deem comparable to ours;
- recommendations by securities analysts;
- news relating to our industry as a whole and news relating to trends in our markets;
- results of clinical trials of any of our current and future product candidates or those of our competitors;
- actual or anticipated variations in quarterly or annual operating results;
- failure to meet or exceed financial projections we provide to the public, if any;
- failure to meet or exceed the estimates and projections of the investment community, including securities analysts;
- introduction of competitive products or technologies;

- changes or developments in laws or regulations applicable to our product candidates;
- the perception of the pharmaceutical industry by the public, legislatures, regulators, and the investment community;
- general economic and market conditions and overall fluctuations in U.S. equity markets;
- data or security breaches;
- developments concerning our sources of manufacturing supply, warehousing, and inventory control;
- disputes or other developments relating to patents or other proprietary rights;
- additions or departures of key scientific or management personnel;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- capital commitments;
- investors' general perception of our company and our business;
- announcements and expectations of additional financing efforts, including the issuance of debt, equity or convertible securities;
- sales of our common stock, including sales by our directors and officers or significant stockholders;
- changes in the market valuations of companies similar to us;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, or divestitures;
- general conditions or trends in our industry; and
- the other factors described in this "Risk Factors" section.

In addition, the stock market in general, and the market for mid-cap 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. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business, or our market, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us and our business. We do not have any control over the equity research analysts that provide research coverage of our common stock or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrades our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- the commercial success of our products;
- whether the FDA requires us to complete additional, unanticipated studies, tests, or other activities prior to approving any of our current and future product candidates, which may delay any such approval;

- our ability to identify and enter into third-party manufacturing arrangements capable of manufacturing any of our current or future product candidates in commercial quantities;
- our execution of other collaborative, licensing, or similar arrangements and the timing of payments we may make or receive under these arrangements;
- variations in the level of expenses related to our future development programs;
- any product liability or intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting our current products, or the products of our competitors; and
- the level of underlying demand for our products

If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Raising additional funds by issuing securities may cause dilution to existing stockholders and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

We may finance our cash needs through a combination of equity offerings, debt financings, grants, and license and development agreements in connection with any collaborations until such time, if ever, as our product sales are sufficient to meet our cash needs. To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends.

If we raise additional funds through collaborations, strategic alliances, or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. Any debt financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem our stock, or make investments. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our principal stockholders and management own a significant percentage of our stock and may be able to exert significant control over matters subject to stockholder approval.

As of May 1, 2023, our executive officers, directors, and 5% stockholders and their affiliates beneficially owned an aggregate of approximately 44% of our outstanding common stock. As a result, these stockholders have significant influence and may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This concentration of ownership could delay or prevent any acquisition of our company on terms that other stockholders may desire and may adversely affect the market price of our common stock.

Some of these persons or entities may have interests different than our other stockholders. For example, these stockholders, if they acted together, could significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. These stockholders may be able to determine all matters requiring stockholder approval. The interests of these stockholders may not always coincide with our interests or the interests of other stockholders. This may also prevent or discourage unsolicited acquisition proposals or offers for our common stock that other stockholders may feel are in their best interest and our large stockholders may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise adequate capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

As of May 1, 2023, we have outstanding 43,573,213 shares of common stock and 8,960,627 shares of common stock equivalents that would increase the number of common stock outstanding if these instruments were exercised or converted, including stock options to purchase common stock based on vesting requirements and warrants to purchase common stock, as well as outstanding restricted stock units. Of our currently outstanding shares of common stock, 35,553,712 are freely tradable. The remainder of the outstanding shares of common stock are held by our affiliates and may be considered “control securities” for purposes of Rule 144 under the Securities Act.

In addition, we have filed one or more registration statements on Form S-8 registering the issuance of an aggregate of 13,705,956 shares of common stock subject to options or other equity awards issued or reserved for future issuance under our 2015 Omnibus Incentive Compensation Plan, or the Plan (inclusive of shares registered pursuant to the Form S-8 filed contemporaneously herewith). Shares registered under registration statements on Form S-8 will be available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and the restrictions of Rule 144 in the case of our affiliates.

Our management will have broad discretion in the use of the net proceeds from our capital raises, including the proceeds from sales pursuant to our Sales Agreement, and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from our capital raises, which we refer to as our Capital Raises, including the proceeds from sales pursuant to our March 2022 "at-the-market" sales agreement with SVB Securities LLC (formerly known as SVB Leerink LLC, or SVB Leerink), or SVB Securities, which provides for the sale of up to $250.0 million of our common stock from time to time, and our stockholders will not have the opportunity as part of their investment decision to assess whether the net proceeds from our Capital Raises are being used appropriately. Our stockholders may not agree with our decisions, and our use of the proceeds may not yield any return on investment for our stockholders. Because of the number and variability of factors that will determine our use of the net proceeds from our Capital Raises their ultimate use may vary substantially from their currently intended use. Our failure to apply the net proceeds of our Capital Raises effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of those net proceeds. Our stockholders will not have the opportunity to influence our decisions on how to use our net proceeds from our Capital Raises. Pending their use, we may invest the net proceeds from our Capital Raises in short-term, investment-grade, interest-bearing instruments and U.S. government securities. These temporary investments are not likely to yield a significant return.

The use of our net operating loss carryforwards and research tax credits may be limited.

Our net operating loss carryforwards and any future research and development tax credits may expire and not be used. As of December 31, 2022, we had U.S. federal net operating loss, NOL, carryforwards of approximately $458 million and foreign NOL carryforwards of $7.8 million. U.S. federal net operating loss carry forwards amounting to $60 million generated before the 2018 tax year will start expiring beginning 2032, if we have not used them prior to that time, and the U.S. federal net operating losses of approximately $398 million generated in 2018 and later have an indefinite carryforward period. Net operating loss carry forwards arising in taxable years ending after December 31, 2017, are no longer subject to expiration under the Internal Revenue Code of 1986, as amended, or the Code. Additionally, our ability to use any net operating loss and credit carryforwards to offset taxable income or tax, respectively, in the future will be limited under Sections 382 and 383 of the Code, respectively, if we have a cumulative change in ownership of more than 50% within a three-year period. The completion of our initial public offering, together with our other public and private Capital Raises, and other transactions that have occurred, may trigger, or may have already triggered, such an ownership change. In addition, since we may need to raise additional funding to finance our operations, we may undergo further ownership changes in the future. We have never completed an analysis as to whether such a change of ownership has occurred, but in such an event, we will be limited regarding the amount of net operating loss carryforwards and research tax credits that could be utilized annually in the future to offset taxable income or tax, respectively. Any such annual limitation may significantly reduce the utilization of the net operating loss carryforwards and research tax credits before they expire. In addition, certain states have suspended use of net operating loss carryforwards for certain taxable years, and other states are considering similar measures. As a result, we may incur higher state income tax expense in the future. Depending on our future tax position, continued suspension of our ability to use net operating loss carryforwards in states in which we are subject to income tax could have an adverse impact on our results of operations and financial condition.

Because we do not intend to pay dividends on our common stock, returns for our stockholders will be limited to any increase in the value of our stock.

We have never declared or paid any cash dividends on our capital stock. In addition, the terms of our existing credit facility with Hercules preclude us from paying cash dividends without Hercules' consent. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business and do not anticipate declaring or paying any cash dividends on our common stock for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock, if any. Investors seeking cash dividends should not purchase our common stock.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our amended and restated certificate of incorporation and amended and restated bylaws that may make it difficult for a third-party to acquire, or attempt to acquire, control of our company, even if a change in control was considered favorable by you and other stockholders. For example, our board of directors will have the authority to issue up to 10.0 million shares of preferred stock and to fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. We do not currently have any preferred stock outstanding. The issuance of shares of preferred stock may delay or prevent a change in control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Our amended and restated certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternate form, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders, (3) any action asserting a claim arising pursuant to the DGCL, or (4) any other action asserting a claim against us that is governed by the internal affairs doctrine, in each such case subject to such Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein.

Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees or agents, which may discourage such lawsuits against us and our directors, officers, employees, and agents. Further, this choice of forum provision does not preclude or contract the scope of exclusive federal or concurrent jurisdiction for any actions brought under the Securities Act or the Exchange Act. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. In addition, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Securities Act or any other claim for which the federal and state courts have concurrent jurisdiction. Accordingly, our exclusive forum provision will not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations.

If a court were to find these provisions of our amended and restated certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition, and results of operations. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and other employees.

Item 6. Exhibits.

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which is incorporated herein by reference.

INDEX OF EXHIBITS

Exhibit Number	Description
10.1**	License Agreement, dated February 21, 2023, by and between Axsome Malta Ltd. and Atnahs Pharma UK Limited.
10.2**	Third Amendment to Loan and Security Agreement, dated January 9, 2023, by and among Axsome Therapeutics, Inc., the Lenders who from time to time may be party thereto, and Hercules Capital, Inc., in its capacity as administrative agent and collateral agent for itself and the Lenders.
10.3**	Sublease, dated February 21, 2023, between Advance Magazine Publishers d/b/a Conde Nast and Axsome Therapeutics, Inc.
31.1**	Certification of Principal Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2**	Certification of Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
32.2**	Certification of Principal Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Database Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.)

**Filed herewith.

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.

AXSOME THERAPEUTICS, INC.

Date: May 8, 2023

By /s/ Herriot Tabuteau, M.D.
Herriot Tabuteau, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 8, 2023

By /s/ Nick Pizzie
Nick Pizzie
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.1

LICENSE AGREEMENT

This License Agreement (the "**Agreement**") is entered on February 21, 2023 (the "**Effective Date**"), by and between Axsome Malta Ltd., a Malta limited company with offices at Pinto Business Centre, Level 4, Office 4, Mill Street, Orme, QRM 3104, Malta ("**Axsome**"), on the one hand, and Atnahs Pharma UK Limited, a company organized and existing under the laws of England and Wales with offices at Sovereign House, Miles Grey Road, Basildon, Essex SS14 3FR ("**Licensee**"). Axsome and Licensee may be referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Axsome owns or otherwise controls the Licensed Intellectual Property (as defined below) and desires to grant an exclusive license to Licensee in the Territory (as defined below) for use of the Licensed Intellectual Property for the development and commercialization of Licensed Products (as defined below) in the Field (as defined below) in the Territory; and

WHEREAS, Licensee has extensive experience and expertise in the development and commercialization of pharmaceutical products and desires to acquire such an exclusive license in the Territory to the Licensed Intellectual Property solely for purposes of developing and commercializing Licensed Products in the Field in the Territory.

NOW, THEREFORE, in consideration of the mutual covenants and agreements provided herein, the Parties hereby agree as follows:

1. DEFINITIONS.

1.1. "**Additional Upstream License Payments**" has the meaning set forth in Section 2.1.5.

1.2. "**Affiliate**" means, as of any point in time and for so long as such relationship continues to exist with respect to any Person, any Person that controls, is controlled by or is under common control with such Person. A Person shall be regarded as in control of another Person if it (a) owns or controls at least fifty percent (50%) of the equity securities of the subject Person entitled to vote in the election of directors or (b) possesses, directly or indirectly, the power to direct or cause the direction of the management or policies of any such Person (whether through ownership of securities or other ownership interests, by contract or otherwise).

1.3. "**Agreement**" has the meaning set forth in the preamble.

1.4. "**Arbitration Notice**" has the meaning set forth in Section 10.9.1(a).

1.5. "**Applicable Law**" means any law, statute, rule, regulation, order, judgment or ordinance of any Governmental Authority.

1.6. "**Axsome**" has the meaning set forth in the preamble.

1.7. "**Axsome Developed IP**" has the meaning set forth in Section 5.2.

1.8. "**Axsome Indemnified Party**" has the meaning set forth in Section 9.2.

1.9. "**Bankruptcy Code**" has the meaning set forth in Section 8.4.1.

1.10. "**Bankruptcy Event**" has the meaning set forth in Section 8.4.1.

1.11. "**Binding Obligation**" means, with respect to a Party (a) any oral or written agreement or arrangement that binds or affects such Party's operations or property, including any assignment, license agreement, loan agreement, guaranty, or financing agreement, (b) the provisions of such Party's charter, bylaws or other organizational documents or (c) any order, writ, injunction, decree or judgment of any court or Governmental Authority entered against such Party or by which any of such Party's operations or property are bound.

1.12. "**Business Day**" means a day other than a Saturday, Sunday or bank or other public holiday in New York, New York.

1.13. "**Calendar Quarter**" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.14. "**Commercialize**", "**Commercialized**" or "**Commercializing**" means to register, market, promote, distribute, offer for sale, sell, have sold, import, have imported, export, have exported, transport or otherwise commercialize a pharmaceutical product, and to interact with Regulatory Authorities regarding any of the foregoing. When used as a noun, "Commercialization" means any and all activities involved in Commercializing.

1.15. "**Commercial Milestone**" has the meaning set forth in Section 4.3.

1.16. "**Commercial Milestone Payment**" has the meaning set forth in Section 4.3.

1.17. "**Commercially Reasonable Efforts**" means, with respect to the efforts to be expended by any Person, with respect to any objective, those efforts that would be used by a pharmaceutical or biotechnology company in the same industry as such Person and with resources and capabilities similar to such Person to accomplish a similar objective under similar circumstances. With respect to any objective relating to the research, Development or Commercialization of a Licensed Product, "Commercially Reasonable Efforts" means that level, caliber and quality of efforts and resources consistent with those efforts and resources commonly used by a pharmaceutical or biotechnology company under similar circumstances for similar products or product candidates owned by it or to which it has similar rights, which product or product candidate is at a similar stage in its development or product life and is of similar market potential, taking into account, without limitation, with respect to each Licensed Product, (a) issues of safety, efficacy, product profile, (b) likelihood of receiving Regulatory Approval for the applicable Licensed Product, (c) potential to accelerate the development and regulatory timelines for the Licensed Product, (d) regulatory structure involved, (e) Regulatory Authority-approved labeling, (f) market potential of the Licensed Product, (g) potential benefit of the Licensed Product to patients with the relevant indication, (h) competitiveness in the marketplace, (i) proprietary position and (j) other relevant scientific, technical and business factors. "Commercially Reasonable Efforts" shall be determined on a country-by-country basis and activities that are conducted in one (1) country that have an effect on achieving the relevant objective in another

country shall be considered in determining whether Commercially Reasonable Efforts have been applied in such other countries.

1.18. "**Confidential Information**" has the meaning set forth in Section 6.1.

1.19. "**Control**" or "**Controlled**" means with respect to any Intellectual Property Right or material (including any Patent Right, Know-How or other data, information or material), the ability (whether by sole, joint or other ownership interest, license or otherwise, other than pursuant to this Agreement) to, without violating the terms of any agreement with a Third Party, grant a license or sublicense or provide or provide access or other right in, to or under such Intellectual Property Right or material.

1.20. "**CTA**" means a Clinical Drug Application submitted under Applicable Law to the applicable Regulatory Authority(ies) for the purposes of obtaining permission to conduct clinical trials of a pharmaceutical product in one or more countries or regulatory jurisdictions in the Territory.

1.21. "**Develop**", "**Developed**" or "**Developing**" means to discover, research or otherwise develop a process, compound or product, including conducting non-clinical and clinical research and development activities. When used as a noun, "Development" means any and all activities involved in Developing.

1.22. "**Development Milestone**" has the meaning set forth in Section 4.2.

1.23. "**Development Milestone Payment**" has the meaning set forth in Section 4.2.

1.24. "**Disclosing Party**" has the meaning set forth in Section 6.2.

1.25. "**Disclosure Schedule**" has the meaning set forth in Section 7.3.

1.26. "**Dispute**" has the meaning set forth in Section 10.9.1.

1.27. "**Dossier**" means a copy of all updated administrative, quality, non-clinical and clinical documents, in Axsome's possession in an e-submission ready format, which are required to obtain and maintain the Regulatory Approval in each country of the Territory, written in English and (a) compiled according to the requirements of applicable laws and regulations in each country of the Territory including those of the EU Notices to Applicants (EU CTD), in force from time to time, and (b) in such form and of such content as is required by the Regulatory Authorities, in order for them to accept application for, grant and maintain the Regulatory Approval.

1.28. "**Effective Date**" has the meaning set forth above in the preamble of this Agreement.

1.29. "**Field**" means (i) therapeutic treatment to reduce excessive daytime sleepiness in human adults with narcolepsy or obstructive sleep apnea and (ii) treatment of attention deficit hyperactivity disorder in humans, and (iii) such other indications as may be added to the Field pursuant to Section 2.1.7.

1.30. "**First Commercial Sale**" shall mean, with respect to any Licensed Product in any country of the Territory, the first sale in such country for use or consumption by the end user of such Licensed Product to a Third Party by Licensee or its Affiliates or their Sublicensee after Regulatory Approval (and, where applicable, (i) pricing or reimbursement approval in such country and (ii) labeling approval) has been granted by the applicable Regulatory Authority.

1.31. "**Force Majeure**" has the meaning set forth in Section 10.3.

1.32. "**Governmental Authority**" means any court, agency, department, authority or other instrumentality of any supranational, national, state, county, city or other political subdivision. For clarity, for purposes of this Agreement, the EU Medicines Agency and the EU Commission shall each be considered to be a Governmental Authority.

1.33. "**ICC**" has the meaning set forth in Section 10.9.2(a).

1.34. "**Improvement**" means, whether or not patentable, any improvement, modification or variation of any of the Licensed Know-How or any invention claimed or disclosed in any of the Licensed Patent Rights, including without limitation, any improvement, modification or variation to the composition, method of manufacture of or methods of using any Licensed Compound or product containing any Licensed Compound, which improvement, modification or variation is made after the Effective Date.

1.35. "**Indemnified Party**" has the meaning set forth in Section 9.4.1.

1.36. "**Indemnifying Party**" has the meaning set forth in Section 9.4.1.

1.37. "**Infringement Claim**" has the meaning set forth in Section 5.7.1.

1.38. "**Intellectual Property Rights**" means all copyrights, trade secrets, Trademarks, moral rights, Patent Rights, Know-How and any and all other intellectual property or proprietary rights now known or hereafter recognized in any jurisdiction.

1.39. "**Joint Developed IP**" has the meaning set forth in Section 5.2

1.40. "**Know-How**" means any invention, discovery, development, data, information, process, method, technique, material (including any chemical or biological material), technology, result, cell line, compounds, probe, sequence or other know-how, whether or not patentable, and any physical embodiments of any of the foregoing.

1.41. "**Licensee**" has the meaning set forth in the preamble.

1.42. "**Licensee Developed IP**" has the meaning set forth in Section 5.2

1.43. "**Licensee Diligence Obligations**" means Licensee's Development and Regulatory Approval diligence obligations under Section 3.2.1 and Licensee's Commercialization diligence obligations under Section 3.2.2.

1.44. "**Licensee Indemnified Party**" has the meaning set forth in Section 9.3.

1.45. "**Liability**" has the meaning set forth in Section 9.2.

1.46. "**Licensed Activities**" has the meaning set forth in Section 5.6.1.

1.47. "**Licensed Compound**" means (*R*)-2-amino-3-phenylpropylcarbamate (also known as "solriamfetol") and any stereoisomer, polymorph, prodrug, esters, salt or other chemical or pharmaceutical modification thereof.

1.48. "**Licensed Intellectual Property**" means the Licensed Patent Rights, the Dossier, and the Licensed Know-How, including any Improvements.

1.49. "**Licensed Know-How**" means any Know-How that

(a) either (i) is Controlled by Axsome or any of its Affiliates as of the Effective Date or (ii) comes into the Control of Axsome or any of its Affiliates during the Term; and

(b) relates to any Licensed Compound or Licensed Product or to the Development, Commercialization or Manufacture in the Territory or use of any Licensed Compound or Licensed Product.

Notwithstanding the foregoing, any Know-How Controlled by Axsome or its Affiliates pursuant to the grant by a Third Party to Axsome or such Affiliate of a license which license is not granted under an Upstream License (including those licenses entered during the Term) shall not be included in Licensed Know-How.

1.50. "**Licensed Patent Rights**" means any Patent Right in the Territory that (a) is Controlled by Axsome or any of its Affiliates as of the Effective Date or otherwise comes into the Control of Axsome or any of its Affiliates during the Term and (b) claims or discloses any (i) Licensed Compound or Licensed Product (including the composition of matter thereof), or (ii) method of using any Licensed Compound of Licensed Product. Licensed Patent Rights includes, without limitation, the existing Patent Rights listed in Schedule 1.50. Notwithstanding the foregoing, any Patent Right Controlled by Axsome or its Affiliates pursuant to the grant by a Third Party to Axsome or such Affiliate of a license which license is not granted under an Upstream License (including those entered during the Term) shall not be included in Licensed Patent Rights.

1.51. "**Licensed Product**" means any pharmaceutical product containing a Licensed Compound as an active ingredient, including the product which, as of the Effective Date, is being sold by Axsome under the trademark Sunosi®.

1.52. "**Licensed Trademarks**" means such Trademarks in the Territory as are listed in Schedule 1.52. For the avoidance of doubt, (i) any Trademark owned or Controlled by Axsome or its Affiliates which is not listed on Schedule 1.52 and (ii) the names and logos of Axsome or its Affiliates, shall not be considered to be Licensed Trademarks.

1.53. "**Licensee Data**" has the meaning set forth in Section 3.3.3.

1.54. "**Litigation Conditions**" has the meaning set forth in Section 9.4.2.

1.55. "**Marketing Authorization Holder**" or "**MAH**" has the meaning set forth in Section 3.4.1.

1.56. "**Manufacture**", "**Manufactured**" or "**Manufacturing**" means to make, produce, manufacture, process, fill, finish, package, label, perform quality assurance testing, release, ship or store a compound or product or any component thereof. When used as a noun, "Manufacture" or "Manufacturing" means any and all activities involved in Manufacturing a compound or product or any component thereof.

1.57. "**Net Sales**" means the gross amounts invoiced by any of Licensee, its Affiliates or its their Sublicensees (each, a "**Selling Party**") for sales of Licensed Product in the Territory to unaffiliated Third Parties (other than sales by Licensee or its Affiliates to Sublicensees for resale to Third Parties) in bona fide, arms-length transactions, less the following amounts actually paid or incurred by the Selling Party with respect to the sale of such Licensed Products, to the extent not already reflected or deducted: (i) trade, cash or quantity discounts, allowances, adjustments and rejections; (ii) rebates, chargebacks, recalls and returns; (iii) price reductions or rebates imposed by competent authorities; (iv) price reductions or rebates accorded to managed care systems (that is, systems that integrate the financing and delivery of healthcare services to covered members, including but not limited to, pharmacy benefit managers (PBMs), prescription drug plans (PDPs), health maintenance organizations (HMOs), preferred provider organizations (PPOs), independent practice associations (IPAs) and other similar healthcare organizations); (v) sales, excise, turnover, value-added tax (except to the extent that the net VAT amounts collected by the Selling Party exceed the net VAT paid to a taxing authority) and similar taxes assessed on the royalty-bearing sale of such Licensed Product, but not including any income tax or franchise tax of any kind; and (vi) to the extent separately itemized on the applicable invoice, transportation, importation, shipping, insurance and other handling expenses; in each case as calculated in accordance with United States generally accepted accounting principles or such other accounting principles as the Selling Party shall apply on a consistent basis.

A sale of a Licensed Product shall be deemed consummated upon the first to occur of: (a) receipt of payment from the purchaser; (b) ninety (90) days after the Selling Party has invoiced the purchaser; (c) disposition of Licensed Products by gift or without issuance of invoice; provided that the supply of Licensed Products without cost or receipt of other consideration (x) as commercial samples, (y) as charitable donations, or (z) for use in clinical studies shall be excluded from the computation of Net Sales. Sales to wholesalers and other distributors shall be considered bona fide, arms-length transactions to Third Parties to the extent that each such distributor purchases its requirements of such Licensed Product from the Selling Party in finished package form (ready for use by the ultimate consumer) at fair market value for resale and/or distribution, but does not otherwise make any royalty payment, or give any other consideration (in whatever form, including barter of property, lump sums payments, marketing, distribution, option or milestone payments, or any premium/discount paid over fair market value for securities), to any Selling Party, directly or indirectly, with respect to the Licensed Product or the Intellectual Property Rights controlled by any Selling Party with respect to such Licensed Product.

Net Sales with respect to sales in non-arms-length transactions will be computed at the average price of bona fide, arms-length sales by a Selling Party to Third Parties during the preceding three (3)-month period; or, if no bona fide, arms-length sale to a Third Party has yet occurred, at the non-discounted list price for the Licensed Product sold directly by the Selling Party to end users.

In the event no list price has been established, the price will be set at the average list price of three (3) commercially similar products.

1.58. "**Party**" or "**Parties**" has the meaning set forth in the preamble.

1.59. "**Patent Rights**" means any and all (a) issued patents, (b) pending patent applications, including all provisional applications, substitutions, continuations, continuations-in-part, divisions and renewals, and all patents granted thereon, (c) patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including patent term adjustments, patent term extensions, supplementary protection certificates or the equivalent thereof, (d) inventor's certificates, and (e) other forms of government-issued rights substantially similar to any of the foregoing.

1.60. "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision or department or agency of a government.

1.61. "**Projection Period**" has the meaning set forth in Section 3.7(b).

1.62. "**Receiving Party**" has the meaning set forth in Section 6.2.

1.63. "**Regulatory Approval**" means, with respect to a country or extra-national territory, any and all required approvals, licenses, registrations, or authorizations of any Regulatory Authority necessary in order to commercially distribute, sell or market a product in such country or some or all of such extra-national territory, including emergency use authorizations in any country or extra-national territory.

1.64. "**Regulatory Authority**" means, with respect to a particular country or jurisdiction, the Governmental Authority having responsibility for granting Regulatory Approvals in such country or jurisdiction.

1.65. "**Regulatory Exclusivity**" means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to a Licensed Product in a country or jurisdiction in the Territory, other than a Patent Right, including orphan drug exclusivity, pediatric exclusivity, rights conferred in the European Union under Directive 2001/EC/83, or rights similar thereto in any country or jurisdiction in the Territory.

1.66. "**Representatives**" means, with respect to a Party, such Party, its Affiliates, its sublicensees and each of their respective officers, directors, employees, consultants, contractors and agents.

1.67. "**Response"** has the meaning set forth in Section 10.9.1(a).

1.68. "**Review Period**" has the meaning set forth in Section 6.7.

1.69. "**Royalty Term**" means, with respect to any particular Licensed Product in any particular country in the Territory, the later of (a) the twelfth (12^{th}) anniversary of the First Commercial Sale by or on behalf of Licensee of such Licensed Product in such country, (b) the expiration of all applicable Regulatory Exclusivities of such Licensed Product in the country or

(c) the end of the period during which the Manufacture, sale, offer for sale or importation of such Licensed Product in or for the country would infringe a Valid Claim included within any Licensed Patent Rights or any Patent Rights included in the Joint Developed IP, but for any such licenses granted to Licensee by Axsome under this Agreement.

1.70. "**Selling Party**" has the meaning set forth in Section 1.57.

1.71. "**SK Biopharmaceuticals**" means SK Biopharmaceuticals Co., Ltd., a Korean corporation having a place of business at 99, seorin-dong. Jongro-gu, Seoul, the Republic of Korea, who is the owner of the SK Intellectual Property.

1.72. "**SK Intellectual Property**" means the Patent Rights and Know-How licensed to Axsome pursuant to that certain License Agreement dated as of August 30, 2011, entered into by and between SK Biopharmaceuticals and Aerial Biopharma, LLC (from whom Axsome, through a series of transactions, has acquired the licensed rights under such license agreement).

1.73. "**Steering Committee**" has the meaning set forth in Section 3.8.

1.74. "**Sublicense Agreement**" has the meaning set forth in Section 2.1.6.

1.75. "**Sublicensee**" means any Person to whom Licensee grants or has granted, directly or indirectly, a sublicense of rights licensed by Axsome to Licensee under this Agreement.

1.76. "**Supply Agreement**" has the meaning set forth in Section 3.6.

1.77. "**Term**" has the meaning set forth in Section 8.1.

1.78. "**Territory**" means all member countries of the European Union (as constituted on the Effective Date), the United Kingdom, Switzerland, Iceland, Norway, Lichtenstein, Algeria, Bahrain, Egypt, Iran, Iraq, Jordan, Kuwait, Lebanon, Libya, Morocco, Oman, Qatar, Saudi Arabia, Syria, Tunisia, Turkey, United Arab Emirates and Yemen.

1.79. "**Third Party**" means any Person other than Licensee, Axsome or their respective Affiliates.

1.80. "**Third Party Claim**" has the meaning set forth in Section 9.4.1.

1.81. "**Third Party Infringement**" has the meaning set forth in Section 5.5.1.

1.82. "**Trademark**" means any trademark, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan or other indicia of origin or ownership, including the goodwill and activities associated with each of the foregoing.

1.83. "**Transferred Clinical Trials**" means those clinical trials of the Licensed Product which are listed in Schedule 1.83.

1.84. "**Transferred Regulatory Approvals**" means those Regulatory Approvals listed on Schedule 1.84 .

1.85. "**Transition Plan**" has the meaning set forth in Section 2.5.1.

1.86. "**Upstream Licenses**" means those agreements to which Axsome or an Affiliate of Axsome is a party or becomes a party during the Term (whether initially or by assignment from a Third Party) and under which Axsome or such Affiliate has received an assignment of or been granted a license, with a right to grant sublicenses, under, certain of the Patent Rights included in the Licensed Patent Rights and/or certain of the Know-How included in the Licensed Know-How, provided that, any such agreement entered into by Axsome or an Affiliate of Axsome after the Effective Date, shall only be included as an Upstream License if Licensee, pursuant to Section 2.1.5, agrees to include such agreement as an Upstream License and to pay to Axsome the Additional Upstream License Payments applicable thereto. Those Upstream Licenses existing as of the Effective Date are listed on Schedule 1.86 and, for the avoidance of doubt, no additional payments are payable by Licensee to Axsome in relation thereto.

1.87. "**Upstream Licensor**" means, with respect to an Upstream License, the Third Party under such Upstream License that has granted to Axsome or an Affiliate of Axsome a license, with a right to grant sublicenses, under certain of the Patent Rights included in the Licensed Patent Rights and/or certain of the Know-How included in the Licensed Know-How. For clarity and without limiting the foregoing, SK Biopharmaceuticals is an Upstream Licensor.

1.88. "**Valid Claim**" means, with respect to a particular country, a claim of a Patent Right that (a) is issued or in a pending patent application, (b) has not been held permanently revoked, unenforceable or invalid by a decision of a court or other Governmental Authority of competent jurisdiction, which decision is unappealed or unappealable within the time allowed for appeal, and (c) has not expired or been cancelled, withdrawn, abandoned, disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise.

1.89. "**VAT**" has the meaning set forth in Section 4.5.3.

1.90. **Interpretation**. Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, (b) the use of the singular shall be deemed to include the plural (and vice versa), (c) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation", (d) the word "will" shall be construed to have the same meaning and effect as the word "shall", (e) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (f) any reference herein to any Person shall be construed to include the Person's successors and assigns, (g) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (h) all references herein to Sections, Exhibits or Schedules shall be construed to refer to Sections, Exhibits or Schedules of this Agreement, and references to this Agreement include all Exhibits and Schedules hereto, (i) the word "notice" means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (j) provisions that require that a Party, the Parties or any committee hereunder "agree", "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (k) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any

replacement or successor law, rule or regulation thereof, and (l) the term "or" shall be interpreted in the inclusive sense commonly associated with the term "and/or."

2. LICENSES.

2.1. Licenses Granted by Axsome to Licensee.

2.1.1. Exclusive License Grant. Subject to the terms of this Agreement, Axsome hereby grants to Licensee (a) an exclusive, sublicensable (subject to Section 2.1.6) license under the Licensed Intellectual Property (other than the SK Intellectual Property) and (b) an exclusive, sublicensable (subject to Section 2.1.6) sublicense under the SK Intellectual Property, in each case ((a) and (b)), to use, have used, Develop and have Developed (in each case solely for purposes of seeking or maintaining Regulatory Approvals of the Licensed Product in the Territory or supporting the Commercialization of the Licensed Product in the Territory in the Field), Manufacture and have Manufactured (in each case solely for purposes of Manufacturing Licensed Product to be Commercialized by Licensee, its Affiliates or Sublicensees in the Territory for use in the Field pursuant to this Agreement), Commercialize, have Commercialized, import and have imported Licensed Products in the Field in the Territory. Such license and sublicense grants are exclusive even as to Axsome; provided, however, that, without limiting the right of Licensee to conduct Development of Licensed Products in the Territory, each of Axsome, its Affiliates and its Upstream Licensors shall have the right (x) to conduct research or to Develop or have Developed (but not to Commercialize or have Commercialized) Licensed Products in the Territory and (b) to Manufacture of have Manufactured in the Territory Licensed Compound or products containing the Licensed Compound solely for Commercialization or use outside of the Territory.

2.1.2. Exclusive License Grant to Improvements. During the Term, Axsome shall, without delay at no additional charge, disclose to Licensee any Improvements made by or on behalf of or, subject to Section 2.1.5, otherwise Controlled by Axsome or its Affiliates and shall provide Licensee with all relevant information and materials with respect to such Improvements. For the avoidance of doubt but subject to Section 2.1.5, such Improvements are included within the scope of the Licensed Intellectual Property. Subject to Section 2.1.5, any patents, patent applications or other Patent Rights, each in the Territory, owned by, or Controlled by, or licensed to the Axsome or its Affiliates which relates to or covers Improvements shall be considered Licensed Patent Rights.

2.1.3. Trademark License. Subject to the terms of this Agreement, Axsome hereby grants to Licensee an exclusive (in the Territory), sublicensable (subject to Section 2.1.6), license to use the Licensed Trademarks solely in connection with the exercise of Licensee's rights under Section 2.1.1 for the Commercialization in the Territory of the Licensed Products for use in the Field and solely as set forth in Sections 3.5 and 5.3.

2.1.4. Axsome Covenant. Axsome hereby covenants and agrees with Licensee that, during the Term, neither it nor any of its Affiliates, shall grant any license or right with respect to the Licensed Intellectual Property in the Territory which conflicts with the rights granted by Axsome to Licensee under Sections 2.1.1 or 2.1.2.

2.1.5. Third Party IP. To the extent that, after the Effective Date, Axsome comes into the Control of any Know-How or Patent Rights in the Territory by way of entering into an agreement with a Third Party pursuant to which Axsome acquires ownership of or a license, with the right to grant sublicenses under such Know-How or Patent Rights, where such Know-How relates to, or such Patent Rights claims or disclose any (i) Licensed Compound or Licensed Product (including the composition of matter thereof), or (ii) method of using any Licensed Compound of Licensed Product, Axsome shall notify Licensee and Licensee may elect, by written notice provided to Axsome within thirty (30) days of Axsome's notice to Licensee, whether or not to treat such agreement as an Upstream License and, as a result to, include such Know-How as part of the Licensed Know-How or such Patent Rights as part of the Licensed Patent Rights, provided, however, that in the event Licensee elects to so include such Know-How or Patent Rights in the Licensed Know-How or Licensed Patent Rights, respectively, Licensee, in addition to the payments Licensee is to make to Axsome pursuant to any other provision of this Agreement, including, Article 4 and Sections 3.6, 5.3, 5.4 and 5.5,shall reimburse Axsome for all payments (including upfront fees (to the extent reasonably allocable to the rights for the Territory, milestones, royalties and sublicensing fees) Axsome is required to pay to such Third Party as a result of the grant of a license under or to use or practice such Know-How or Patent Rights or Licensee's use or practice of such Know-How or Patent Rights, including through the development or commercialization of any Licensed Compound or Licensed Product ("**Additional Upstream License Payments**"). If Licensee fails to timely make such election, the agreement entered into with such Third Party shall not be an Upstream License and such Know-How and Patent Rights shall not be included as part of the Licensed Know-How or Licensed Patent Rights, as applicable. For the avoidance of doubt, no additional payments will be made by Licensee in relation to Upstream Licenses in place as of the Effective Date.

2.1.6. Sublicenses. Licensee shall have the right to sublicense, through multiple tiers, the rights granted pursuant to Sections 2.1.1, 2.1.2 and 2.1.3 (a) without Axsome's consent, to Licensee's Affiliates (only for so long as they remain Affiliates of Licensee) and (b) subject to Axsome's prior written consent, not to be unreasonably withheld or delayed, to Third Parties, in each case subject to the requirements of this Section 2.1.6. Each such sublicense shall be granted only pursuant to a written agreement signed by Licensee and the applicable Sublicensee (each, a "**Sublicense Agreement**"). Each Sublicense Agreement shall contain terms and conditions not inconsistent with the terms of this Agreement and with Axsome's obligations under its Upstream Licenses and, without limiting the foregoing, shall impose substantially similar or greater obligations upon such Sublicensees as are imposed upon Licensee by this Agreement, including provisions regarding confidentiality, indemnification, insurance, audit, record-keeping, no challenge, sublicensing and termination, in each case for Axsome's and its Upstream Licensors' protection and shall further require each Sublicensee to (i) comply with all applicable terms of this Agreement, (ii) submit applicable sales or other reports to Licensee to the extent necessary or relevant to the reports required to be made or records required to be maintained under this Agreement, (iii) maintain the confidentiality of and limit the use of all of Axsome's Confidential Information in accordance with Article 6, (iv) cooperate with each of Licensee and Axsome in the prosecution, maintenance and enforcement of

any Licensed Patent Rights and (v) undertake and agree to indemnify the Axsome Indemnified Parties in accordance with Section 9.2. Where Axsome's consent for a Sublicense is required, Licensee shall provide to Axsome a detailed summary of the proposed Sublicensee's marketing and financial capabilities and such other information as Axsome may reasonably request, for Axsome's prior review and consideration in determining whether to provide its consent for such sublicense. Licensee shall provide Axsome with an accurate and complete copy of each Sublicense Agreement entered into by it or its Affiliates, within thirty (30) days after entering into such Sublicense Agreement and Axsome may provide a copy of such Sublicense Agreement to its Upstream Licensors to the extent required under the applicable Upstream License. To the extent that any terms, conditions or limitations of any Sublicense Agreement are inconsistent with this Agreement, those terms, conditions and limitations shall not impose additional obligations, conditions and limitations against Axsome or any Upstream Licensor, except to the extent that Axsome or, if applicable, such Upstream Licensor, at its sole discretion, has expressly consented thereto in writing. Any requests for such consent from an Upstream Licensor shall be submitted through Axsome, unless Axsome provides its written consent (which may be provided or withheld in Axsome's sole discretion) to Licensee for Licensee to communicate directly with such Upstream Licensor with respect thereto. Licensee shall remain directly responsible for all of its obligations under this Agreement whether any such obligations have been delegated, subcontracted or sublicensed to any of Licensee's Affiliates or Sublicensees.

2.1.7. Expansion of Field. In the event that Axsome Develops the version of Licensed Product that Axsome is selling outside of the Territory for a therapeutic indication, other than the therapeutic indications listed in clauses (i) and (ii) of Section 1.29, Axsome shall so notify Licensee and the definition of Field shall automatically be expanded to include such additional therapeutic indications.

2.2. Right of Reference.

2.2.1. Axsome Grant of Right of Reference. Axsome hereby grants to Licensee a "Right of Reference," defined substantially similarly as that term is defined in 21 C.F.R. § 314.3(b) (or any analogous Applicable Law recognized outside of the United States), to all regulatory filings Controlled by Axsome, its Affiliates or any of its or their sublicensees that relates to any Licensed Product to enable Licensee to conduct, to the extent permitted under Section 3.3, Development activities with respect to the Licensed Products and for use by Licensee in connection with the filing and maintenance of Regulatory Approvals or applications for Regulatory Approvals, in each case, solely for the Licensed Products in the Territory, and Axsome shall and shall cause such Affiliates or sublicensees, as applicable, to provide a signed statement to this effect, if requested by Licensee, in accordance with 21 C.F.R. § 314.50(g)(3) (or any analogous Applicable Law recognized outside of the United States).

2.2.2. Licensee Grant of Right of Reference. Licensee hereby grants to Axsome a "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b) (or any analogous Applicable Law recognized outside of the United States), to all regulatory filings made by or on behalf of, or otherwise owned or Controlled by or on behalf of, Licensee

that relates to any Licensed Product to enable Axsome to conduct independent Development activities with respect to the Licensed Products and for Axsome to use in connection with the filing and maintenance of marketing authorization applications for the products containing the Licensed Compound outside of the Territory. Axsome has the right to extend and sublicense (including the right to further sublicense), in whole or in part, such right of references to its Affiliates and, to the extent required by any Upstream License, its Upstream Licensors. Licensee shall and shall cause any Affiliates or sublicensees, as applicable, to provide a signed statement to this effect, if requested by Axsome, in accordance with 21 C.F.R. § 314.50(g)(3) (or any analogous Applicable Law recognized outside of the United States).

2.3. No Implied Rights. Except as expressly provided in this Agreement, neither Party shall be deemed to have granted the other Party (by implication, estoppels or otherwise) any right, title, license or other interest in or with respect to any Intellectual Property Rights or information Controlled by such Party.

2.4. Retained Rights. Axsome retains all rights under the Licensed Intellectual Property, any and all other Patent Rights and Know-How owned or Controlled by Axsome or its Affiliates for use thereof either (a) outside the Territory for any and all purposes or (b) in the Territory but outside of the Field, and no such rights (either (a) or (b)) are granted under this Agreement to Licensee. Axsome further retains all rights under the Licensed Trademarks (or any Trademark identical or similar to any Licensed Trademark) for use outside of the Territory

2.5. Transfer Activities.

2.5.1. Transition Plan . Axsome shall cooperate with and provide timely free-of-charge (provided that Licensee shall reimburse Axsome for any documented out-of-pocket expenses, which have been agreed in advance in writing by Licensee, in the aggregate are in excess of [*****] incurred by Axsome or its Affiliates in providing unless otherwise agreed by the Parties) assistance to Licensee to ensure the smooth transition of ongoing Development and Commercialization activities for the Licensed Products and the Transferred Clinical Trials (under Section 3.3.1 below) and to facilitate the disclosure of the Licensed Know-How to Licensee. As soon as reasonably practicable after the Effective Date, the Parties shall meet to establish a mutually agreed transition plan setting forth (a) the Licensed Know-How to be disclosed pursuant to Section 2.5.3, (b) other information reasonably requested by Licensee to the extent in Axsome's possession and control and relating to the Licensed Product in the Territory, (c) the activities to be undertaken by each Party to transfer the Transferred Regulatory Approvals to Licensee (d) the timing by which each of the foregoing is to be provided and (e) the number of hours of consultation by Axsome that may be provided to Licensee to answer questions regarding the Licensed Know-How so disclosed, (as such transition plan may be updated from time to time upon agreement of the Parties, the "**Transition Plan**"). Notwithstanding the foregoing, the Transition Plan independent of the Supply Agreement to be entered into by the Parties pursuant to Section 3.6. If there is an inconsistency between the Transition Plan and this Agreement or the Supply Agreement, the terms of this Agreement or the Supply Agreement shall prevail, provided that in the event of any inconsistency between the Transition Plan

and both the terms of this Agreement and the terms of the Supply Agreement, the terms of this Agreement shall prevail.

2.5.2. Regulatory Approval Transition Protocol. Pending transfer from Axsome to Licensee (or to its Affiliates or Sublicensees) of each Transferred Regulatory Approval, the Parties shall cooperate in accordance with the Regulatory Approval Transition Protocol set forth in Schedule 2.5.2.

2.5.3. Initial Disclosure and Knowledge Transfer. As soon as reasonably possible, but not later than thirty (30) days after the Effective Date, Axsome shall, at its own cost, transfer to Licensee

(a) **Regulatory materials:** true, accurate and complete copies of all Licensed Know-How and documentation directly related to Licensed Products for use in the Field in the Territory, in each case to the extent in the possession and Control of Axsome on or prior to the Effective Date and in such format as that such documentation then exists, including for the avoidance of doubt, all (i) documentation comprising the Dossier and any Regulatory Approval in the Territory, (including associated CMC (chemistry, manufacturing and controls) data and clinical and other data referenced in the Dossier); (ii) applications, registrations, licenses, approvals, correspondence and reports submitted to or received from any Regulatory Authority in the Territory in relation to the Licensed Product and all supporting documents with respect thereto and referenced therein, including all pricing reimbursement information, agreements and communications, customer lists, tenders/customer contracts, marketing material etc. and all Adverse Event files and complaint files; and (iii) such further documentation related to a Regulatory Approval in the Territory for the Licensed Product requested by a Regulatory Authority in the Territory;

(b) **Marketing and promotion materials:** copies of the marketing materials used prior to the Effective Date by Axsome or its Affiliates or their nominees with respect to the Licensed Product in the Territory; Axsome's or its Affiliates' customer lists with respect to Licensed Product sold in the Territory prior to the Effective Date; lists of prescribers who prescribe the Licensed Product in the Territory, which lists are in Axsome's possession and which Axsome has a right to provide to Licensee without violating any agreement between Axsome or its Affiliates and any Third Party, lists of key opinion leaders with respect to the Licensed Product in the Territory that Axsome engaged prior to the Effective Date, provided, however, that with respect to each of the foregoing, Axsome shall provide such copies only to the extent permitted by Applicable Law;

(c) **Due Diligence Materials**: a complete copy of the Virtual Data Room (VDR) as of the Effective Date.

3. DEVELOPMENT AND COMMERCIALIZATION.

3.1. General. Licensee shall have the sole authority over and control of Commercialization and, subject to Section 3.3, Development of the Licensed Products in the Territory.

3.2. Diligence.

3.2.1. Development and Regulatory Diligence . Licensee will use and will cause its Affiliates and Sublicensees to use Commercially Reasonable Efforts to (i) Develop Licensed Products (consistent with Section 3.3) for use in the Territory, (ii) to the extent additional indications or uses, or additional Licensed Products, are Developed, to seek Regulatory Approvals therefore, and (iii) to maintain in good standing and effect all Regulatory Approvals in the Territory for Licensed Products, including both those Regulatory Approvals transferred to Licensee pursuant to this Agreement and new Regulatory Approvals obtained by Licensee during the Term.

3.2.2. Commercial Diligence . Licensee will use and will cause its Affiliates and Sublicensees, as applicable, to use Commercially Reasonable Efforts to Commercialize each Licensed Product in each country in the Territory where such Licensed Product is the subject of an existing Regulatory Approval or where Licensee or its designated Affiliates or Sublicensees seek and receive Regulatory Approval for such Licensed Product. To the extent that Licensee elects not to commercialize the Licensed Product (at all or for any indication) in any country in the Territory, Licensee shall notify Axsome of this decision and the business rationale therefore and, upon Axsome's request, the Parties, in good faith, shall discuss such matter further.

3.2.3. Remedies for Breach of Licensee Diligence Obligations . If Licensee materially breaches any Licensee Diligence Obligation and fails to remedy such breach within ninety (90) days of Licensee's receipt of notice of such breach from Axsome, then, without limiting and in addition to any other remedies that may be available to Axsome at law or in equity, Axsome may, in its sole discretion, elect to either (a) terminate this Agreement pursuant to the provisions of Section 8.2 or (b) convert any exclusive license granted to Licensee under this Agreement with respect to one or more Licensed Products in the Territory into a non-exclusive license.

3.3. Development.

3.3.1. Transferred Clinical Trials. Without limiting its obligations under Section 3.2.1, Licensee shall be solely responsible, at its own cost and expense, for conducting and completing all Transferred Clinical Trials and any other trial to satisfy post-marketing commitments necessary or desirable to obtain or maintain Regulatory Approval of and enable and support the Manufacture and Commercialization of Licensed Products in the Territory. Axsome and Licensee shall undertake all actions reasonably necessary to transfer Axsome's responsibilities and obligations under the Transferred Clinical Trials to Licensee and to assign to Licensee those clinical trial agreements listed in Schedule 3.3.1, which are in existence as of the Effective Date and under which such Transferred Clinical Trials are being conducted.

3.3.2. Additional Development Activities in the Territory. Licensee, at its own cost and expense, shall have the right, subject to Axsome's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed, to conduct Development activities of the Licensed Products in the Field in the Territory solely for the purposes of complying with any post-approval requirements imposed or agreed to with any Regulatory Authority in the Territory as a condition of granting or maintaining the Regulatory Approval in the Territory for such Licensed Product in the Field and for otherwise enhancing the label for, or adding additional indications (in the Field) to enable and support the Commercialization of the Licensed Products, in each case for use in the Field in the Territory. Prior to initiating any such Development activity, Licensee shall notify and consult with Axsome with respect thereto and Axsome shall have the right to review, and Licensee shall provide to Axsome for review, the plans and protocols for any such Development activities prior to Axsome providing its written consent to permit Licensee to conduct such Development activities. In the event Axsome provides written consent for such proposed Development activities, Licensee shall consider in good faith, and not unreasonably refuse to address, any of Axsome's comments and suggestions provided by Axsome to Licensee with respect to the plans and protocols of any such Development activities. For clarity, (i) it shall be reasonable for Axsome to withhold its consent for Licensee to conduct any particular Development activity with respect to any Licensed Product if Axsome, in good faith, reasonably believes that such Development activity may have an adverse impact on any product containing the Licensed Compound (including on any Regulatory Approval with respect thereto) that Axsome, its Upstream Licensors or its or their Affiliates or licensees is developing or Commercializing or is planning to develop or Commercialize outside of the Territory and (ii) Axsome is hereby deemed to have provided its consent for Licensee to conduct the studies listed on Schedule 3.3.2. Licensee shall use reasonable efforts to conduct all such approved Development activities and to conduct them in compliance with all applicable legal and regulatory requirements, good clinical practices, ethical requirements and industry guidelines.

3.3.3. Licensee Data. Licensee, at no cost to Axsome, shall provide Axsome with any and all data obtained from any of the research activities that were conducted, pursuant to either of Sections 3.3.1 or 3.3.2, by, on behalf of or under the direction of Licensee or its Affiliates ("**Licensee Data**"). Licensee shall grant Axsome a right and license to use (including the right to provide access to and to license or sublicense to Third Parties, including Axsome's Upstream Licensors) such Licensee Data in support of the Development for use or Commercialization of Licensed Products and to otherwise support the Commercialization of products containing the Licensed Compound for use outside the Territory. Licensee acknowledges that Axsome and its Upstream Licensors shall retain all right, but have no obligation, to conduct clinical trials, both outside and within the Territory, of any products containing any Licensed Compound for purposes of seeking Regulatory Approval of and Commercializing such products solely outside of the Territory, including seeking approval of additional indications for such products. Upon Licensee's request, and solely to the extent necessary for Licensee to obtain Regulatory Approval of Licensed Products for use in such additional indications, Axsome shall provide Licensee access to and a right to use any data arising out of the aforementioned clinical trials conducted by or on behalf of Axsome.

3.4. Regulatory Matters.

3.4.1. Marketing Authorization Holder. Without limiting its obligations under Section 3.2, Licensee or its Affiliates or nominees shall be the Marketing Authorization Holder ("**MAH**") for the Licensed Products in the Territory and shall be responsible for preparing, seeking, submitting and maintaining all regulatory filings and Regulatory Approvals for all Licensed Products in the Territory.

3.4.2. Transfer of Existing CTAs and Marketing Authorizations to Licensee. Unless otherwise agreed upon by the Parties, Axsome shall transfer to Licensee the CTAs and Regulatory Approvals for the Licensed Products which CTAs and Regulatory Approvals are listed on Schedule 1.84 to the extent that such CTAs exist and are active as of the Effective Date and are held by Axsome in the Territory. Licensee will use all reasonable efforts to maintain in full effect such CTAs (for so long as needed to complete the Transferred Clinical Trials) and Regulatory Approvals, and Licensee will use all reasonable efforts to timely perform all responsibilities of the regulatory sponsor or the MAH, as applicable, with respect thereto.

3.4.3. Participation Right. Axsome shall have the right (and may extend such right to its Upstream Licensors) and Licensee shall and shall cause its Affiliates and Sublicensees, as applicable to allow Axsome and Axsome's Upstream Licensors to (1) participate in all meetings, telephone or video calls, discussions and correspondences with any Governmental Authority with respect to any Licensed Product, (2) participate in meetings, telephone or video calls held in preparation for such meetings or communication with any Governmental Authorities; (3) participate in the preparation and review of minutes of such meetings with any Governmental Authorities, (4) review and comment (which comments Licensee shall consider in good faith and shall not unreasonably refuse to address) upon all regulatory filings with respect to any Licensed Product and (5) receive regular updates to any and all regulatory matters relating to the Licensed Product in the Territory. Licensee shall promptly notify Axsome of any notices and inspections or any issues raised by any Regulatory Authority with respect to any regulatory filings or Licensed Products, and Licensee shall promptly notify Axsome of the resolution thereof. Axsome shall be free to share all such information with its Upstream Licensors.

3.4.4. Ongoing Regulatory Support. Axsome shall, at no additional cost to Licensee provide to Licensee such assistance, including technical assistance, as is necessary (i) to obtain the Regulatory Approvals for the Licensed Product in the Territory in Licensee's or its Affiliates' or its nominee's name and (ii) for the Licensee, its Affiliates or nominees to subsequently maintain those Regulatory Approvals in the Territory. For the avoidance of doubt, Axsome shall have no obligation to conduct any post marketing studies of the Licensed Product but will from time to time (as requested by Licensee) provide ad hoc consultation for any such studies provided that any out-of-pocket costs associated with Axsome's compliance with this Section 3.4.4shall be borne by Licensee in the same way as expenses incurred pursuant to Section 2.5.1.

3.5. Commercialization Activities.

3.5.1. General. Without limiting its obligations under Section 3.2.2, Licensee shall have sole and exclusive control over all matters relating to the Commercialization of Licensed Products in the Territory; provided that, Licensee shall distribute and otherwise Commercialize such Licensed Products only to the extent permitted by, in a manner consistent with and in compliance with, the applicable Regulatory Approvals for the Licensed Products in the Territory, Applicable Law and applicable pharmaceutical industry guidelines. Licensee shall not at any time during the Term directly or indirectly (including by assisting any Third Party in any manner) distribute, offer for sale, sell or otherwise provide any Licensed Compound or Licensed Products to any Third Party outside of or for use outside of the Territory.

3.5.2. Branding. Licensee or its Affiliates may Commercialize the Licensed Products under the Licensed Trademarks (subject to Sections 3.5.3 and 5.3) or under separate Trademarks owned or Controlled by Licensee, provided, however, that Licensee shall not and shall cause its Affiliates and Sublicensees to not use any Trademark (other than the Licensed Trademarks) or tradename that may be confusingly similar to any Trademarks or tradenames (including the corporate or business names) of Axsome or its Affiliates.

3.5.3. Licensed Trademarks. If Licensee elects to use any Licensed Trademark in connection with any Licensed Product, Licensee shall so notify Axsome in writing and Axsome shall provide to Licensee any trademark usage guidelines that Axsome may reasonably specify with respect to such Licensed Trademark. Licensee shall comply with and shall cause its Affiliates and Sublicensees to comply with such trademark usage guidelines in respect of any use of such Licensed Trademark.

3.6. Manufacturing . Notwithstanding that Axsome's grant of the license to Licensee under Section 2.1 is not conditioned on Licensee electing to have Axsome manufacture Licensed Product for Licensee, Licensee shall have the option to have Axsome Manufacture or have Manufactured the Licensed Compound and any Licensed Products for use by Licensee. If Licensee makes such election it shall notify Axsome immediately after the Effective Date and thereafter the Parties, within thirty (30) days after the Effective Date, shall negotiate and enter into such supply agreement that contains the terms in the manufacturing term sheet attached hereto as Schedule 3.6 the together with other material and non-material terms typically included in agreements of such type and scope (the "**Supply Agreement**"). In the event Licensee exercises such option and the Parties enter into the Supply Agreement, Licensee shall purchase from Axsome all requirements of any such Licensed Products at the price set forth therein.

3.7. Reports and Data Disclosure. Licensee shall provide Axsome with written reports and disclosures as follows:

(a) every six (6) months, aligned to meetings of the Steering Committee, a report summarizing activities taken by or on behalf of Licensee, its Affiliates and its or their Sublicensees to Develop and Commercialize Licensed Products, including status of clinical trials conducted and planned, status of Regulatory Approvals submitted and obtained, and actual and projected launch dates of Licensed Product (both initial launch and launch of each new indication) in each country; and

(b) every year, aligned to meetings of the Steering Committee, Licensee's projection of sales (whether by or on behalf of Licensee, its Affiliates and/or its or their sublicensees) of Licensed Product, which projection shall include number of units of Licensed Product anticipated to be sold during each Calendar Quarter of the three (3) year period beginning on the first day of the Calendar Quarter following the date that such projection is provided (the "**Projection Period**"), projected revenues anticipated to be obtained during each Calendar Quarter of the Projection Period from such sales of Licensed Product. For the avoidance of doubt, all projections shall be non-binding on Licensee.

3.8. Steering Committee. The Parties shall establish a steering committee (the "**Steering Committee**") comprising a relationship manager from each Party. The Steering Committee shall have responsibility for managing operational matters between the Parties in connection with this Agreement. The Steering Committee shall meet once every six (6) months during the Term to discuss and review the performance of this Agreement, at a time and location to be agreed between the Parties. The Steering Committee may meet more frequently if so agreed between the Parties or (in the case of urgency or necessity) at short notice at the request of either Party.

4. PAYMENTS.

4.1. Upfront Payment. Licensee shall pay to Axsome a one-time payment of sixty-two million euros (€62,000,000), **[*****]**. In the event Licensee fails to pay either such payment on or before the date due and fails to cure such failure within five (5) Business Days, Axsome may terminate this Agreement by written notice with immediate effect without obligation to refund any payments made under this Section 4.1.

4.2. Development Milestone Payments. Licensee shall pay to Axsome the following development milestone payment (the "**Development Milestone Payment**") upon the achievement of the following milestone for the Licensed Product (the "**Development Milestone**"), whether achieved by Licensee or an Affiliate or Sublicensee. Licensee shall promptly (but in no event later than seven (7) Business Days after) notify Axsome in writing of the achievement of the Development Milestone and Licensee shall pay Axsome in full the Development Milestone

Payment within thirty (30) days of Axsome's invoice for the achievement thereof. For the avoidance of doubt the Development Milestone is only payable once.

Development Milestone	Milestone Payment (in Euros)
[*****]	[*****]

4.3. Commercial Milestone Payments. Licensee shall pay to Axsome the following commercial milestone payments (each, a "**Commercial Milestone Payment**") upon the achievement of the corresponding level of cumulative Net Sales of the Licensed Products in the Territory (the "**Commercial Milestone**"), whether achieved, individually or collectively, by Licensee, Licensee's Affiliate(s) or its or their Sublicensees. Licensee shall promptly (but in no event later than seven (7) Business Days after) notify Axsome in writing of the achievement of any such Commercial Milestone and Licensee shall pay Axsome in full the corresponding Commercial Milestone Payment within thirty (30) days of Axsome's invoice for such achievement thereof. For the avoidance of doubt, each Commercial Milestone will only be paid once.

Cumulative Net Sales of the Licensed Product in the Territory	Milestone Payment (in Euros)
[*****]	[*****]
[*****]	[*****]
[*****]	[*****]
[*****]	[*****]
[*****]	[*****]

4.4. Royalty/Profit Share Payments. With respect to the sales of Licensed Products made during the applicable Royalty Terms, Licensee shall pay to Axsome royalties in the amount of **[*****]** of the Net Sales from the sale of all Licensed Products in the Territory obtained by each of Licensee, its Affiliates and Sublicensees.

4.5. Reports and Payments.

4.5.1. Cumulative Royalties. The obligation to pay royalties under this Agreement shall be imposed only once with respect to any sale of any Licensed Product.

4.5.2. Royalty Statements and Payments. Within thirty (30) days of the end of each Calendar Quarter, Licensee shall deliver to Axsome a report setting forth, for such Calendar Quarter, the following information, on a Licensed Product-by-Licensed Product, country-by-country, and Territory-wide basis: (a) Net Sales of each Licensed Product, (b) deductions taken from gross sales in the calculation of such Net Sales, (c) the royalty due hereunder for the sale of each such Licensed Product, including all information pertaining to the calculation of each of the foregoing, and (d) the exchange rates, if any, used in determining the amount of Euros.. Following receipt of such report Axsome shall invoice Licensee for the royalties due for the previous Calendar Quarter and such invoice shall be payable within thirty (30) days of receipt. On an annual basis the parties will perform a reconciliation to adjust for any adjustments to be made to Net Sales in the previous year following the reporting date for each Calendar Quarter. To the extent required under any

Upstream License, Axsome may share any such reports with the relevant Upstream Licensor.

4.5.3. Taxes and Withholding. It is understood and agreed between the Parties that any payments made under this Agreement are exclusive of any value added or similar tax ("**VAT**"), which shall be added thereon as applicable. Where VAT is properly added to a payment made under this Agreement, the Party making the payment will pay the amount of VAT only on receipt of a valid tax invoice issued in accordance with the laws and regulations of the country in which the VAT is chargeable. In addition, in the event any payments made by Licensee pursuant to this Agreement become subject to withholding taxes under the Applicable Laws or regulations of any jurisdiction or Governmental Authority, Licensee shall pay such additional amount as will, after such withholding taxes has been made, leave Axsome with the full amount which would have been received by it had no such deduction or withholding been required to be made; and Licensee shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner. Axsome will provide to Licensee any necessary information or documentation requested by Licensee allowing the Licensee to comply with its tax obligations in relation to such withholding taxes (for example, and without limitation, a tax resident certificate withing the meaning of the applicable double tax treaty to be provided on an annual basis and before the deadline of each payment under this Agreement).

4.5.4. Currency. All amounts payable and calculations under this Agreement shall be in Euros. As applicable, Net Sales and any royalty deductions shall be translated into Euros using the exchange rate published by the European Central Bank or, for any particular exchange rate not published by the European Central Bank, published by Bloomberg, in each case on the last Business Day of each month during the applicable Calendar Quarter. If, due to restrictions or prohibitions imposed by national or international authority, a given payment cannot be made as provided in this Section 4.5.4, the Parties shall consult with a view to finding a prompt and acceptable solution. If the Parties are unable to identify a mutually acceptable solution regarding such payment, then Licensee may elect, in its sole discretion, to deliver such payment in the relevant jurisdiction and in the local currency of the relevant jurisdiction.

4.5.5. Method of Payment. Except as permitted pursuant to Section 4.5.4, each payment hereunder shall be made by electronic transfer in immediately available funds via either a bank wire transfer, an ACH (automated clearing house) mechanism or any other means of electronic funds transfer, at Licensee's election, to the bank account as designated by Axsome in writing to Licensee at least three (3) days before the payment is due.

4.5.6. Late Payments. In the event that any payment due hereunder is not made when due, the payment shall accrue interest beginning on the tenth (20^{th}) day following the due date thereof, calculated at the annual rate of the sum of (a) [*****] plus (b) the prime interest rate quoted by The Wall Street Journal on the date said payment is due, the interest being compounded on the last day of each Calendar Quarter; provided however, that in no event shall said annual interest rate exceed the maximum legal interest rate. Each such payment when made shall be accompanied by all interest so accrued. Said interest and the payment and acceptance thereof shall not negate or waive the right of either

Party to seek any other remedy, legal or equitable, to which it may be entitled because of the delinquency of any payment, including termination of this Agreement as set forth in Section 8.2.

4.6. Inspection of Records.

4.6.1. Record Keeping. Licensee shall keep and shall cause its Affiliates and each of its and their sublicensees and assignees to keep books and accounts of record in connection with the sale of Licensed Products in sufficient detail to permit accurate determination of all figures necessary for verification of royalties and other payments to be paid hereunder. Licensee and its Affiliates shall maintain such records for a period of at least five (5) years after the end of the Calendar Quarter in which they were generated.

4.6.2. Audits. Upon thirty (30) days prior notice from Axsome, Licensee shall permit an independent certified public accounting firm of nationally recognized standing selected by Axsome and reasonably acceptable to Licensee, to examine, at Axsome's sole expense, the relevant books and records of Licensee and its Affiliates as may be reasonably necessary to verify the amounts reported by Licensee in accordance with Section 4.5.2 and the payment of royalties and other payments hereunder. An examination by Axsome under this Section 4.6.2 shall not occur 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 five (5) years before the date of the request. The accounting firm shall be provided access to such books and records at Licensee's or its Affiliates' facility(ies) where such books and records are normally kept, and such examination shall be conducted during Licensee's normal business hours. Licensee may require the accounting firm to sign a reasonably acceptable non-disclosure agreement before providing the accounting firm with access to Licensee's or its Affiliates' facilities or records. Upon completion of the audit, the accounting firm shall provide both Licensee and Axsome a written report disclosing any discrepancies in the reports submitted by Licensee or the royalties or other payments paid by Licensee and, in each case, the specific details concerning any discrepancies. No other information shall be provided to Axsome. To the extent required under any Upstream License, Axsome may share the results of any such audit with the relevant Upstream Licensor.

4.6.3. Underpayments. If, after conducting an audit pursuant to Section 4.6.2, the applicable accounting firm concludes that additional royalties or other payments were due to Axsome, then Licensee, within ten (10) Business Days of the date Licensee receives such accountant's written report, will pay to Axsome the additional royalties or other payments and all interest accruing thereon. Further, if the amount of such underpayment of either royalties or any other payment exceeds more than [*****] of the amount of such royalties or other payment that was properly payable to Axsome, then Licensee shall reimburse Axsome for Axsome's out-of-pocket costs in connection with the audit.

4.6.4. Overpayments. If, after conducting an audit pursuant to Section 4.6.2, the applicable accounting firm concludes that Licensee has overpaid royalties or other payments to Axsome, then Axsome, within ten (10) Business Days of the date Axsome receives such accountant's written report, will refund to Licensee the excess royalties or other payments.

4.7. Confidentiality . Notwithstanding any provision of this Agreement to the contrary, all reports and financial information of Licensee, its Affiliates or its sublicensees which are provided to or subject to review by Axsome under this Article 4 shall be deemed to be Licensee's Confidential Information and subject to the provisions of Article 6, provided, however, that to the extent required under any Upstream License, Axsome may share such reports and financial information with the relevant Upstream Licensor.

5. INTELLECTUAL PROPERTY.

5.1. Pre-Existing IP. Subject to the license and rights granted pursuant to Sections 2.1.1, 2.1.2 and 2.1.3 and Section 2.2, each Party shall retain all right, title and interest in and to any Intellectual Property Rights that are Controlled by such Party prior to or independent of this Agreement.

5.2. Ownership of Developed IP. Subject to the license and rights granted in Sections 2.1.1, 2.1.2, and Section 2.2 and the license granted to Axsome in this Section 5.2, (i) Axsome shall own all right, title and interest in and to any and all inventions, Know-How, data, results and other Intellectual Property Rights and proprietary information, conceived individually by Axsome or its Affiliates ("**Axsome Developed IP**"), (ii) Licensee shall own all right, title and interest in and to any and all inventions, Know-How, data, results and other Intellectual Property Rights and proprietary information, conceived individually by Licensee or its Affiliates ("**Licensee Developed IP**") and (iii) Axsome and Licensee shall jointly own and have an undivided interest in and to any and all inventions, Know-How, data, results and other Intellectual Property Rights and proprietary information, conceived or jointly by Axsome or Licensee, and its or their Affiliates and sublicensees ("**Joint Developed IP**"), in each case under this Agreement with respect to the Licensed Products, in connection with any Development or Commercialization of the Licensed Products. For clarity, the Axsome Developed IP and Axsome's interest in the Joint Developed IP each shall be included in the Licensed Intellectual Property. Licensee hereby grants to Axsome a perpetual, irrevocable, fully paid and royalty free, sublicensable (through multiple tiers) license under the Licensee Developed IP and Licensee's interest in any Joint Developed IP for all purposes, provided, however that, (a) inside the Territory such license shall be non-exclusive and shall not include the right to commercialize any product containing a Licensed Compound and (b) outside the Territory such license shall be exclusive, even as to Licensee.

5.3. Licensed Trademarks.

5.3.1. Registration; Usage and Costs. Axsome shall be responsible for the application and registration, in the Territory, of any Licensed Trademark that Licensee notifies Axsome it elects to use. All costs of the filing of applications for registration, or of the prosecution or maintenance of, any Licensed Trademark in the Territory shall be borne solely by Licensee, and Licensee shall reimburse Axsome for all costs and expensed incurred by or on behalf of Axsome or its Affiliates in connection with the filing, prosecution or maintenance of any Licensed Trademarks, provided, however, that if Licensee is not utilizing any of the Licensed Trademarks it can notify Axsome in writing and such Trademark will not be a Licensed Trademark. Licensee shall not seek to register or use and shall cause its Affiliates and its and their sublicensees to not seek to register or use, in each case, in any country, whether within or outside the Territory, any such Trademark that is the same as or confusingly similar to any Trademark owned or used by

Axsome or Axsome's Affiliates for Axsome's or such Affiliates' other products or services. Additionally, Licensee shall not and shall cause its Affiliates and its and their sublicensees to not use the corporate name of Axsome or Axsome's Affiliates for any purpose without Axsome's prior written consent.

5.3.2. Third Party Infringement. If either Party has a reasonable basis to believe that a Third Party is or may be engaging in commercially significant infringement of any Licensed Trademark in the Territory, such Party shall notify the other Party in writing and provide it with any evidence of such infringement that is reasonably available. Licensee shall have the right and option to respond to any infringement or potential infringement with respect to any Licensed Trademark that Licensee is using in the Territory by appropriate steps, including filing an infringement suit or taking other similar action, and shall notify Axsome of, and consult with Axsome from time to time regarding, any such suit or other action. Axsome shall provide reasonable assistance to Licensee, including providing access to relevant documents and other evidence, making its employees available at reasonable business hours, and joining the action to the extent necessary to allow Licensee to maintain the action. Any amounts recovered by Licensee pursuant to this Section 5.3.2, whether by settlement or judgment, shall first be used to reimburse Licensee for the costs of such enforcement action and the remainder, if any, shall be retained by Licensee for its own account, provided that (1) such recoveries treated as Net Sales in the Calendar Quarter in which they are received for all purposes under this Agreement.

5.4. Patent Prosecution and Maintenance.

5.4.1. Right to File, Prosecute and Maintain. Subject to Licensee's rights set forth in Section 5.4.3 below, Axsome, in consultation with Licensee, shall be responsible for filing, prosecuting and maintaining the Licensed Patent Rights throughout the Territory. The direct reasonable out-of-pocket costs incurred in such activities, including the reasonable fees of attorneys or patent agents, and filing and maintenance fees shall be borne solely by Licensee, and Licensee shall reimburse Axsome for all reasonable costs and expenses incurred by or on behalf of Axsome or its Affiliates in connection with the filing, prosecution and maintenance of the Licensed Patent Rights, provided, however, if Licensee notifies Axsome in writing that it does not wish Axsome to file, prosecute or maintain a Licensed Patent Right pursuant to this Section 5.4.1, any such costs and expenses that Axsome incurs following such notification shall not be borne by Licensee. Notwithstanding any such written notice provided by Licensee, Axsome may, in its sole discretion, continue to prosecute and maintain in effect such Licensed Patent Right at its own expense and, in such case, such Licensed Patent Right will continue as a Licensed Patent Right for purposes of Section 1.69, provided, however, that Axsome shall have the sole right and without Licensee's consent to discontinue such prosecution or maintenance at any time.

5.4.2. Review and Comment. Axsome shall use its commercially reasonable efforts to prosecute and seek to procure the grant of any of the Licensed Patent Rights that, as of the Effective Date are patent applications that have been filed, but not yet granted as patents, in each country of the Territory. Axsome shall keep Licensee advised on the status

of the prosecution and maintenance of all Licensed Patent Rights in the Territory annually and at other times as necessary to comply with its obligations hereunder or as reasonably requested by Licensee. Axsome shall allow Licensee a reasonable opportunity and reasonable time to review and comment regarding substantive communications from the relevant patent offices or Governmental Authorities and drafts of any responses or other proposed substantive filings before any such filings are submitted to any relevant patent offices or Governmental Authorities, and Axsome shall consider in good faith any reasonable comments offered by Licensee in preparing any final filings to be submitted to any relevant patent offices or Governmental Authorities. To the extent practicable, Axsome shall give Licensee at least forty-five (45) days' notice before filing in the Territory any new Licensed Patent Right during the Term that relates to any Licensed Product or to the Development, Commercialization or use of any Licensed Product. For clarity, Axsome's obligations and Licensee's rights under this Section 5.4.2 shall not apply with respect to any Patent Rights outside of the Territory.

5.4.3. Axsome Election to Not Prosecute or Maintain. If Axsome at any time decides to abandon or declines to continue prosecution or maintenance of the patents and applications in a particular country in the Territory for any Licensed Patent Right, Axsome shall provide Licensee with at least ninety (90) days' prior written notice to such effect, and Axsome shall have no responsibility with respect to the prosecution or maintenance of the applicable Licensed Patent Right after the end of such ninety (90) day period. If Licensee gives written notice to Axsome before the end of such ninety (90) day period that Licensee elects to continue prosecution or maintenance, (a) Axsome, upon Licensee's request and subject to Axsome's obligations under any Upstream License with respect to such Licensed Patent Right, shall make reasonable efforts to timely execute such documents and perform such acts, at Licensee's expense, as may be reasonably necessary to permit Licensee to prosecute and maintain, in Axsome's name, such Licensed Patent Right at its sole expense and (b) Licensee shall keep Axsome advised on the status of the prosecution and maintenance of such Licensed Patent Right annually and at other times as reasonably requested by Axsome. If Licensee does not give written notice to Axsome before the end of such forty-five (45) day period that Licensee elects to continue prosecution or maintenance of such Licensed Patent Right, Axsome shall be entitled to allow such Licensed Patent Right to lapse or take any other action with respect thereto as may be required or permitted under any applicable Upstream License. For avoidance of doubt, nothing herein shall be construed to give Licensee the right to use Axsome's Confidential Information in prosecuting Licensed Patent Rights or in connection with such prosecution without Axsome's prior written consent.

5.4.4. Patent Term Restoration and Extension. Axsome shall be responsible for, in consultation with Licensee, seeking patent term extensions, supplemental protection certificates and the like available under Applicable Law in any country in the Territory in relation to the Licensed Patent Rights. Axsome and Licensee will cooperate in connection with all such activities. Axsome will give due consideration to all suggestions and comments of Licensee regarding any such activities, but in the event of a disagreement between the Parties, Axsome will have the final decision-making authority; provided, however, that Axsome will seek (or will allow Licensee to seek) to extend, including through the use of supplemental protection certificates and the like, any Licensed Patent

Right at Licensee's request unless in Axsome's reasonable legal determination such Licensed Patent Right may not be extended under Applicable Law without limiting Axsome's right to extend any other Licensed Patent Right owned or controlled by Axsome or its Affiliates.

5.4.5. Cooperation. Each Party shall provide the other Party all reasonable assistance and cooperation in the patent prosecution and extension efforts in accordance with this Section 5.4, including by providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution or extension applications.

5.4.6. Status Updates. Axsome shall provide Licensee with a written status update on the Licensed Patent Rights no less than once every year, including any updates to the list in Schedule 1.50.

5.5. Enforcement and Defense of Patent Rights.

5.5.1. Notification . Each Party will promptly notify the other Party in writing of any actual, potential, suspected or threatened infringement, misappropriation or other violation in the Territory by a Third Party of any Licensed Patent Right in the Field of which it becomes aware ("**Third Party Infringement**").

5.5.2. Control.

(a) **Third Party Infringement.** Except as otherwise provided in this Section 5.5, Licensee will have the first right, but not the obligation, to institute litigation or take other steps to remedy Third Party Infringement, and any such litigation or steps will be at Licensee's expense. Licensee will not, without the prior written consent of Axsome (such consent not to be unreasonably withheld, delayed or conditioned), enter into any compromise or settlement relating to such litigation that (a) admits the invalidity or unenforceability of any Licensed Patent Right, (b) requires that any Licensed Patent Right be abandoned or (c) otherwise adversely affects the rights or interest of Axsome or, if applicable with respect to such Licensed Patent Right, the Upstream Licensor of such Licensed Patent Right. In order to establish standing, Axsome, upon request of Licensee, agrees to timely commence or to join in any such litigation or to request that the applicable Upstream Licensor join in such litigation, in each case at Licensee's expense, and in any event to cooperate with Licensee in such litigation or steps at Licensee's expense. Axsome and any applicable Upstream Licensor will have the right to consult with Licensee about such litigation and to participate in and be represented by independent counsel in such litigation at Axsome's expense. Any recoveries obtained by Licensee in connection with any such litigation or steps taken in relation to such infringement shall first be used to reimburse Licensee for the reasonable out-of-pocket costs incurred by Licensee in litigating such Third Party Infringement and the remainder, if any, shall be retained by Licensee for its own account, provided that (1) such recoveries treated as Net Sales in the Calendar Quarter in which they are received for all purposes under this Agreement.

(b) **Infringement Outside the Field.** Axsome, at its sole expense, shall have the sole and exclusive right, but not the obligation, to institute litigation or take other steps to remedy any infringement in the Territory solely outside the Field of any Licensed Patent Right. Any recoveries obtained by Axsome in connection with any such litigation or steps taken in relation to such infringement shall be retained by Axsome for its own account.

5.5.3. Licensee Election to Not Enforce or Defend. If Licensee fails to institute litigation or otherwise take steps to remedy Third Party Infringement within one hundred twenty (120) days of its receipt of notice, then Axsome will have the right, but not the obligation, upon twenty (20) days' prior notice to Licensee, at Axsome's expense, to institute any such litigation or take other steps to remedy Third Party Infringement, and any such litigation or steps will be at Axsome's expense; provided that any recoveries (whether by way of judgment, settlement or otherwise) resulting from such litigation or steps relating to such Third Party Infringement, after deducting Axsome's out of pocket expenses (including counsel fees and expenses) in pursuing such claim, will be retained by Axsome. Axsome will not, without the prior written consent of Licensee (such consent not to be unreasonably withheld, delayed or conditioned), enter into any compromise or settlement relating to such litigation that (a) admits the invalidity or unenforceability of any Licensed Patent Right or (b) requires Axsome to abandon any Licensed Patent Right. Licensee, upon request of Axsome, agrees to timely join in any such litigation, at Axsome's expense, and in any event to cooperate with Axsome in such litigation or steps at Axsome's expense. Licensee will have the right to consult with Axsome about such litigation and to participate in and be represented by independent counsel in such litigation at Licensee's expense.

5.5.4. Other Actions by Third Parties. Each Party will promptly notify the other Party in the event of any legal or administrative action by any Third Party involving any Licensed Patent Rights of which it becomes aware, including any nullity, revocation, interference, reexamination, *inter partes* review, post grant review or compulsory licensing proceeding. Axsome will have the first right, but not the obligation, to defend against any such action involving any Licensed Patent Rights, in its own name or Licensee's name (to the extent permitted by Applicable Law), and any such defense will be at Licensee's expense. Licensee, at Axsome's request, agrees to join in any such action at Licensee's expense and in any event to cooperate with Axsome at Licensee's expense. If Axsome fails to defend against any such action involving a Licensed Patent Right, then Licensee will have the right to defend such action, in its own name and at its own expense.

5.6. Allegations of Infringement; Third Party Licenses.

5.6.1. Notification. If the Development, Manufacture, Commercialization or use of any Licensed Product, the practice of any Licensed Intellectual Property, or the exercise of any other right granted by Axsome to Licensee hereunder, in each case, in the Territory (collectively, the "**Licensed Activities**") by Licensee or any of its Affiliates or sublicensees or the practice of any Licensed Intellectual Property by Axsome is alleged by a Third Party to infringe, misappropriate or otherwise violate such Third Party's Patent Rights or other Intellectual Property Rights in the Territory, the Party to whom such

allegation is made will notify the other Party in writing promptly upon becoming aware of such allegation. Additionally, if Licensee determines that, based upon the review of any Third Party Patent Rights or other Third Party Intellectual Property Rights, it may be desirable to obtain a license from such Third Party with respect thereto so as to avoid any potential claim of infringement by such Third Party against either Party or their respective Affiliates or sublicensees, then Licensee will promptly notify Axsome of such determination.

5.6.2. Licensee Option to Negotiate. If Licensee determines, in its sole discretion, that, in order for Licensee, its Affiliates or sublicensees to engage in the Licensed Activities, it is necessary or desirable to obtain a license under one or more Patent Rights or other Intellectual Property Rights Controlled in the Territory by a Third Party, then Licensee shall notify Axsome and Licensee will have the right, but not the obligation, to negotiate and enter into a license or other agreement with such Third Party, provided that Licensee shall not seek to obtain any such license or rights with respect to the Licensed Compound or products containing the Licensed Compound outside of the Territory. All costs and expenses of assessing the need for, negotiating and obtaining any such license or other agreement shall be borne by Licensee and all fees and payments payable under any such license or other agreement shall be the sole responsibility of and paid by Licensee.

5.7. Third Party Infringement Suits.

5.7.1. Notification. Each Party will promptly notify the other Party in the event that any Third Party files suit or brings any other action alleging patent infringement by Licensee or Axsome or any of their respective Affiliates or sublicensees with respect to any of the Licensed Activities (any such suit or other action referred to herein as an "**Infringement Claim**").

5.7.2. Control. In the case of any Infringement Claim against Licensee (including its Affiliates or sublicensees) alone or against both Licensee and Axsome (including its Affiliates), Axsome will have the right, but not the obligation, to control the defense of such Infringement Claim, including control over any related litigation, settlement, appeal or other disposition arising in connection therewith. Licensee will cooperate with Axsome and will have the right to consult with Axsome concerning any Infringement Claim and to participate in and be represented by independent counsel in any associated litigation in which Licensee is a party at Licensee's own expense. In the case of any Infringement Claim against Axsome alone, Licensee will have the right to consult with Axsome concerning such Infringement Claim, and Licensee, upon request of Axsome, will reasonably cooperate with Axsome at Axsome's expense.

6. CONFIDENTIALITY.

6.1. Definition. "**Confidential Information**" means, with respect to each Party, all Licensed Know-How or other information, including proprietary information and materials (whether or not patentable) regarding or embodying such Party's technology, products, business information or objectives, that is communicated by or on behalf of the Disclosing Party to the Receiving Party or its permitted recipients, on or after the Effective Date, but only to the extent

that such Licensed Know-How or other information in written form is marked in writing as "confidential" at the time of disclosure, and such Licensed Know-How or other information disclosed orally or in non-tangible form is (a) identified by the Disclosing Party as "confidential" at the time of disclosure and (b) within thirty (30) days thereafter, the Disclosing Party provides a written summary of such Know-How or other information marked as "confidential". Notwithstanding the foregoing, information disclosed by a Party shall be treated as Confidential Information if the circumstances of the disclosure or the nature of the information would reasonably be expected to be confidential. Confidential Information does not include any Licensed Know-How or other information that (i) was already known by the Receiving Party (other than under an obligation of confidentiality to the Disclosing Party) at the time of disclosure by or on behalf of the Disclosing Party, (ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party, (iii) became generally available to the public or otherwise part of the public domain after its disclosure to the Receiving Party, other than through any act or omission of the Receiving Party in breach of its obligations under this Agreement, (iv) was disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to the Receiving Party or (v) was independently discovered or developed by or on behalf of the Receiving Party without the use of or reference to any Confidential Information belonging to the Disclosing Party. The terms and conditions of this Agreement will be considered Confidential Information of both Parties. For clarity, confidential information of any Upstream Licensor that is disclosed by or on behalf of Axsome or its Affiliates to Licensee or Licensee's Affiliates shall be treated as confidential by Licensee and its Affiliates and its or their Sublicensees and they each shall have all obligation with respect thereto under this Agreement as if it were Axsome's Confidential Information.

6.2. Obligation; Term. Except to the extent otherwise expressly authorized by this Agreement, the Parties agree that, during the Term and thereafter, each Party (the "**Receiving Party**") receiving any Confidential Information of the other Party (the "**Disclosing Party**") hereunder will: (a) keep the Disclosing Party's Confidential Information confidential; (b) not disclose, or permit the disclosure of, the Disclosing Party's Confidential Information; and (c) not use, or permit to be used, the Disclosing Party's Confidential Information for any purpose other than as expressly permitted under the terms of this Agreement.

6.3. Disclosure to Party Representatives. Notwithstanding the provisions of Section 6.2, the Receiving Party may disclose Confidential Information belonging to the Disclosing Party to the Receiving Party's Representatives who (a) have a need to know such Confidential Information in connection with the performance of the Receiving Party's obligations or the exercise of the Receiving Party's rights under this Agreement and (b) have agreed in writing to non-disclosure and non-use provisions with respect to such Confidential Information that are at least as restrictive as those set forth in this Article 6.

6.4. Disclosure to Third Parties. Notwithstanding the provisions of Section 6.2, each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary:

(a) with respect to disclosure to Governmental Authorities, (i) to obtain or maintain INDs or Regulatory Approvals for any Licensed Product within the

Territory, and (ii) to respond to inquiries, requests or investigations relating to Licensed Products or this Agreement;

(b) for outside consultants, contractors, advisory boards, managed care organizations, non-clinical and clinical investigators, and bona fide potential or actual sublicensees, collaborators, partners or permitted assignees, in each case to the extent desirable, to Develop, register or Commercialize any Licensed Product; provided that the Receiving Party will obtain the same confidentiality obligations from such Third Parties as it obtains with respect to its own similar types of confidential information;

(c) in connection with filing or prosecuting Patent Rights or Trademarks as permitted by this Agreement;

(d) in connection with prosecuting or defending litigation as permitted by this Agreement;

(e) in connection with or included in posting results of and other information about clinical trials to clinicaltrials.gov or PhRMA websites; and

(f) to the extent necessary or desirable in order to enforce its rights under this Agreement.

If a Party deems it reasonably necessary to disclose Confidential Information belonging to the other Party pursuant to this Section 6.4, then the Disclosing Party shall to the extent possible give reasonable advance written notice of such disclosure to the other Party and take such measures to ensure confidential treatment of such information as is reasonably required by the other Party, at the other Party's expense.

6.5. SEC Filings and Other Disclosures. Either Party may disclose the terms of this Agreement to the extent required, in the reasonable opinion of such Party's legal counsel, to comply with Applicable Law, including the rules and regulations promulgated by the United States Securities and Exchange Commission or any equivalent governmental agency in any country in the Territory. Before disclosing this Agreement or any of the terms hereof pursuant to this Section 6.5, the Parties will consult with one another on the terms of this Agreement to be redacted in making any such disclosure, with the Disclosing Party providing as much advanced notice as is feasible under the circumstances and giving consideration to the comments of the other Party. Further, if a Party discloses this Agreement or any of the terms hereof in accordance with this Section 6.5, such Party shall, at its own expense, seek such confidential treatment of confidential portions of this Agreement and such other terms, as may be reasonably requested by the other Party.

6.6. Announcements. Except as may be expressly permitted under Section 6.5, neither Party will make any public announcement regarding this Agreement without the prior written approval of the other Party.

6.7. Publications. During the Term, Licensee shall submit to Axsome for review and approval any proposed academic, scientific and medical publication or public presentation which contains Axsome's Confidential Information or, in the case of academic, scientific and medical

publications, which otherwise relate to the Licensed Compound or any Licensed Product. Such review and approval will be conducted for the purposes of preserving the value of the Licensed Intellectual Property and determining whether any portion of the proposed publication or presentation containing Axsome's Confidential Information should be modified or deleted. Written copies of such proposed publication or presentation required to be submitted hereunder shall be submitted to Axsome no later than twenty (20) days before submission for publication or presentation (the "**Review Period**"). Axsome shall provide its comments with respect to such publications and presentations within ten (10) days of its receipt of such written copy. The Review Period may be extended for an additional thirty (30) days in the event Axsome can, within ten (10) days of receipt of the written copy, demonstrate reasonable need for such extension including for the preparation and filing of patent applications. Licensee will comply with standard academic practice regarding authorship of scientific publications and recognition of contribution of other parties in any publication governed by this Section 6.7, including International Committee of Medical Journal Editors standards regarding authorship and contributions. For the sake of clarity, Licensee's obligation to submit any publication to Axsome for review and approval under this Section 6.7 shall not apply to any publication which does not contain Axsome's Confidential Information.

7. REPRESENTATIONS, WARRANTIES AND COVENANTS.

7.1. Mutual Representations and Warranties. Each of Axsome and Licensee hereby represents and warrants to the other Party that:

7.1.1. it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization;

7.1.2. the execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite action under the provisions of its charter, bylaws and other organizational documents, and does not require any action or approval by any of its shareholders or other holders of its voting securities or voting interests;

7.1.3. it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;

7.1.4. this Agreement has been duly executed and is a legal, valid and Binding Obligation on each Party, enforceable against such Party in accordance with its terms; and

7.1.5. the execution, delivery and performance by such Party of this Agreement and its compliance with the terms and provisions hereof does not and will not conflict with or result in a breach of or default under any Binding Obligation existing as of the Effective Date.

7.2. Mutual Covenants. Each of Axsome and Licensee hereby covenants to the other Party that:

7.2.1. from the Effective Date until expiration or termination of this Agreement, it will perform its obligations and exercise its rights under this Agreement in compliance with Applicable Laws;

7.2.2. with respect to any Licensed Products, payments or services provided under this Agreement, such Party has not taken and will not during the Term take any action directly or indirectly to offer, promise or pay, or authorize the offer or payment of, any money or anything of value in order to improperly or corruptly seek to influence any government official or any other Person in order to gain an improper advantage, and has not accepted, and will not accept in the future such payment;

7.2.3. it will maintain valid and enforceable agreements with all Persons acting by or on behalf of such Party or its Affiliates under this Agreement which require such Persons to assign to such Party or its Affiliates their entire rights, title and interests in and to the Licensed Intellectual Property that is created through activities conducted under this Agreement such that Licensee can comply with its obligations under Section 5.2 and Axsome is able to grant to Licensee the licenses with respect thereto under Section 2.1, and

7.2.4. if, at any time after execution of this Agreement, such Party becomes aware that it, any of its Affiliates, or any employee, agent, or subcontractor of it or any of its Affiliates or permitted subcontractors or in the case of Licensee, any Sublicensees, who participated or is participating in the performance of any activities hereunder in connection with the Development or Commercialization of any Licensed Product is or becomes debarred under 21 U.S.C. § 335a, it shall provide written notice of such fact to the other Party within five (5) Business Days of its discovery thereof.

7.3. Axsome Representations and Warranties. Axsome hereby represents and warrants to Licensee that, as of the Effective Date and except as disclosed in the disclosure schedule attached hereto as Schedule 7.3 (the "**Disclosure Schedule**"):

7.3.1. it has the full right, power and authority to grant all of the right, title and interest in the licenses and other rights granted or to be granted to Licensee, Licensee's Affiliates or Licensee's sublicensees under this Agreement;

7.3.2. (i) Schedule 1.50 sets forth a true and complete list of all Patent Rights owned or otherwise Controlled by Axsome or its Affiliates that relate to the Licensed Products or use in the Field, (ii) Axsome is not aware (with no duty of investigation) of any issued patents in the Territory not Controlled by Axsome, which issued patents relate to and would be infringed by the Commercialization of the Licensed Products (in the form as they exist on the Effective Date) for use in the Field in the Territory; and (iii) Axsome or its Affiliates have timely paid all filing and renewal fees payable with respect to such Patent Rights;

7.3.3. From and after the time that Axsome had become responsible for the maintenance of each of the Licensed Patent Rights, it has complied with all Applicable Laws in connection with the filing, prosecution and maintenance of such Licensed Patent Rights and all filings necessary to preserve the rights in the Licensed Patent Rights have been made and all applicable fees have been timely;

7.3.4. it has obtained from all inventors of Licensed Patent Rights owned by Axsome, which Licensed Patent Rights is existing as of the Effective Date, valid and enforceable agreements assigning to Axsome each such inventor's entire right, title and interest in and to all such Licensed Patent Rights;

7.3.5. to Axsome's knowledge, there are no allegations or proceedings, pending or threatened, which challenge Axsome's license to, or the validity or the enforceability of, the Licensed Patent Rights;

7.3.6. it has not previously assigned, transferred, conveyed, or granted any license or other rights under the Licensed Intellectual Property or Licensed Trademarks that would conflict with or materially limit the scope of any of the rights or licenses granted to Licensee hereunder; and

7.3.7. there is no (a) claim, demand, suit, proceeding, arbitration, inquiry, investigation or other legal action of any nature, civil, criminal, regulatory or otherwise, pending or, to the knowledge of Axsome, threatened against Axsome or any of its Affiliates or (b) judgment or settlement against or owed by Axsome or any of its Affiliates, in each case in connection with the Licensed Intellectual Property or any Licensed Product or relating to the transactions contemplated by this Agreement.

7.4. Representation by Legal Counsel. Each Party hereto represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption shall exist or be implied against the Party which drafted such terms and provisions.

7.5. Disclaimer. THE FOREGOING REPRESENTATIONS AND WARRANTIES OF EACH PARTY ARE IN LIEU OF ANY OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR ANY IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, ALL OF WHICH ARE HEREBY SPECIFICALLY EXCLUDED AND DISCLAIMED. LICENSEE ACKNOWLEDGES AND AGREES THAT AXSOME MAKES AND HAS MADE NO REPRESENTATION OR WARRANTY THAT THE LICENSED PRODUCTS CAN BE SUCCESSFULLY DEVELOPED FOR ANY ADDITIONAL INDICATION OR THAT LICENSED PRODUCTS CAN BE SUCCESSFULLY COMMERCIALIZED IN ANY COUNTRY OF THE TERRITORY FOR THE INDICATIONS INCLUDED IN THE TRANSFERRED REGUALTORY APPROVALS OR FOR ANY ADDITIONAL INDICATION THAT IS INCLUDED IN ANY REGULATORY APPROVAL OBTAINED BY LICENSEE.

8. TERM AND TERMINATION.

8.1. Term . The term of this Agreement (the "**Term**") will commence on the Effective Date and, unless earlier terminated in accordance with this Article 8, will continue until all Royalty Terms for all Licensed Products have expired in all countries of the Territory.

8.2. Termination for Cause.

8.2.1. Material Breach. Subject to Section 3.2.3, either Party may terminate this Agreement for cause at any time during the Term by giving written notice to the other Party in the event that such other Party commits a material breach of its obligations under this Agreement and such material breach remains uncured for ninety (90) days from the date of such notice; provided, however, that if any breach is not reasonably curable within ninety (90) days and if the breaching Party is making a bona fide effort to cure such breach, such termination shall be delayed for a time period to be agreed by both Parties in order to permit the breaching Party a reasonable period of time to cure such breach.

8.2.2. **Breach of Upstream License**. In the event that, as a result of any act or omission of Licensee or any of Licensee's Affiliates or Sublicensees, Axsome is in breach of any Upstream License, Axsome shall so notify Licensee and if Licensee fails to cure such breach within sixty (60) days of such notice, Axsome may terminate this Agreement by written notice with immediate effect.

8.3. Patent Challenge. Licensee acknowledges that prior to its entry into this Agreement it has had sufficient opportunity to review and assess the Patent Rights included in the Licensed Intellectual Property. Axsome shall have the right, exercisable in its sole discretion, to immediately, at Axsome's sole option, terminate this Agreement or convert the licenses and sublicenses granted to Licensee from exclusive to nonexclusive licenses (with all other terms remaining unchanged), upon written notice to Licensee, effective upon receipt, if Licensee or any of its Affiliates or its or their respective Sublicensees, directly or indirectly, challenges the validity, enforceability or scope of any of the Licensed Patent Right. Neither Party shall, and each Party shall ensure that its Affiliates and their respective sublicensees do not, use or disclose any Confidential Information of the other Party or any nonpublic information regarding the prosecution or enforcement of any Licensed Patent Rights to which a Party or any of its Affiliates or sublicensees are or become privy as a consequence of the rights granted to such Party pursuant to this Agreement, in initiating, requesting, making, filing or maintaining, or in funding or otherwise assisting any other Person with respect to, any Challenge. For purposes of this Section 8.3, "Challenge" will be interpreted as follows: Licensee, its Affiliates or any of its or their Sublicensees will be deemed to have made a "Challenge" of a Licensed Patent Right included in the Licensed Intellectual Property if Licensee or such Affiliate or Sublicensee, respectively: (a) institutes or voluntarily joins as a party to, or causes its counsel to institute on Licensee's or such Affiliate's or such Sublicensee's behalf, any interference, opposition, re-examination, *inter partes* review, post-grant review or similar proceeding with respect to any such Licensed Patent Right with any patent office; or (b) makes any filing or institutes or voluntarily joins as a party to any legal proceeding, or causes its counsel to make any filing or institute or voluntarily join as a party to any legal proceeding on Licensee's or such Affiliate's or such Sublicensee's behalf, with a court or other Governmental Authority (including any patent office) having authority to determine the validity, enforceability or scope of such Licensed Patent Rights, in which one (1) or more claims or allegations challenges the validity or enforceability of any such Licensed Patent Rights.

8.4. Termination for a Bankruptcy Event.

8.4.1. **Termination Right.** Except where prohibited by Applicable Law, each Party shall have the right to terminate this Agreement in the event of a Bankruptcy Event with respect to the other Party. "**Bankruptcy Event**" means the occurrence of any of the

following: (a) the institution, on a voluntary or involuntary basis, of any bankruptcy, receivership, insolvency, reorganization, corporate rescue, liquidation or other similar proceedings by or against a Party under any bankruptcy, insolvency, or other similar law now or hereinafter in effect, including any section or chapter of the United States Bankruptcy Code, as amended or under any similar laws or statutes of the United States or any state thereof (the "**Bankruptcy Code**") or of any relevant foreign jurisdiction, where in the case of involuntary proceedings such proceedings have not been dismissed or discharged within ninety (90) days after they are instituted, (b) the filing of an insolvency proceeding or making of an assignment for the benefit of creditors or the admittance by a Party of any involuntary debts as they mature, (c) the institution of any reorganization, arrangement or other readjustment of debt plan of a Party not involving the Bankruptcy Code, (d) appointment of a receiver for all or substantially all of a Party's assets, or (e) any corporate action taken by the board of directors of a Party in furtherance of any of the foregoing actions.

8.4.2. Rights to Intellectual Property. All rights and licenses granted under or pursuant to this Agreement by one Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any similar law in effect in a foreign jurisdiction, licenses of rights to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code or the relevant foreign law. The Parties agree that Axsome or Licensee, as licensee of intellectual property under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or relevant foreign law. The Parties further agree that in the event of a rejection of this Agreement by Axsome or Licensee, as applicable, in any bankruptcy proceeding by or against Axsome or Licensee, as applicable, under the U.S. Bankruptcy Code or foreign equivalent, (a) Licensee or Axsome, as applicable, 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, which, if not already in Licensee's or Axsome's, as applicable, possession, shall be promptly delivered to it upon Licensee's or Axsome's, as applicable, written request therefore, and (b) Axsome or Licensee, as applicable shall not interfere with the other Party's rights to intellectual property and all embodiments of intellectual property, and shall assist and not interfere with such other Party in obtaining intellectual property and all embodiments of intellectual property from another entity. The term "embodiments" of intellectual property includes all tangible, intangible, electronic or other embodiments of rights and licenses hereunder, including all compounds and products embodying intellectual property, Licensed Products, filings with Regulatory Authorities and related rights, and Licensed Intellectual Property.

8.5. Effects of Termination. In the event that this Agreement is terminated for any reason, the following will apply:

(a) Except as otherwise expressly provided herein, all rights and obligations of each Party hereunder shall cease (including all rights and licenses granted by either Party to the other Party hereunder).

(b) all unpaid royalty payments due pursuant to Section 4.4 for Licensed Product sold as of the effective date of termination shall remain due and payable as scheduled; and

(c) provided any Development Milestone or Commercial Milestone, as applicable, has been achieved on or before the date of expiration or the effective date of termination, any unpaid Development Milestone Payment or Commercial Milestone Payment shall remain due and payable and shall be paid within ten (10) Business Days of such date of expiration or termination.

(d) Licensee shall discontinue its Development and Commercialization of Licensed Products unless and then only to the extent and for the period of time as otherwise authorized in writing by Axsome.

(e) As and to the extent requested by Axsome in writing (which request may require one or more of the following),

(i) Licensee shall provide, disclose and transfer to Axsome all data obtained or collected solely to the extent such data or information relates to the Development or Commercialization of Licensed Products and is necessary to permit Axsome or Axsome's designee to continue to Develop and Commercialize Licensed Products in the Field in the Territory;

(ii) Licensee shall transfer and assign to Axsome all Regulatory Approvals and other regulatory filings relating to any Licensed Product and to the extent that any such Regulatory Approval or other regulatory filing is necessary to permit Axsome to continue to Develop or Commercialize such Licensed Product in the Field in the Territory;

(iii) Licensee shall transfer to Axsome or Axsome's designee the useable quantities of Licensed Product in Licensee's or its Affiliates possession and Axsome shall reimburse the amount paid by Licensee to Axsome for the purchase of those quantities of Licensed Product so transferred to Axsome;

(iv) Licensee, at its expense, shall destroy or cause to be destroyed those quantities of Licensed Product in Licensee's, its Affiliates or its or their Sublicensee's possession or control that Axsome in excess of those quantities that Licensee is to deliver to Axsome or its designee pursuant to Section 8.5.2(b)(iii); and

(v) Licensee shall return to Axsome all of Axsome's Confidential Information, provided, however, that Licensee may retain a copy of such Confidential Information in segregated files solely for purposes of determining its ongoing obligations with respect to maintaining the confidentiality of or limiting its use of such Confidential Information.

8.6. Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing hereunder prior to such expiration or termination. Without limiting the

foregoing, the following sections, together with this Section 8.6 and any sections that expressly survive, shall survive expiration or termination of this Agreement for any reason: Article 1 (Definitions), Section 2.2.2 (Licensee Grant of Right of Reference), Section 3.3.3 (Licensee Data), Section 4.5 (Reports and Payments) (with respect to Licensed Product sold prior to expiration or termination), Section 4.6 (Inspection of Records), Section 4.7 (Confidentiality), Section 5.1 (Pre-Existing IP), Section 5.2 (Ownership of Developed IP), Section 5.7 (Third Party Infringement Suits) (with respect to alleged infringement occurring prior to expiration or termination), Article 6 (Confidentiality), Section 8.5 (Effects of Termination), Section 9.1 (Limitation of Liability), Section 9.2 (Indemnification by Licensee), Section 9.3 (Indemnification by Axsome), Section 9.4 (Procedure) and Article 10 (Miscellaneous).

9. LIMITATION OF LIABILITY, INDEMNIFICATION AND INSURANCE.

9.1. LIMITATION OF LIABILITY. EXCEPT WITH RESPECT TO LIABILITY ARISING FROM A BREACH OF ARTICLES 5 OR 6, FROM ANY WILLFUL MISCONDUCT OR INTENTIONALLY WRONGFUL ACT, OR TO THE EXTENT SUCH PARTY MAY BE REQUIRED TO INDEMNIFY THE OTHER PARTY UNDER THIS ARTICLE 9, IN NO EVENT WILL EITHER PARTY OR ITS REPRESENTATIVES BE LIABLE UNDER THIS AGREEMENT FOR ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, INCLUDING LOSS OF PROFITS OR REVENUE SUFFERED BY EITHER PARTY OR ANY OF ITS REPRESENTATIVES REGARDLESS OF WHETHER ANY PARTY OR SUCH REPRESENTATIVES KNOWS OR SHOULD KNOW OF THE POSSIBILITY OF SUCH DAMAGES.

9.2. Indemnification by Licensee. Licensee will indemnify, defend and hold harmless Axsome, each of its Affiliates, and each of its and its Affiliates' employees, officers, directors and agents (each, a "**Axsome Indemnified Party**") from and against any and all liability, loss, damage, expense (including reasonable attorneys' fees and expenses) and cost (collectively, a "**Liability**") that the Axsome Indemnified Party may be required to pay to one or more Third Parties resulting from or arising out of:

(a) the Development, Commercialization or use of any Licensed Product by, on behalf of, or under the authority of, Licensee, its Affiliates or any of its or their sublicensees (in each case other than by any Axsome Indemnified Party), other than claims for which Axsome is required to indemnify Licensee pursuant to Section 9.3; or

(b) the material breach by Licensee of any of its representations, warranties or covenants set forth in Article 7;

except, in each case, to the extent caused by the negligence, recklessness or intentional misconduct of Axsome or any Axsome Indemnified Party.

9.3. Indemnification by Axsome . Axsome will indemnify, defend and hold harmless Licensee, its Affiliates, sublicensees, contractors, distributors and each of its and their respective employees, officers, directors and agents (each, a "**Licensee Indemnified Party**") from and

against any and all Liabilities that the Licensee Indemnified Party may be required to pay to one or more Third Parties resulting from or arising out of the material breach by Axsome of any of its representations, warranties or covenants set forth in Article 7 except to the extent caused by the negligence, recklessness or intentional misconduct of Licensee or any Licensee Indemnified Party.

9.4. Procedure.

9.4.1. **Notice**. Each Party will notify the other Party in writing in the event it becomes aware of a claim for which indemnification may be sought hereunder. In the event that any Third Party asserts a claim or other proceeding (including any governmental investigation) with respect to any matter for which a Party (the "**Indemnified Party**") is entitled to indemnification hereunder (a "**Third Party Claim**"), then the Indemnified Party shall promptly notify the Party obligated to indemnify the Indemnified Party (the "**Indemnifying Party**") thereof; provided, however, that no delay on the part of the Indemnified Party in notifying the Indemnifying Party shall relieve the Indemnifying Party from any obligation hereunder unless (and then only to the extent that) the Indemnifying Party is prejudiced thereby.

9.4.2. **Control**. The Indemnifying Party shall have the right, exercisable by notice to the Indemnified Party within ten (10) Business Days after receipt of notice from the Indemnified Party of the commencement of or assertion of any Third Party Claim, to assume direction and control of the defense, litigation, settlement, appeal or other disposition of the Third Party Claim (including the right to settle the claim solely for monetary consideration) with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party; provided that (a) the Indemnifying Party has sufficient financial resources, in the reasonable judgment of the Indemnified Party, to satisfy the amount of any adverse monetary judgment that is sought, (b) the Third Party Claim seeks solely monetary damages and (c) the Indemnifying Party expressly agrees in writing that as between the Indemnifying Party and the Indemnified Party, the Indemnifying Party shall be solely obligated to satisfy and discharge the Third Party Claim in full (the conditions set forth in clauses (a), (b) and (c) above are collectively referred to as the "**Litigation Conditions**"). Within ten (10) Business Days after the Indemnifying Party has given notice to the Indemnified Party of its exercise of its right to defend a Third Party Claim, the Indemnified Party shall give notice to the Indemnifying Party of any objection thereto based upon the Litigation Conditions. If the Indemnified Party reasonably so objects, the Indemnified Party shall continue to defend the Third Party Claim, at the expense of the Indemnifying Party, until such time as such objection is withdrawn. If no such notice is given, or if any such objection is withdrawn, the Indemnifying Party shall be entitled, at its sole cost and expense, to assume direction and control of such defense, with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party. During such time as the Indemnifying Party is controlling the defense of such Third Party Claim, the Indemnified Party shall cooperate, and shall cause its Affiliates and agents to cooperate upon request of the Indemnifying Party, in the defense or prosecution of the Third Party Claim, including by furnishing such records, information and testimony and attending such conferences, discovery proceedings, hearings, trials or appeals as may reasonably be requested by the Indemnifying Party. In the event that the Indemnifying Party does not satisfy the Litigation Conditions or does not notify the Indemnified Party of the Indemnifying Party's intent to defend any Third Party Claim within ten (10) Business

Days after notice thereof, the Indemnified Party may (without further notice to the Indemnifying Party) undertake the defense thereof with counsel of its choice and at the Indemnifying Party's expense (including reasonable, out-of-pocket attorneys' fees and costs and expenses of enforcement or defense). The Indemnifying Party or the Indemnified Party, as the case may be, shall have the right to join in (including the right to conduct discovery, interview and examine witnesses and participate in all settlement conferences), but not control, at its own expense, the defense of any Third Party Claim that the other Party is defending as provided in this Agreement.

9.4.3. Settlement. The Indemnifying Party shall not, without the prior written consent of the Indemnified Party, enter into any compromise or settlement that commits the Indemnified Party to take, or to forbear to take, any action. The Indemnified Party shall have the sole and exclusive right to settle any Third Party Claim, on such terms and conditions as it deems reasonably appropriate to the extent such Third Party Claim involves equitable or other non-monetary relief but shall not have the right to settle such Third Party Claim to the extent such Third Party Claim involves monetary damages without the prior written consent of the Indemnifying Party. Each of the Indemnifying Party and the Indemnified Party shall not make any admission of liability in respect of any Third Party Claim without the prior written consent of the other Party, and the Indemnified Party shall use reasonable efforts to mitigate Liabilities arising from such Third Party Claim.

9.5. Insurance. Each Party further agrees to obtain and maintain and Licensee shall cause its sublicensees to obtain and maintain, during the Term, commercial general liability insurance, including products liability insurance, with reputable and financially secure insurance carriers (or pursuant to a program of self-insurance reasonably satisfactory to the other Party) to cover its indemnification obligations under Section 9.2 or Section 9.3, as applicable, in each case with limits of not less than [*****] (or the equivalent amount in Euros) per occurrence and in the aggregate. Insurance shall be procured with carriers having an A.M. Best Rating of A-VII or better. Each Party shall maintain such insurance for so long as it continues to research, Develop, Manufacture or Commercialize any Licensed Products and thereafter for so long as is necessary to cover any claims made prior to expiration of any applicable statute of limitations.

10. MISCELLANEOUS.

10.1. Assignment. Neither this Agreement nor any interest hereunder shall be assignable by a Party without the prior written consent of the other Party, except as follows: (a) a Party may assign its rights and obligations under this Agreement by way of sale of itself or the sale of the portion of its business to which this Agreement relates, through merger, sale of assets and/or sale of stock or ownership interest, provided that the assignee shall expressly agree to be bound by such Party's obligations under this Agreement and that such sale is not primarily for the benefit of its creditors, and (b) a Party may assign its rights and obligations under this Agreement to any of its Affiliates, provided that the assignee shall expressly agree to be bound by such Party's obligations under this Agreement and that such Party shall remain liable for all of its rights and obligations under this Agreement. Each Party shall promptly notify the other Party of any assignment or transfer under the provisions of this Section 10.1. This Agreement shall be binding upon the successors and permitted assigns of the Parties and the name of a Party appearing herein shall be deemed to include the names of such Party's successors and permitted assigns to the extent

necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 10.1 shall be void.

10.2. 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 to carry out the purposes and intent of the Agreement.

10.3. Force Majeure. Each Party shall be excused from the performance of its obligations under this Agreement to the extent that such performance is prevented by Force Majeure and the non-performing Party promptly provides written notice of such Force Majeure to the other Party. Such excuse shall be continued so long as the condition constituting Force Majeure continues and the non-performing Party takes Commercially Reasonable Efforts to remove the condition. "**Force Majeure**" shall include conditions beyond the reasonable control of the Parties, including an act of God, voluntary or involuntary compliance with any regulation, Applicable Law or order of any government, war, act of terror, civil commotion, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe.

10.4. Notices. Each communication and document made or delivered by one Party to the other Party under this Agreement shall be made in the English language. All notices, consents, approvals, request or other communications required hereunder given by one Party to the other shall be in writing and made by (a) personal delivery, (b) first class certified mail with return receipt requested, (c) next-day delivery by major international courier with confirmation of deliver, or (d) email with a confirmation copy delivered by one of the foregoing methods. Notices will be deemed given upon receipt.

To Licensee:

Atnahs Pharma UK Limited
Sovereign House
Miles Grey Road
Basildon
Essex SS14 3FR
United Kingdom
Attention: Chief Executive Officer
[*****] [*****]

with a copy to:

[*****]
[*****]

To Axsome:

Axsome Malta Ltd. c/o
Axsome Therapeutics, Inc.
22 Cortlandt Street, 16th Floor
New York, NY 10007
Essex SS14 3FR
United Kingdom
Attention: Nick Pizzie
Chief Financial Officer
[*****]

Herriot Tabuteau, M.D.
President and Chief Executive Officer
[*****] [*****]

with a copy to:

Hunter Murdock
General Counsel
[*****]

with a copy to:

DLA Piper LLP (US)
One Liberty Place
1650 Market Street, Suite 5000
Philadelphia, PA 19103
Attention: Arthur Cohn
[*****] [*****]

10.5. Amendment. No amendment, modification or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized representative of each Party.

10.6. Waiver. No provision of this Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized representative of the waiving Party. The waiver by either Party of any breach of any provision by the other Party shall not be construed to be a waiver of any succeeding breach of such provision or a waiver of the provision itself.

10.7. Severability. If any clause or portion thereof in this Agreement is for any reason held to be invalid, illegal or unenforceable, the same shall not affect any other portion of this Agreement, as it is the intent of the Parties that this Agreement shall be construed in such fashion as to maintain its existence, validity and enforceability to the greatest extent possible. In any such

event, this Agreement shall be construed as if such clause of portion thereof had never been contained in this Agreement, and there shall be deemed substituted therefor such provision as will most nearly carry out the intent of the Parties as expressed in this Agreement to the fullest extent permitted by Applicable Law.

10.8. Export Control. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States of America or other countries which may be imposed upon or related to Axsome or Licensee from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity.

10.9. Dispute Resolution.

10.9.1. Notice; Consultation. In the event of any dispute, controversy or claim arising out of, relating to or in connection with this Agreement (including any schedule or exhibit hereto) or the breach, termination or validity thereof or the negotiation, execution or performance thereof (a "**Dispute**"), the Parties shall first attempt to settle such Dispute in the first instance by mutual discussions between representatives of senior management of each Party.

(a) Within ten (10) Business Days of the receipt by a Party or Parties of a notice from another Party or Parties of the existence of a Dispute (the "**Arbitration Notice**"), the receiving Party or Parties shall submit a written response to the other Party or Parties (the "**Response**"). The Arbitration Notice and the Response shall each include (i) a statement of the applicable Party's position with regard to the Dispute and a summary of arguments supporting that position and (ii) the name and title of the senior executive who will represent the applicable Party in attempting to resolve the Dispute pursuant to this Section 10.9.1.

(b) Within fifteen (15) Business Days of receipt of the Response, the designated executives shall meet and attempt to resolve the Dispute. All negotiations pursuant to this Section shall be confidential and shall be treated as compromise and settlement negotiations, and no oral or documentary representations made by the Parties during such negotiations shall be admissible for any purpose in any subsequent arbitration or legal proceedings.

(c) If any Dispute is not resolved within thirty (30) Business Days of receipt of the Arbitration Notice (or within such longer period as to which the Parties have agreed in writing), then the Dispute shall be submitted to arbitration in accordance with Section 10.9.2.

10.9.2. Arbitration. Any Dispute not timely resolved by negotiation pursuant to Section 10.9.1(a) shall be finally resolved by confidential binding arbitration in accordance with the following:

(a) The arbitration shall be conducted by three (3) arbitrators, in accordance with the Rules of Arbitration of the International Chamber of Commerce ("**ICC**"). The claimant shall nominate an arbitrator in its request for arbitration. The respondent shall nominate an arbitrator within thirty (30) days of the receipt of the request for arbitration. The two (2) arbitrators nominated by the Parties shall nominate a third arbitrator within thirty (30) days after the nomination of the later-nominated arbitrator. The third arbitrator shall act as chair of the tribunal. If any of the three (3) arbitrators are not nominated within the time prescribed above, then the ICC shall appoint the arbitrator(s).

(b) The seat of the arbitration shall be New York, New York, USA, and it shall be conducted in the English language.

(c) The costs of the arbitration, including the Parties' reasonable legal fees, shall in principle be borne by the unsuccessful Party or Parties, however, the arbitral tribunal may apportion such costs between the Parties if it determines that apportionment is reasonable, taking into account the circumstances of the case. The arbitration award shall be final and binding on the Parties, and the Parties undertake to carry out any award without delay. Judgment upon the award may be entered by any court having jurisdiction of the award or having jurisdiction over the relevant Party or its assets.

(d) The Parties agree that the arbitration shall be kept confidential. The existence of the arbitration, any non-public information provided in the arbitration, and any submissions, orders or awards made in the arbitration shall be deemed Confidential Information and shall not be disclosed to any non-Party except the tribunal, the ICC, the Parties' counsel, experts, witnesses, accountants and auditors, insurers and reinsurers, and any other Person necessary to the conduct of the arbitration. Notwithstanding the foregoing, a Party may disclose Confidential Information to the extent that disclosure may be required to fulfil a legal duty, protect, or pursue a legal right, or enforce or challenge an award in bona fide legal proceedings. This confidentiality provision survives termination of the Agreement and of any arbitration brought pursuant to the Agreement.

10.9.3. Provisional Remedies. Notwithstanding any provision of this Agreement to the contrary, either Party may immediately initiate litigation in any court of competent jurisdiction seeking any remedy at law or in equity, including the issuance of a preliminary, temporary or permanent injunction, to preserve or enforce its rights under this Agreement. The procedures specified in this Section 10.9 shall be the sole and exclusive procedures for the resolution of Disputes between the Parties arising out of or relating to this Agreement; *provided*, that a Party, without prejudice to the above procedures, may seek injunctive relief or other provisional judicial relief if in its sole judgment such action is necessary to avoid irreparable damage; *provided* that, both Parties agree the arbitrators shall be fully empowered to modify, set aside or continue such injunctive or other provisional relief in the arbitrators' discretion. Despite such action the Parties will continue to participate in good faith in the procedures specified in this Section 10.9.

10.10. Governing Law. This Agreement, and all claims arising under or in connection therewith, shall be governed by and interpreted in accordance with the laws of the State of New York, without regard to conflict of law principles thereof. The provisions of the United Nations Convention on Contracts for the International Sale of Goods will not apply to this Agreement or any subject matter hereof.

10.11. Entire Agreement. This Agreement, together with the Exhibits and Schedules attached hereto, sets forth the entire agreement between the Parties as to its subject matter and supersedes all proposals, oral or written, and all other prior communications between the Parties with respect to such subject matter.

10.12. Independent Contractors. The Parties are independent contractors under this Agreement. Nothing herein contained shall be deemed to create an employment, agency, joint venture or partnership relationship between the Parties hereto or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act, or failure to act, of the other Party. Neither Party shall have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever. The Parties acknowledge and agree that neither Party owes the other any fiduciary or similar duties or obligations by virtue of the relationship created by this Agreement. Without limiting the foregoing, the Parties also acknowledge and agree that if a court of competent jurisdiction or an arbitrator should determine that, notwithstanding the terms of this Section 10.12, that such fiduciary or other obligations exist, the Parties hereby waive such duties and obligations and agree not to assert or rely upon such duties or obligations in connection with any Dispute arising out of or relating to this Agreement.

10.13. No Third Party Rights or Obligations. No provision of this Agreement shall be deemed or construed in any way to result in the creation of any rights or obligation in any Person not a Party to this Agreement. However, Licensee may decide, in its sole discretion, to use one or more of its Affiliates to perform its obligations and duties hereunder, provided that Licensee shall remain liable hereunder for the performance by any such Affiliates of any such obligations.

10.14. Third Party Beneficiary. Licensee agrees that SK Biopharmaceuticals shall be a third party beneficiary of the rights granted to Axsome and the obligations undertaken by Licensee under this Agreement (including those under Article 6 and Sections 5.2 and 9.5), and shall, to that extent, have the right to enforce this Agreement against Licensee directly to the extent SK Biopharmaceuticals may deem such enforcement necessary or advisable to protect its rights hereunder or under the Upstream License for which SK Biopharmaceuticals Co., Ltd. is the Upstream Licensor.

10.15. Headings. The descriptive headings of this Agreement are included herein for ease of reference only and shall be of no force and effect in construing or interpreting any of the provisions of this Agreement.

10.16. Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same document. Counterparts may be signed and delivered by facsimile or PDF file, with the same effect as if delivered personally.

IN WITNESS WHEREOF, authorized representatives of the Parties have duly executed this Agreement as of the Effective Date.

AXSOME THERAPEUTICS, INC.

By: /s/ Herriot Tabuteau, M.D.
Name: Herriot Tabuteau, M.D.
Title: President and Chief Executive Officer

ATNAHS PHARMA UK LIMITED

By: /s/ James Burt
Name: James Burt
Title: Chief Executive Officer

OMITTED SCHEDULES

SCHEDULE 1.50
LICENSED PATENT RIGHTS

SCHEDULE 1.52
LICENSED TRADEMARKS

SCHEDULE 1.83
TRANSFERRED CLINICAL TRIALS

SCHEDULE 1.84
TRANSFERRED REGULATORY APPROVALS

SCHEDULE 1.86
UPSTREAM LICENSES

SCHEDULE 2.5.2
REGULATORY APPROVAL TRANSITION PROTOCOL

SCHEDULE 3.3.1
TRANSFERRED CLINICAL TRIAL AGREEMENTS

SCHEDULE 3.3.2
STUDIES APPROVED TO BE CONDUCTED BY LICENSEE

SCHEDULE 3.6
TERM SHEET FOR SUPPLY AGREEMENT

SCHEDULE 7.3
DISCLOSURE SCHEDULE

**Exhibit B intentionally omitted. It is not material and would be competitively harmful if publicly disclosed.

Exhibit 10.2

THIRD AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS THIRD AMENDMENT TO LOAN AND SECURITY AGREEMENT (this "Amendment"), dated as of January 9, 2023, is entered into by and among AXSOME THERAPEUTICS, INC., a Delaware corporation ("Borrower"), and the several banks and other financial institutions or entities party hereto as Lender, constituting the Required Lenders and HERCULES CAPITAL, INC., a Maryland corporation, in its capacity as administrative agent and collateral agent for Lender (in such capacity, "Agent").

A. Borrower, Lenders and Agent are parties to that certain Loan and Security Agreement, dated as of September 25, 2020 (as amended by the First Amendment to Loan and Security Agreement, dated as of October 14, 2021, and the Second Amendment to Loan and Security Agreement, dated as of March 27, 2022, the "Existing Loan Agreement"; and the Existing Loan Agreement, as amended by this Amendment and as further amended, restated, supplemented or otherwise modified from time to time, the "Loan Agreement").

B. Borrower, Lenders and Agent desire to modify the terms of the Existing Loan Agreement as set forth in this Amendment.

SECTION 1Definitions; Interpretation.

(a) **Terms Defined in Loan Agreement**. 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.

(b) **Rules of Construction**. The rules of construction that appear in Section 1.3 of the Loan Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2Amendments to the Loan Agreement.

(a) Upon satisfaction of the conditions set forth in Section 5 hereof, the Existing Loan Agreement is hereby amended as follows:

(i) Exhibit A attached hereto sets forth a clean copy of the Loan Agreement as amended hereby;

(ii) In Exhibit B hereto, deletions of the text in the Existing Loan Agreement (including, to the extent included in such Exhibit B, each Schedule or Exhibit to the Existing Loan Agreement) are indicated by ~~struck-through text~~, and insertions of text are indicated by **bold, double-underlined text**.

(b) **References Within Existing Loan Agreement**. Each reference in the Existing Loan Agreement to "this Agreement" and the words "hereof," "herein," "hereunder," or words of like import, shall mean and be a reference to the Existing Loan Agreement as amended by this Amendment. This Amendment shall be a Loan Document.

SECTION 3Conditions to Effectiveness of this Amendment. The effectiveness of this Amendment shall be subject to Agent's receipt of the following documents, in form and substance satisfactory to Agent, or, as applicable, the following conditions being met:

(a) Agent's receipt of this Amendment, executed by Agent, each Lender and Borrower;

(b) on the date hereof, (i) the representations and warranties contained in Section 6 shall be true and correct on and as of the date hereof as though made on and as of such date; and (ii) there exist no Events of Default or events that with the passage of time would result in an Event of Default;

(c) an amendment fee equal to $150,000 payable to the Agent on behalf of the Lender on the date hereof. If the due date of such fee would otherwise fall on a day that is not a Business Day (the "Amendment Fee Due Date"), such fee shall be considered paid on the Amendment Fee Due Date, if received on the next succeeding Business Day; and

(d) Borrower shall have paid (i) all invoiced costs and expenses then due in accordance with Section 8(e), and (ii) all other fees, costs and expenses, if any, due and payable as of the date hereof under the Loan Agreement.

SECTION 4Section 2 Effective Date. Section 2 of this Amendment shall become effective (the "Third Amendment Effective Date") when Agent receives evidence, in form and substance satisfactory to Agent, that all the conditions to effectiveness set forth in Section 5 below have been met which may be delivered at Borrower's discretion; provided that Borrower shall deliver all the conditions to effectiveness set forth in Section 5 below.

SECTION 5Conditions to Section 2 Effective Date. Section 2 of this Amendment shall be subject to Agent's receipt of each of the following documents, in form and substance satisfactory to Agent, or, as applicable, each of the following conditions being met:

(a) Agent's receipt of Warrants for each Lender, dated the Third Amendment Effective Date, in form and substance satisfactory to Agent with respect to this Amendment (the "Tranche 1B Warrants");

(b) a duly executed certificate of an officer of Borrower certifying and attaching copies of (A) the certificate of incorporation of the Borrower, certified as of a recent date by the jurisdiction of organization of Borrower and as in effect as of the Third Amendment Effective Date; (B) the bylaws of Borrower, as in effect as of the Third Amendment Effective Date; (C) resolutions of Borrower's board of directors evidencing approval of this Amendment, the Tranche 1B Warrants and the Tranche 1B Advance to be made on the Third Amendment Effective Date, as such resolutions remain in full force and effect as of the Third Amendment Effective Date; and (D) a schedule setting forth the name, title and specimen signature of officers or other authorized signers on behalf of Borrower;

(c) a certificate of good standing for Borrower from its jurisdiction of organization;

(d) an Advance Request for the Tranche 1B Advance, in accordance with Section 4.2 of the Loan Agreement;

(e) a legal opinion of Borrower's counsel in form and substance reasonably acceptable to Agent;

(f) such other documents as Agent may reasonably request;

(g) on the Third Amendment Effective Date, after giving effect to the amendment of the Existing Loan Agreement contemplated hereby: (i) the representations and warranties contained in Section 6 shall be true and correct on and as of the Third Amendment Effective Date as though made on and as of such date; and (ii) there exist no Events of Default or events that with the passage of time would result in an Event of Default; and

(h) Borrower shall have paid (i) all invoiced costs and expenses then due in accordance with Section 8(e), and (ii) all other fees, costs and expenses, if any, due and payable as of the Third Amendment Effective Date under the Loan Agreement, including the Third Amendment Facility Charge (as defined in the Loan Agreement attached hereto in Exhibit A).

SECTION 6Representations and Warranties. To induce Agent and Lender to enter into this Amendment, Borrower hereby confirms, as of the date hereof, (a) that the representations and warranties made by it in Section 5 of the Loan Agreement and in the other Loan Documents are true and correct in all material respects; *provided*, *however*, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof and that any representations and warranties made as of a specific date are only true and correct in all material respects as of such date, and that no Event of Default has occurred and is continuing, (b) that no event that has had or could reasonably be expected to have a Material Adverse Effect has occurred and is continuing and Borrower is not aware of any event likely to occur that is reasonably expected to result in a Material Adverse Effect; (c) that the information included in the Perfection Certificate delivered to Agent on the date hereof is true and correct; (d) Lenders have and shall continue to have valid, enforceable and perfected first-priority liens, subject only to Permitted Liens, on and security interests in the Collateral and all other collateral heretofore granted by Borrower to Lenders, pursuant to the Loan Documents or otherwise granted to or held by Lenders; (e) the agreements and obligations of Borrower contained in the Loan Documents and in this Amendment constitute the legal, valid and binding obligations of Borrower, enforceable against Borrower in accordance with their respective terms, except as the enforceability thereof may be limited by bankruptcy, insolvency or other similar laws of general application affecting the enforcement of creditors' rights or by the application of general principles of equity; and (f) the execution, delivery and performance of this Amendment by Borrower will not violate any law, rule, regulation, order, contractual obligation or organizational document of Borrower and will not result in, or require, the creation or imposition of any lien, claim or encumbrance of any kind on any of its properties or revenues. For the purposes of this Section 6, each reference in Section 5 of the Loan Agreement to "this Agreement," and the words "hereof," "herein," "hereunder," or words of like import in such Section, shall mean and be a reference to the Loan Agreement as amended by this Amendment.

SECTION 7Post-Closing. Notwithstanding any provision herein or in the Loan Documents to the contrary, to the extent not actually delivered on or prior to the Third Amendment Effective Date, Borrower shall deliver to Agent:

(a) Within forty five (45) days (or such longer period as the Agent may agree) of the Third Amendment Effective Date, (i) a Maltese debenture or security agreement granting a lien in substantially all of the assets of the Malta Subsidiary, (ii) a Maltese law governed bank account pledge agreement in favor of Agent, as applicable, (iii) a Maltese law governed receivables pledge agreement in favor of Agent, as applicable, (iv) a Maltese law governed intellectual property pledge agreement in favor of Agent, as applicable, (v) a customary legal opinion of local Malta counsel for the Malta Subsidiary and (vi) such other documentation relating to such categories of assets as the Borrower and Agent may reasonably agree, in each case, in form and substance satisfactory to Agent in its sole discretion.

(b) Within fourteen (14) days (or such longer period as the Agent may agree) of the Third Amendment Effective Date, a perfection certificate, executed by Borrower, in form and substance reasonably satisfactory to Agent.

SECTION 8Miscellaneous.

(a) **Loan Documents Otherwise Not Affected; Reaffirmation**.

(i) Except as expressly amended pursuant hereto or referenced herein, the Loan Agreement and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. Lender's and Agent's execution and delivery of, or acceptance of, this Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future.

(ii) Borrower hereby expressly (1) reaffirms, ratifies and confirms all Secured Obligations under the Loan Agreement and the other Loan Documents, (2) reaffirms, ratifies and confirms the grant of security under Section 3.1 of the Loan Agreement, (3) reaffirms that such grant of security in the Collateral secures all Secured Obligations under the Loan Agreement, and with effect from (and including) the Third Amendment Effective Date, such grant of security in the Collateral: (x) remains in full force and effect notwithstanding the amendments expressly referenced herein; and (y) secures all Secured Obligations under the Loan Agreement, as amended by this Amendment, and the other Loan Documents, (4) agrees that this Amendment shall be a "Loan Document" under the Loan Agreement and (5) agrees that the Loan Agreement and each other Loan Document shall remain in full force and effect following any action contemplated in connection herewith.

(iii) This Amendment is not a novation and the terms and conditions of this Amendment shall be in addition to and supplemental to all terms and conditions set forth in the Loan Documents. Nothing in this Amendment is intended, or shall be construed, to constitute an accord and satisfaction of Borrower's Secured Obligations under or in connection with the Loan Agreement and any other Loan Document or to modify, affect or impair the perfection or continuity of Agent's security interest in, (on behalf of itself and the Lenders) security titles to or other liens on any Collateral for the Secured Obligations.

(b) **Conditions**. For purposes of determining compliance with the conditions specified in Section 5, each Lender that has signed this Amendment shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Lender unless Agent shall have received notice from such Lender prior to the Third Amendment Effective Date specifying its objection thereto.

(c) **Release**. In consideration of the agreements of Agent and each Lender contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Borrower, on behalf of itself and its successors, assigns, and other legal representatives, hereby fully, absolutely, unconditionally and irrevocably releases, remises and forever discharges Agent and each Lender, and its successors and assigns, and its present and former shareholders, affiliates, subsidiaries, divisions, predecessors, directors, officers, attorneys, employees, agents and other representatives (Agent, Lenders and all such other persons being hereinafter referred to collectively as the "Releasees" and individually as a "Releasee"), of and from all demands, actions, causes of action, suits, covenants, contracts, controversies, agreements, promises, sums of money, accounts, bills, reckonings, damages and any and all other claims, counterclaims, defenses, rights of set-off, demands and liabilities whatsoever of every name and nature, both at law and in equity, to the extent Borrower has actual knowledge as of the date hereof that it owns, holds, has or claims to have against the Releasees or any of them for, upon, or by reason of any circumstance, action, cause or thing whatsoever which arises at any time on or prior to the day and date of this Amendment, including, without limitation, for or on account of, or in relation to, or in any way in connection with the Loan Agreement, or any of the other Loan Documents or transactions thereunder or related thereto.

Borrower understands, acknowledges and agrees that the release set forth above may be pleaded as a full and complete defense and may be used as a basis for an injunction against any action, suit or other proceeding which may be instituted, prosecuted or attempted in breach of the provisions of such release. Borrower agrees that no fact, event, circumstance, evidence or transaction which Borrower has actual knowledge of could now be asserted or shall affect in any manner the final, absolute and unconditional nature of the release set forth above. The provisions of this section shall survive payment in full of the Secured Obligations, full performance of all the terms of this Amendment and the other Loan Documents.

In connection with the releases set forth above, Borrower expressly and completely waives and relinquishes any and all rights and benefits that it has or may ever have pursuant to Section 1542 of the Civil Code of the State of California, or any other similar provision of law or principle of equity in any jurisdiction pertaining to the matters released herein. Section 1542 provides as follows:

A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY.

(d) **No Reliance**. Borrower hereby acknowledges and confirms to Agent and Lenders that Borrower is executing this Amendment on the basis of its own investigation and for its own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.

(e) **Costs and Expenses**. Borrower agrees to pay to Agent on the date hereof the reasonable out-of-pocket costs and expenses of Agent and Lender party hereto, and the fees and disbursements of counsel to Agent and Lender party hereto in connection with the negotiation, preparation, execution and delivery of this Amendment and any other documents to be delivered in connection herewith on the Third Amendment Effective Date.

(f) **Binding Effect**. This Amendment binds and is for the benefit of the successors and permitted assigns of each party.

(g) **Governing Law.** THIS AMENDMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF CALIFORNIA (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES THAT WOULD RESULT IN the application of ANY laws OTHER THAN THE LAWS OF THE STATE OF CALIFORNIA), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL.

(h) **Complete Agreement; Amendments**. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

(i) **Severability of Provisions.** Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

(j) **Counterparts**. This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

(k) **Loan Documents**. This Amendment and the documents related thereto shall constitute a Loan Document.

(l) **Electronic Execution of Certain Other Documents**. The words "execution," "execute", "signed," "signature," and words of like import in or related to any document to be signed in connection with this Amendment and the transactions contemplated hereby (including without limitation assignments, assumptions, amendments, waivers and consents) shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by the Agent, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the California Uniform Electronic Transactions Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

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IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

BORROWER:

AXSOME THERAPEUTICS, INC.

Signature: /s/ Nick Pizzie

Print Name: Nick Pizzie

Title: Chief Financial Officer

[SIGNATURES CONTINUE ON THE NEXT PAGE]

AGENT:

HERCULES CAPITAL, INC.

Signature: /s/ Seth Meyer

Print Name: Seth Meyer

Title: Chief Financial Officer

LENDER:

HERCULES CAPITAL, INC.

Signature: /s/ Seth Meyer

Print Name: Seth Meyer

Title: Chief Financial Officer

HERCULES PRIVATE CREDIT FUND 1 L.P.

By: Hercules Private Global Venture Growth Fund GP I LLC, its general partner

By: Hercules Adviser LLC, its sole member

Signature: /s/ Seth Meyer

Print Name: Seth Meyer

Title: Authorized Signatory

HERCULES PRIVATE GLOBAL VENTURE GROWTH FUND I L.P.

By: Hercules Private Global Venture Growth Fund GP I LLC, its general partner

By: Hercules Adviser LLC, its sole member

Signature: /s/ Seth Meyer

Print Name: Seth Meyer

Title: Authorized Signatory

EXHIBIT A

(See Attached)

LOAN AND SECURITY AGREEMENT

THIS LOAN AND SECURITY AGREEMENT is made and dated as of September 25, 2020 and is entered into by and among AXSOME THERAPEUTICS, INC., a Delaware corporation, and each of its Subsidiaries other than Excluded Subsidiaries (individually and collectively referred to as the "Borrower"), the several banks and other financial institutions or entities from time to time parties to this Agreement (collectively, referred to as the "Lenders") and HERCULES CAPITAL, INC., a Maryland corporation, in its capacity as administrative agent and collateral agent for itself and the Lenders (in such capacity, the "Agent").

RECITALS

A. Borrower has requested the Lenders make available to Borrower a loan in an aggregate principal amount of up to Three Hundred Million Dollars ($350,000,000) (the "Term Loan"); and

B. The Lenders are willing to make the Term Loan on the terms and conditions set forth in this Agreement.

AGREEMENT

NOW, THEREFORE, Borrower, Agent and the Lenders agree as follows:

SECTION 1. DEFINITIONS AND RULES OF CONSTRUCTION

1.1Unless otherwise defined herein, the following capitalized terms shall have the following meanings:

"Account Control Agreement(s)" means any agreement entered into by and among the Agent, Borrower and a third party bank or other institution (including a Securities Intermediary) in which Borrower maintains a Deposit Account or an account holding Investment Property and which perfects Agent's first priority security interest in the subject account or accounts.

"ACH Authorization" means the ACH Debit Authorization Agreement in substantially the form of Exhibit H, which account numbers shall be redacted for security purposes if and when filed publicly by the Borrower.

"ACH Failure" means the failure of the Automated Clearing House (ACH) system to effect a transfer of funds requested by Lender to be used to satisfy all or part of Borrower's obligations to pay principal and interest due hereunder, unless any such failure results from insufficient funds in Borrower's account(s).

"Acquisition" means any transaction or series of related transactions for the purpose of or resulting, directly or indirectly, in (a) the acquisition of all or substantially all of the assets of a Person, or any division, line of business or other business unit of another Person, (b) the acquisition of fifty percent (50%) or more of the Equity Interests of any Person, whether or not involving a merger, consolidation or similar transaction with such other Person, or otherwise causing any Person to become a Subsidiary of Borrower, or (c) the acquisition of, or the right to use, develop or sell (in each case, including through licensing), any product that would constitute a Borrower Product upon acquisition.

"Acquisition Deferred Payments" means, with respect to an Acquisition, any "earnouts," holdbacks, performance based-milestones, royalties, purchase price adjustments, profit sharing arrangements, deferred purchase money amounts, indemnifications, non-competition agreements, incentive payments, and other similar payment obligations, and other contingent obligations and agreements consisting of the adjustment of purchase price or similar adjustments.

"Advance(s)" means a Term Loan Advance.

"Advance Date" means the funding date of any Advance.

"Advance Request" means a request for an Advance submitted by Borrower to Agent in substantially the form of Exhibit A, which account numbers shall be redacted for security purposes if and when filed publicly by the Borrower.

"Affiliate" means with respect to any Person (a) any Person that directly or indirectly controls, is controlled by, or is under common control with such Person, (b) any Person directly or indirectly owning, controlling or holding with power to vote ten percent (10%) or more of the outstanding voting securities of such Person, and (c) any Person ten percent (10%) or more of whose outstanding voting securities are directly or indirectly owned, controlled or held by such Person with power to vote such securities. As used in the definition of "Affiliate," the term "control" means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through ownership of voting securities, by contract or otherwise.

"Agreement" means this Loan and Security Agreement, as amended from time to time.

"Antecip Direct Agreement" means that certain Direct Agreement dated as of the date hereof, by and among the Company, Antecip Bioventures II LLC and the Agent (as amended, supplemented or otherwise modified from time to time).

"Antecip License Agreement" means that certain License Agreement, dated as of April 17, 2012 by and between Borrower and Antecip Bioventures II LLC, as amended by the First Amendment to License Agreement dated as of August 21, 2015, as amended by the Antecip Direct Agreement and as may be further amended from time to time pursuant to terms of the Antecip Direct Agreement.

"Anti-Corruption Laws" means all laws, rules, and regulations of any jurisdiction applicable to Borrower or any of its Affiliates from time to time concerning or relating to bribery or corruption, including without limitation the United States Foreign Corrupt Practices Act of 1977, as amended, the UK Bribery Act 2010 and other similar legislation in any other jurisdictions.

"Anti-Terrorism Laws" means any laws, rules, regulations or orders relating to terrorism or money laundering, including without limitation Executive Order No. 13224 (effective September 24, 2001), the USA PATRIOT Act, the laws comprising or implementing the Bank Secrecy Act, and the laws administered by OFAC.

"Australian Subsidiary" means Axsome Therapeutics Australia Pty Ltd, a company organized under the laws of Australia.

"Auvelity" means Borrower's AXS-05 product currently marketed in the United States under the trade name "Auvelity," together with any improvements or modifications thereto, including any current or future pharmaceutical or biological product (including any product in development or that may be developed) that includes the combination of dextromethorphan and bupropion (regardless of what trade name is utilized).

"Auvelity Licensing" means the licensing of rights to Auvelity for discrete geographical areas outside of the United States of America, pursuant to a Permitted License.

"AXS-05" means Borrower's AXS-05 product candidate (bupropion and dextromethorphan) for the treatment of Major Depressive Disorder (MDD) and other indications.

"AXS-07" means Borrower's AXS-07 product candidate (MoSEIC meloxicam and rizatriptan) for the acute treatment of migraine.

"AXS-12" means Borrower's AXS-12 product candidate (reboxetine) for the treatment of narcolepsy.

"AXS-14" means Borrower's AXS-14 product candidate (esreboxetine) for the treatment of fibromyalgia.

"Blocked Person" means any Person: (a) listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (b) a Person owned or controlled by, or acting for or on behalf of, any Person that is listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (c) a Person with which any Lender is prohibited from dealing or otherwise engaging in any transaction by any Anti-Terrorism Law, (d) a Person that commits, threatens or conspires to commit or supports "terrorism" as defined in Executive Order No. 13224, or (e) a Person that is named a "specially designated national" or "blocked person" on the most current list published by OFAC or other similar list.

"Borrower's Books" means Borrower's or any of its Subsidiaries' books and records including ledgers, federal, state, local and foreign tax returns, records regarding Borrower's or its Subsidiaries' assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

"Borrower Products" means all products currently being designed, manufactured or that are under preclinical or clinical investigation or development by Borrower or which Borrower intends to sell, license, or distribute in the future subject to applicable regulatory approvals including any products under development, collectively, together with all products that have been sold, licensed or distributed by Borrower since its incorporation.

"Business Day" means any day other than Saturday, Sunday and any other day on which banking institutions in the State of California are closed for business.

"Cash" means all cash, cash equivalents and liquid funds.

"Change in Control" means any (x) reorganization, recapitalization, consolidation or merger (or similar transaction or series of related transactions) of Borrower, sale or exchange of outstanding shares (or similar transaction or series of related transactions) of Borrower in which the holders of Borrower's outstanding shares immediately before consummation of such transaction or series of related transactions do not, immediately after consummation of such transaction or series of related transactions, retain shares representing more than fifty percent (50%) of the voting power of the surviving entity of such

transaction or series of related transactions (or the parent of such surviving entity if such surviving entity is wholly owned by such parent), in each case without regard to whether Borrower is the surviving entity or (y) "change of control", "fundamental change", "make-whole fundamental change" or any comparable term under and as defined in any indenture governing any Permitted Convertible Debt has occurred.

"Closing Date" means the date of this Agreement.

"Code" means the Internal Revenue Code of 1986, as amended.

"Common Stock" means the Common Stock, $0.0001 par value per share, of the Borrower.

"Company IP" means any and all of the following, as they exist in and throughout the United States: (a) Current Company IP; (b) improvements, continuations, continuations-in-part, divisions, provisionals or any substitute applications, any patent issued with respect to any of the Current Company IP, any patent right claiming the composition of matter of, or the method of making or using, the Borrower Products in the United States, any reissue, reexamination, renewal or patent term extension or adjustment (including any supplementary protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent; (c) trade secrets or trade secret rights, including any rights to unpatented inventions, know-how, show-how, operating manuals, confidential or proprietary information, research in progress, algorithms, data, databases, data collections, designs, processes, procedures, methods, protocols, materials, formulae, drawings, schematics, blueprints, flow charts, models, strategies, prototypes, techniques, and the results of experimentation and testing, including samples, in each case, as specifically related to any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of the Borrower Products; (d) any and all IP Ancillary Rights specifically relating to any of the foregoing; and (e) regulatory filings, submissions and approvals related to any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of the Borrower Products and all data provided in any of the foregoing.

"Contingent Obligation" means, as applied to any Person, any direct or indirect liability, contingent or otherwise, of that Person with respect to (i) any Indebtedness, lease, dividend, letter of credit or other obligation of another, including any such obligation directly or indirectly guaranteed, endorsed, co-made or discounted or sold with recourse by that Person, or in respect of which that Person is otherwise directly or indirectly liable; (ii) any obligations with respect to undrawn letters of credit, corporate credit cards or merchant services issued for the account of that Person; and (iii) all obligations arising under any interest rate, currency or commodity swap agreement, interest rate cap agreement, interest rate collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; provided, however, that the term "Contingent Obligation" shall not include endorsements for collection or deposit in the ordinary course of business or guaranties of operating leases that do not constitute Indebtedness. The amount of any Contingent Obligation shall be deemed to be an amount equal to the stated or determined amount of the primary obligation in respect of which such Contingent Obligation is made or, if not stated or determinable, the maximum reasonably anticipated liability in respect thereof as determined by such Person in good faith; provided, however, that such amount shall not in any event exceed the maximum amount of the obligations under the guarantee or other support arrangement. For the avoidance of doubt, no Permitted Bond Hedge Transaction or Permitted Warrant Transaction will be considered a Contingent Obligation of Borrower.

"Copyright License" means any written agreement granting any right to use any Copyright or Copyright registration, now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest.

"Copyrights" means all copyrights, whether registered or unregistered, held pursuant to the laws of the United States of America, any State thereof, or of any other country.

"Cross-Default Reference Obligation" has the meaning assigned to such term in the definition of "Permitted Convertible Debt."

"Deposit Accounts" means any "deposit accounts," as such term is defined in the UCC, and includes any checking account, savings account, or certificate of deposit.

"Domestic Subsidiary" means any Subsidiary organized under the laws of the United States of America, any State thereof, the District of Columbia, or any other jurisdiction within the United States of America.

"Due Diligence Fee" means $75,000, which fee has been paid to the Lenders prior to the Closing Date, and shall be deemed fully earned on such date regardless of the early termination of this Agreement.

"Equity Interests" means, with respect to any Person, the capital stock, partnership or limited liability company interest, or other equity securities or equity ownership interests of such Person.

"ERISA" means the Employee Retirement Income Security Act of 1974, as amended, and the regulations promulgated thereunder.

"Excluded Account" means (i) accounts used solely to fund payroll or employee benefits in an aggregate amount not to exceed the then-next two payroll cycles, (ii) any Account (including, for the avoidance of doubt, any cash, cash equivalents, or other property contained therein) to the extent, and for so long as, such Account is pledged and used exclusively to secure performance of obligations arising and permitted under clauses (vi), (xiv) and (xv) of the definition of "Permitted Liens" and (iii) other Accounts that have a balance not to exceed One Hundred Thousand Dollars ($100,000.00) in the aggregate at any time.

"Excluded Subsidiary" means (a) the Irish Subsidiary, (b) the Australian Subsidiary, and (c) each Foreign Subsidiary of Borrower designated by Borrower as an "Excluded Subsidiary"; provided that, in each of the foregoing cases, the Excluded Subsidiary Condition is satisfied with respect to such Subsidiary at all times, and in each case as long as no Excluded Subsidiary owns any Intellectual Property.

"Excluded Subsidiary Condition" means (a) the aggregate revenues (under GAAP) of all Excluded Subsidiaries does not exceed five percent (5%) of the consolidated revenues (under GAAP) of Borrower and its Subsidiaries; and (b) value of the total assets of all Excluded Subsidiaries does not exceed five percent (5%) of the consolidated total assets of Borrower and its Subsidiaries.

"FDA" means the U.S. Food and Drug Administration or any successor thereto.

"FDA Good Manufacturing Practices" means the applicable requirements and standards set forth in the Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations (for example, for pharmaceuticals being used in Phase 2 or 3 studies, and commercial pharmaceuticals, 21 C.F.R. Parts 210 and 211) and relevant FDA guidance documents (for example, for pharmaceuticals in Phase 1, FDA guidance entitled "CGMP for Phase 1 Investigational Drugs").

"FDA Laws" means all applicable statutes, rules, regulations, standards, guidelines, policies and orders and Requirements of Law administered, implemented, enforced or issued by FDA or any comparable governmental authority.

"Federal Health Care Program Laws" means collectively, federal Medicare or federal or state Medicaid statutes, Sections 1128, 1128A, 1128B, 1128C or 1877 of the Social Security Act (42 U.S.C. §§ 1320a-7, 1320a-7a, 1320a-7b, 1320a-7c, 1320a-7h and 1395nn), the federal TRICARE statute (10 U.S.C. § 1071 et seq.), the civil False Claims Act of 1863 (31 U.S.C. § 3729 et seq.), criminal false claims statutes (e.g., 18 U.S.C. §§ 287 and 1001), the Program Fraud Civil Remedies Act of 1986 (31 U.S.C. § 3801 et seq.), HIPAA, or related regulations or other Requirements of Law that directly or indirectly govern the health care industry, programs of governmental authorities related to healthcare, health care professionals or other health care participants, or relationships among health care providers, suppliers, distributors, manufacturers and patients, and the pricing, sale and reimbursement of health care items or services including the collection and reporting requirements, and the processing of any applicable rebate, chargeback or adjustment, under applicable rules and regulations relating to the Medicaid Drug Rebate Program (42 U.S.C. § 1396r-8) and any state supplemental rebate program, Medicare average sales price reporting (42 U.S.C. § 1395w-3a), the Public Health Service Act (42 U.S.C. § 256b), the VA Federal Supply Schedule (38 U.S.C. § 8126) or under any state pharmaceutical assistance program or U.S. Department of Veterans Affairs agreement, and any successor government programs.

"First Amendment Closing Date" means October 14, 2021.

"Forecast" means the projections for Borrower as delivered and accepted by Agent on or before the Third Amendment Closing Date; provided however, that Borrower may from time to time update the Forecast with a forecast approved by the board of directors of the Borrower, subject to the consent of Agent in its reasonable discretion; provided, further, that, it is acknowledged that the Forecast is premised on, among other things, (i) certain assumptions about the possible timing of a launch date for AXS-05 for the treatment of Alzheimer's Disease Agitation, Sunosi for the treatment of ADHD, AXS-07, AXS-12, and AXS-14 and to the extent the assumed launch dates are deferred or delayed, then, for purposes of this Agreement and the other Loan Documents, the Forecast shall be deemed to be automatically updated and revised to defer the expected dates for receipt or recognition of revenues from AXS-05 for the treatment of Alzheimer's Disease Agitation, Sunosi for the treatment of ADHD, AXS-07, AXS-12, and AXS-14, as applicable, by the same amount of time as the deferral or delay of the actual launch dates and, (ii) certain assumptions about Borrower continuing to self-commercialize Sunosi outside of the United States of America and to the extent Borrower licenses rights to Sunosi for discrete geographical areas outside of the United States of America pursuant to a Permitted License (such licensing, "Sunosi Licensing"), then, for purposes of this Agreement and the other Loan Documents, the Forecast shall be deemed to be automatically updated and revised to reduce the projected Sunosi revenue outside of the United States of America to solely the amount of revenue equal to the product of (x) the original amount of projected Sunosi revenue outside of the United States of America and (y) the contractual royalty rates due to Borrower under the license agreement; provided, further that the Forecast must be updated prior to December 31, 2026 to include projections for 2027 and beyond based on a forecast approved by the board of directors demonstrating reasonable growth rates.

"Foreign Subsidiary" means any Subsidiary other than a Domestic Subsidiary.

"GAAP" means generally accepted accounting principles in the United States of America, as in effect from time to time.

"Hedge Agreement" means any interest rate, currency or commodity swap agreement, interest rate cap agreement, interest rate collar agreement, fuel or mineral or other commodity hedge or exchange agreement or any other agreement or arrangement entered into for non-speculative purposes designated to protect a Person against fluctuation in interest rates, currency exchange rates, commodity or mineral prices.

"Indebtedness" means (a) all indebtedness for borrowed money or the deferred purchase price of property or services (excluding trade credit entered into in the ordinary course of business not past due for more than one hundred eighty (180) days), including reimbursement and other obligations with respect to surety bonds and letters of credit, (b) all obligations evidenced by notes, bonds, debentures or similar instruments, (c) all capital lease obligations, (d) equity securities of any Person subject to repurchase or redemption other than at the sole option of such Person, (e) non-contingent "earnouts", purchase price adjustments, profit sharing arrangements, deferred purchase money amounts and similar payment obligations arising out of purchase and sale contracts but only as and to the extent of the amount required to be reflected as a liability on the balance sheet of such Person in accordance with GAAP, (f) non-contingent obligations to reimburse any bank or Person in respect of amounts paid under a letter of credit, banker's acceptance or similar instrument, and (g) all Contingent Obligations. For the avoidance of doubt no Permitted Bond Hedge Transaction or Permitted Warrant Transaction shall be considered Indebtedness of the Borrower.

"Initial Facility Charge" means $737,500, which is payable to the Lenders in accordance with Section 4.1(f).

"Insolvency Proceeding" means any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, arrangement, or other similar relief.

"Intellectual Property" means all of Borrower's Copyrights; Trademarks; Patents; Licenses; trade secrets and inventions; mask works; Borrower's applications therefor and reissues, extensions, or renewals thereof; and Borrower's goodwill associated with any of the foregoing, together with Borrower's rights to sue for past, present and future infringement of Intellectual Property and the goodwill associated therewith.

"Intellectual Property Security Agreement" means the Intellectual Property Security Agreement dated as of the Closing Date between the Borrower and Agent, as the same may from time to time be amended, restated, modified or otherwise supplemented.

"Investment" means (a) any beneficial ownership (including stock, partnership, limited liability company interests, or other securities) of or in any Person, (b) any loan, advance or capital contribution to any Person or (c) any Acquisition.

"IP Ancillary Rights" means, with respect to any Copyright, Trademark, Patent, software, trade secrets or trade secret rights, including any rights to unpatented inventions, know-how, show-how and operating manuals, all income, royalties, proceeds and liabilities at any time due or payable or asserted under or with respect to any of the foregoing or otherwise with respect thereto, including all rights to sue or recover at law or in equity for any past, present or future infringement, misappropriation, dilution, violation or other impairment thereof, and, in each case, all rights to obtain any other intellectual property right ancillary to any Copyright, Trademark, Patent, software, trade secrets or trade secret rights.

"Irish Subsidiary" is Axsome Therapeutics Limited, a company organized under the laws of Ireland.

"IRS" means the United States Internal Revenue Service.

"Joinder Agreements" means for each Subsidiary (other than an Excluded Subsidiary), a completed and executed Joinder Agreement in substantially the form attached hereto as Exhibit F.

"License" means any Copyright License, Patent License, Trademark License or other license of rights or interests.

"Lien" means any mortgage, deed of trust, pledge, hypothecation, assignment for security, security interest, encumbrance, levy, lien or charge of any kind, whether voluntarily incurred or arising by operation of law or otherwise, against any property, any conditional sale or other title retention agreement, and any lease in the nature of a security interest.

"Loan" means the Advances made under this Agreement.

"Loan Documents" means this Agreement, the promissory notes (if any), the ACH Authorization, the Account Control Agreements, the Joinder Agreements, all UCC Financing Statements, the Warrant, the Pledge Agreement, the Intellectual Property Security Agreement, the Antecip Direct Agreement, and any other documents executed in connection with the Secured Obligations or the transactions contemplated hereby, as the same may from time to time be amended, modified, supplemented or restated.

"Malta Subsidiary" is Axsome Malta Ltd., a company organized under the laws of the Republic of Malta.

"Market Capitalization" means, as of any date of determination, the product of (a) the number of outstanding shares of Common Stock publicly disclosed in the most recent filing of Borrower with the United States Securities Exchange Commission as outstanding as of such date of determination and (b) the closing price of Borrower's Common Stock (as quoted on Bloomberg L.P.'s page or any successor page thereto of Bloomberg L.P. or if such page is not available, any other commercially available source).

"Material Adverse Effect" means a material adverse effect upon: (i) the business, operations, properties, assets or financial condition of Borrower and its Subsidiaries taken as a whole; or (ii) the ability of Borrower to perform or pay the Secured Obligations in accordance with the terms of the Loan Documents, or the ability of Agent or the Lenders to enforce any of its rights or remedies with respect to the Secured Obligations; or (iii) the Collateral or Agent's Liens on the Collateral or the priority of such Liens.

"Material Agreement" means (a) the Antecip License Agreement, (b) that certain license agreement dated as of January 10, 2020 by and between Borrower and Pfizer, Inc., (c) the Project Light Agreement and (d) any other license, agreement or other contractual arrangement whereby Borrower or any of its Subsidiaries is required to transfer, either in-kind or in cash, prior to the Term Loan Maturity Date, assets or property valued (book or market) at more than Ten Million Dollars ($10,000,000.00) in the aggregate.

"Material Regulatory Liabilities" means (a) (i) any liabilities arising from the violation of Public Health Laws, Federal Health Care Program Laws, and other applicable comparable Requirements of Law, or from any non-routing terms, conditions of or requirements imposed relative to any Registrations (including costs of actions required under applicable Requirements of Law, including FDA Laws and Federal Health Care Program Laws, or necessary to remedy any violation of any terms or conditions applicable to any Registrations), including, but not limited to, withdrawal of approval, recall, revocation, suspension, import detention and seizure of any Borrower Product, and (ii) any loss of recurring annual revenues as a result of any loss, suspension or limitation of any Registrations, which, in the case of the foregoing clauses (i) and (ii), exceed $2,000,000 individually or in the aggregate, or (b) any Material Adverse Effect.

"Maturity Extension Conditions" means (i) the Borrower achieves T6M Net Product Revenue as of the December 31, 2025 reporting period of at least 60% of the T6M Net Product Revenue included in the Forecast for such period and (ii) the Borrower notifies the Agent in writing of its desire to extend the Term Loan Maturity Date within five (5) Business Days of the delivery of the financial statements for December 31, 2025 reporting period.

"Maximum Term Loan Amount" means Three Hundred Million Dollars ($350,000,000).

"New Drug Application" means a new drug application in the United States for authorization to market a product, as defined in the applicable laws and regulations and submitted to the FDA.

"Non-Disclosure Agreement" means that certain Non-Disclosure Agreement by and between Borrower and Agent, dated as of August 11, 2020.

"OFAC" is the U.S. Department of Treasury Office of Foreign Assets Control.

"OFAC Lists" are, collectively, the Specially Designated Nationals and Blocked Persons List maintained by OFAC pursuant to Executive Order No. 13224, 66 Fed. Reg. 49079 (Sept. 25, 2001) and/or any other list of terrorists or other restricted Persons maintained pursuant to any of the rules and regulations of OFAC or pursuant to any other applicable Executive Orders.

"Patent License" means any written agreement granting any right with respect to any invention on which a Patent is in existence or a Patent application is pending, in which agreement Borrower now holds or hereafter acquires any interest.

"Patents" means all letters patent of, or rights corresponding thereto, in the United States of America or in any other country, all registrations and recordings thereof, and all applications for letters patent of, or rights corresponding thereto, in the United States of America or any other country.

"Performance Covenant A" means satisfaction of each of the following at all times: (i) Borrower's Market Capitalization exceeds One Billion Five Hundred Million Dollars ($1,500,000,000) and (ii) Borrower maintains Qualified Cash in an amount not less than fifty percent (50%) of the sum of the outstanding principal amount of the Term Loan Advances *plus* the Qualified Cash A/P Amount.

"Performance Covenant B" means Borrower at all times maintains Qualified Cash in an amount not less than ninety five percent (95%) of the sum of the outstanding principal amount of the Term Loan Advances *plus* the Qualified Cash A/P Amount.

"Performance Covenant C" means Borrower achieves T6M Net Product Revenue of at least 60% of the T6M Net Product Revenue included in the Forecast, determined on a quarterly basis.

"Permitted Acquisition" means: (a) the Acquisition conducted in accordance with the Project Light Agreement and (b) any Acquisition (including by way of merger), in each case located entirely within the United States of America, which is conducted in accordance with the following requirements:

(i)of assets, Equity Interests, businesses, Persons or products engaged in a line of business incidental or related to that of the Borrower or its Subsidiaries or reasonable extensions thereof;

(ii)unless otherwise agreed by Agent in its sole discretion, if such Acquisition is structured as a stock acquisition, then the Person so acquired shall either (i) become a wholly-owned (other than issuance of shares necessary under local law for the qualification of directors) Subsidiary of Borrower or of a Subsidiary and the Borrower shall comply, or cause such Subsidiary to comply, with Section 7.13 hereof, as applicable, or (ii) such Person shall be merged with and into Borrower (with the Borrower being the surviving entity);

(iii)if such Acquisition is structured as the acquisition or in-licensing of assets, such assets shall be acquired by a Borrower, and shall be free and clear of Liens other than Permitted Liens;

(iv)the Borrower shall have delivered to the Lenders not less than ten (10) days (or such shorter period as Agent may agree in its sole discretion) nor more than forty five (45) days prior to the date of such Acquisition, notice of such Acquisition together with pro forma projected financial information, copies of all material documents relating to such acquisition reasonably requested by Agent, and historical financial statements for such acquired entity (to the extent available), division or line of business, in each case in form reasonably satisfactory to the Lenders and demonstrating compliance with the covenants set forth in Section 7.20 hereof on a pro forma basis as if the Acquisition occurred on the first day of the most recent measurement period;

(v)both immediately before and after such Acquisition no Default or Event of Default shall have occurred and be continuing; and

(vi)the sum of the purchase price of such proposed new Permitted Acquisition (together with all prior Permitted Acquisitions consummated during the term of this Agreement), computed on the basis of total acquisition consideration paid or incurred, or to be paid or incurred, by Borrower with respect thereto (but excluding for such purpose: any unpaid Acquisition Deferred Payments, in each case except to the extent required to be reflected as liabilities on the balance sheet of Borrower), including the amount of Permitted Indebtedness assumed or to which such assets, businesses or business or ownership interest or shares, or any Person so acquired, is subject, shall not be greater than Twenty Five Million Dollars ($25,000,000) *plus* the aggregate amount of Tranche 3 Advances approved by Lenders' investment committee for Acquisitions *minus* the aggregate amount of all Acquisition Deferred Payments that have been paid.

"Permitted Bond Hedge Transaction" means any call or capped call option (or substantively equivalent derivative transaction) relating to the Common Stock (or other securities or property following a merger event or other change of the Common Stock) purchased by Borrower in connection with the issuance of any Permitted Convertible Debt and as may be amended in accordance with its terms; *provided* that, the net purchase price of any such call option transaction, less the amount received by Borrower in respect of any Permitted Warrant Transaction in connection with such issuance of Permitted

Convertible Debt, shall not exceed 25% of the gross proceeds to Borrower from such issuance of Permitted Convertible Debt; *provided further* that the terms, conditions and covenants of each such call option transaction are customary for agreements of such type, as determined in good faith by the board of directors of the Borrower or a committee thereof.

"Permitted Convertible Debt" means Indebtedness of the Borrower that is convertible into a fixed number (subject to customary anti-dilution adjustments, "make-whole" increases and other customary changes thereto) of shares of Common Stock (or other securities or property following a merger event or other change of the Common Stock), cash or any combination thereof (with the amount of such cash or such combination determined by reference to the market price of such Common Stock or such other securities); *provided* that such Indebtedness shall (a) not require any scheduled amortization or otherwise require payment of principal prior to, or have a scheduled maturity date, earlier than, one hundred eighty (180) days after the Term Loan Maturity Date, (b) be unsecured, (c) not be guaranteed by any Subsidiary of Borrower, (d) contain usual and customary subordination terms for underwritten offerings of senior subordinated convertible notes as determined in good faith by the board of directors of the Borrower or a committee thereof, (e) shall specifically designate this Agreement and all Secured Obligations as "designated senior indebtedness" or similar term so that the subordination terms referred to in clause (d) of this definition specifically refer to such notes as being subordinated to the Secured Obligations pursuant to such subordination terms and (f) be on terms and conditions customary for Indebtedness of such type, as determined in good faith by the board of directors of the Borrower or a committee thereof; *provided further*, that any cross-default or cross-acceleration event of default (each howsoever defined) provision contained therein that relates to indebtedness or other payment obligations of Borrower (or any of its Subsidiaries) (such indebtedness or other payment obligations, a "Cross-Default Reference Obligation") contains a cure period of at least thirty (30) calendar days (after written notice to the issuer of such Indebtedness by the trustee or to such issuer and such trustee by holders of at least 25% in aggregate principal amount of such Indebtedness then outstanding) before a default, event of default, acceleration or other event or condition under such Cross-Default Reference Obligation results in an event of default under such cross-default or cross-acceleration provision.

"Permitted Indebtedness" means:

(i)Indebtedness of Borrower in favor of the Lenders or Agent arising under this Agreement or any other Loan Document;

(ii)Indebtedness existing on the Closing Date which is disclosed in Schedule 1A;

(iii)Indebtedness of up to $1,000,000 outstanding at any time secured by a Lien described in clause (vii) of the defined term "Permitted Liens," provided such Indebtedness does not exceed the cost of the Equipment and related software financed with such Indebtedness;

(iv)Indebtedness to trade creditors incurred in the ordinary course of business (other than any trade credit that is past due for more than one hundred eighty (180) days);

(v)Indebtedness that also constitutes a Permitted Investment;

(vi)Subordinated Indebtedness;

(vii)Indebtedness, including reimbursement obligations, in connection with (A) letters of credit, (B) foreign exchange services, ACH Services, and, cash management services (including credit cards, debit cards and similar instruments) and (C) Hedge Agreements (entered into in order to manage existing or anticipated interest rate, exchange rate or commodity price risks and not for speculative purposes), in each case that may or be unsecured or secured by Cash and issued on behalf of the Borrower or a Subsidiary thereof in an aggregate amount not to exceed $6,000,000 at any time outstanding,

(viii)other unsecured Indebtedness in an amount not to exceed $350,000 at any time outstanding,

(ix)intercompany Indebtedness as long as either (A) each of the Subsidiary obligor and the Subsidiary obligee under such Indebtedness is a Subsidiary that has executed a Joinder Agreement, or (B) it is Indebtedness of an Excluded Subsidiary permitted under clause (x) of the definition of Permitted Investments;

(x)Permitted Convertible Debt not to exceed Five Hundred Million Dollars ($500,000,000) in principal amount at any one time outstanding;

(xi)Indebtedness with respect to a Permitted Royalty Transaction that (a) is subordinated to the Secured Obligations pursuant to a subordination or intercreditor agreement on terms and conditions reasonably satisfactory to Agent, (b) does not have a scheduled maturity date earlier than one hundred eighty (180) days after the Term Loan Maturity Date, (c) is in an aggregate amount not to exceed $250,000,000, and (d) shall specifically designate this Agreement and all Secured Obligations as "designated senior indebtedness" or similar term so that the subordination terms referred to in clause (a) of this clause specifically refer to such notes as being subordinated to the Secured Obligations pursuant to such subordination terms;

(xii)Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of business;

(xiii)Indebtedness in respect of surety bonds and other indemnities and similar obligations up to an aggregate amount of One Million Dollars ($1,000,000)[2] at any one time outstanding;

(xiv)Indebtedness arising with respect to Borrower's real property lease and operating lease obligations in the ordinary course of Borrower's business;

(xv)Indebtedness in respect of Acquisition Deferred Payments incurred in connection with Permitted Acquisitions; and

(xvi)extensions, refinancings, renewals, modifications, amendments or restatements of any items of Permitted Indebtedness; provided that the principal amount is not increased or the terms modified to impose materially more burdensome terms upon Borrower or its Subsidiary, as the case may be.

"Permitted Investment" means:

(i)Investments existing on the Closing Date which are disclosed in Schedule 1B;

(ii)(a) marketable direct obligations issued or unconditionally guaranteed by the United States of America or any agency or any State thereof maturing within one year from the date of acquisition thereof currently having a rating of at least A-2 or P-2 from either Standard & Poor's Corporation or Moody's Investors Services, (b) commercial paper maturing no more than one year from the date of creation thereof and currently having a rating of at least A-2 or P-2 from either Standard & Poor's Corporation or Moody's Investors Service, (c) certificates of deposit issued by any bank with assets of at least $500,000,000 maturing no more than one year from the date of investment therein, (d) money market accounts, and (e) Investments permitted by Borrower's Investment Policy and Guidelines dated as of August 2016 and provided to the Agent and Lenders, as amended from time to time; provided that any material amendments thereto have been approved by Agent and the Lenders in their reasonable discretion;

(iii)repurchases of Equity Interests from current or former employees, officers, directors, or consultants of Borrower under the terms of applicable repurchase agreements at the original issuance price of such securities (1) in an aggregate amount not to exceed $250,000 in any fiscal year; provided that no Event of Default has occurred, is continuing or would exist after giving effect to the repurchases or (2) in any amount where the consideration for the repurchase is the cancellation of indebtedness owed by such former employees, officers, directors or consultants to Borrower;

(iv)Investments accepted in connection with Permitted Transfers;

(v)Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of Borrower's business;

(vi)Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business; provided that this subparagraph (vi) shall not apply to Investments of Borrower in any Subsidiary;

(vii)Investments consisting of loans not involving the net transfer on a substantially contemporaneous basis of cash proceeds to employees, officers or directors relating to the purchase of capital stock of Borrower pursuant to employee stock purchase plans or other similar agreements approved by Borrower's board of directors;

(viii)Investments consisting of travel advances and employee relocation loans in the ordinary course of business;

(ix)Investments in Subsidiaries (including creation of a Subsidiary in anticipation of a proposed Permitted Acquisition); provided that, unless such Subsidiary is an Excluded Subsidiary (after giving pro forma effect to such Investment), each such Subsidiary enters into a Joinder Agreement promptly after its formation by Borrower and execute such other related documents as shall be reasonably requested by Agent;

(x)Investments in Excluded Subsidiaries to cover ordinary course of business operating and entity maintenance and regulatory (and, if applicable, wind-down and liquidation) costs and expenses in an aggregate amount not to exceed $500,000 in any fiscal year, and other amounts approved in advance in writing by Agent;

(xi)joint ventures or strategic alliances in the ordinary course of Borrower's business consisting of the nonexclusive licensing of technology, the development of technology or the providing of technical support; provided that any cash Investments by Borrower do not exceed $250,000 in the aggregate in any fiscal year;

(xii)Permitted Acquisitions;

(xiii)Borrower's entry into (including payments of premiums in connection therewith), and the performance of obligations under, any Permitted Bond Hedge Transactions and Permitted Warrant Transactions in accordance with their terms;

(xiv)Hedge Agreements constituting Permitted Indebtedness pursuant to clause (vii) thereof; and

(xv)additional Investments that do not exceed $250,000 in the aggregate in any fiscal year.

"Permitted Liens" means:

(i)Liens in favor of Agent or the Lenders;

(ii)Liens existing on the Closing Date which are disclosed in Schedule 1C;

(iii)Liens for taxes, fees, assessments or other governmental charges or levies, either not yet delinquent or being contested in good faith by appropriate proceedings diligently conducted; provided, that Borrower maintains adequate reserves therefor on Borrower's Books in accordance with GAAP;

(iv)Liens securing claims or demands of materialmen, artisans, mechanics, carriers, warehousemen, landlords and other like Persons arising in the ordinary course of Borrower's business and imposed without action of such parties; provided, that the payment thereof is not yet delinquent or remain payable without penalty, or that are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto;

(v)Liens arising from judgments, decrees or attachments in circumstances which do not constitute an Event of Default hereunder;

(vi)the following Liens, to the extent made in the ordinary course of business: deposits and pledges under worker's compensation, unemployment insurance, social security and other similar laws, or to secure the performance of bids, tenders or contracts (other than for the repayment of borrowed money) or to secure indemnity, performance or other similar bonds for the performance of bids, tenders or contracts (other than for the repayment of borrowed money) or to secure statutory obligations (other than Liens arising under ERISA or environmental Liens) or surety or appeal bonds, or to secure indemnity, performance or other similar bonds;

(vii)Liens on Equipment or software or other intellectual property constituting purchase money Liens and Liens in connection with capital leases securing Indebtedness permitted in clause (iii) of "Permitted Indebtedness";

(viii)Liens incurred in connection with Subordinated Indebtedness;

(ix)leasehold interests in leases or subleases and licenses and sublicenses granted in the ordinary course of business and not interfering in any material respect with the business of the licensor;

(x)Liens in favor of customs and revenue authorities arising as a matter of law to secure payment of custom duties that are promptly paid on or before the date they become due;

(xi)Liens on insurance proceeds securing the payment of financed insurance premiums that are promptly paid on or before the date they become due (provided that such Liens extend only to such insurance proceeds and not to any other property or assets);

(xii)statutory and common law rights of set-off and other similar rights as to deposits of cash and securities in favor of banks, other depository institutions and brokerage firms;

(xiii)easements, zoning restrictions, rights-of-way and similar encumbrances on real property imposed by law or arising in the ordinary course of business so long as they do not materially impair the value or marketability of the related property;

(xiv)(A) Without duplication of any Indebtedness incurred pursuant to clause (vii) of the definition of Permitted Indebtedness, Liens on Cash securing obligations permitted under clause (vii) of the definition of Permitted Indebtedness, and (B) security deposits in connection with real property leases, the combination of (A) and (B) in an aggregate amount not to exceed $3,000,000 at any time;

(xv)Liens solely on any Cash earnest money deposits made by Borrower or any of its Subsidiaries in connection with any letter of intent or purchase agreement that constitutes a Permitted Acquisition in an aggregate amount not to exceed five percent (5%) of the aggregate purchase consideration paid in connection thereto;

(xvi)Liens solely on the royalty interests purchased pursuant to a Permitted Royalty Transaction and proceeds thereof and Intellectual Property being financed by such facility;

(xvii)Licenses that qualify as Permitted Transfers; and

(xviii)Liens incurred in connection with the extension, renewal or refinancing of the Indebtedness secured by Liens of the type described in clauses (i) through (xvii) above; provided, that any extension, renewal or replacement Lien shall be limited to the property encumbered by the existing Lien and the principal amount of the Indebtedness being extended, renewed or refinanced (as may have been reduced by any payment thereon) does not increase.

"Permitted Royalty Transaction" means any synthetic royalty participations (and not royalty purchases or buyouts) with respect to any of AXS-05, AXS-07, AXS-12, AXS-14, and/or Sunosi whereby Borrower receives upfront unrestricted (including, not subject to any redemption, clawback, escrow or similar encumbrance or restriction) net cash proceeds of at least $100,000,000 in exchange for rights to participation payments based on net sales of AXS-05, AXS-07, AXS-12, AXS-14, and/or Sunosi in an amount not to exceed 7.5% of net sales, and on terms (including without limitation, that any security granted in connection with such Permitted Royalty Transaction is limited solely to the respective Intellectual Property being financed by such facility) and with a purchaser satisfactory to Agent.

"Permitted Transfers" means:

(i)sales of Inventory in the ordinary course of business,

(ii)(A) licenses and similar arrangements for the use of Intellectual Property in the ordinary course of business that could not result in a legal transfer of title of the licensed property

that are non-exclusive or may be exclusive in respects other than territory or may be exclusive as to territory but only as to discreet geographical areas outside of the United States of America in the ordinary course; and (B) the abandonment, permitted lapse, cancellation, termination and/or cessation of any immaterial Company IP that is, in the reasonable judgment of the Borrower, no longer economically practicable, commercially desirable to maintain or useful, in each case, in the conduct of business of the Borrower and its Subsidiaries taken as a whole (each, a "Permitted License"),

(iii)dispositions of worn-out, obsolete or surplus Equipment at fair market value in the ordinary course of business,

(iv)to the extent constituting Transfers, Permitted Liens and Permitted Investments,

(v) Permitted Royalty Transactions,

(vi)the disposition of any Permitted Convertible Debt, any Hedge Agreement or in connection with any Permitted Bond Hedge Transaction or Permitted Warrant Transaction, in each case as permitted hereunder,

(vii)the use or transfer of Cash in a manner that is not prohibited by the terms of this Agreement or the other Loan Documents and in the ordinary course of business,

(viii)transfers by and among the Borrower and any of its Subsidiaries (other than Permitted Investments); provided that (a) (x) such transfers are in the ordinary course of business and (y) with respect to any transfers to an Excluded Subsidiary, such transfers do not involve any transfer of any Intellectual Property and are in an aggregate amount not to exceed $500,000 in any fiscal year or (b) such Subsidiary has entered into a Joinder Agreement and such other documents as shall reasonably be required by Agent,

(ix)any Sunosi Business Disposition, and

(x)other transfers of assets having a fair market value of not more than $500,000 in the aggregate in any fiscal year.

"Permitted Warrant Transaction" means any call option, warrant or right to purchase (or substantively equivalent derivative transaction) relating to Common Stock (or other securities or property following a merger event or other change of the Common Stock) and/or cash (in an amount determined by reference to the price of such Common Stock) sold by Borrower substantially concurrently with any purchase by Borrower of a related Permitted Bond Hedge Transaction and as may be amended in accordance with its terms; provided that (x) that the terms, conditions and covenants of each such call option transaction are customary for agreements of such type, as determined in good faith by the board of directors of the Borrower or a committee thereof and (y) such call option transaction would be classified as an equity instrument in accordance with GAAP.

"Person" means any individual, sole proprietorship, partnership, joint venture, trust, unincorporated organization, association, corporation, limited liability company, institution, other entity or government.

"Pledge Agreement" means the Pledge Agreement dated as of the Closing Date between Borrower and Agent, as the same may from time to time be amended, restated, modified or otherwise supplemented.

"Project Light Agreement" means that certain Asset Purchase Agreement, dated as of March 25, 2022, by and among Borrower and Jazz Pharmaceuticals PLC, the effectiveness of which is solely conditioned on the early termination or expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

"Public Health Laws" means all Requirements of Law relating to the procurement, development, clinical and non-clinical evaluation, product approval or licensure, manufacture, production, analysis, distribution, dispensing, importation, exportation, use, handling, quality, sale, labeling, promotion, clinical trial registration or post market requirements of any drug, biologic or other product (including, without limitation, any ingredient or component of the foregoing products) subject to regulation under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.) and the Public Health Service Act (42 U.S.C. § 201 et seq.), including without limitation the regulations promulgated by the FDA at Title 21 of the Code of Federal Regulations and all applicable regulations promulgated by the National Institutes of Health ("NIH") and codified at Title 42 of the Code of Federal Regulations, and guidance, compliance, guides, and other policies issued by the FDA, the NIH and other comparable governmental authorities.

"Qualified Cash" means the amount of Borrower's Cash held in accounts subject to an Account Control Agreement in favor of Agent.

"Qualified Cash A/P Amount" means the amount of Borrower's accounts payable under GAAP not paid after the 180th day following the invoice for such account payable.

"Receivables" means (i) all of Borrower's Accounts, Instruments, Documents, Chattel Paper, Supporting Obligations, letters of credit, proceeds of any letter of credit, and Letter of Credit Rights, and (ii) all customer lists, software, and business records related thereto.

"Redemption Conditions" means, with respect to any payment of cash in respect of the principal amount of any Permitted Convertible Debt, satisfaction of each of the following events: (a) no Default or Event of Default shall exist or result therefrom, and (b) both immediately before and at all times after such redemption, Borrower's Qualified Cash shall be no less than 150% of the outstanding principal amount of the Secured Obligations plus the Qualified Cash A/P Amount.

"Register" has the meaning specified in Section 11.7.

"Registrations" shall mean authorizations, approvals, licenses, permits, certificates, registrations, listings, certificates, or exemptions of or issued by any governmental authority (including marketing approvals, investigational new drug applications, product recertifications, drug manufacturing establishment registration and product listing, pricing and reimbursement approvals, labeling approvals or their foreign equivalent) that are required for the research, development, manufacture, commercialization, distribution, marketing, storage, transportation, pricing, governmental authority reimbursement, use and sale of Borrower Products.

"Regulatory Action" means an administrative or regulatory enforcement action, proceeding or investigation, warning letter, untitled letter, Form 483 or similar inspectional observations, other notice of violation letter, recall, seizure, Section 305 notice or other similar written communication, or consent decree, issued or required by the FDA or under the Public Health Laws, the NIH or a comparable governmental authority in any other regulatory jurisdiction.

"Required Lenders" means at any time, the holders of more than 50% of the sum of the aggregate unpaid principal amount of the Term Loans then outstanding.

"Requirements of Law" means, with respect to any Person, collectively, the common law and all federal, state, provincial, local, foreign, multinational or international laws, statutes, codes, treaties, standards, rules and regulations, guidelines, ordinances, orders, judgments, writs, injunctions, decrees (including administrative or judicial precedents or authorities) and the interpretation or administration thereof by, and other determinations, directives, requirements or requests of, any governmental authority, in each case that are applicable to or binding upon such Person or any of its property or to which such Person or any of its property is subject.

"Restricted License" means any Material Agreement with respect to which Borrower is the licensee (other than over-the-counter software and software that is commercially available to the public) (a) that prohibits or otherwise restricts Borrower from granting a security interest in Borrower's interest in such Material Agreement or any other property, or (b) for which a default under or termination of could reasonably be expected to interfere in any material respect with the Agent's right to sell any Collateral.

"Sanctioned Country" means, at any time, a country or territory which is the subject or target of any Sanctions.

"Sanctioned Person" means, at any time, (a) any Person listed in any Sanctions-related list of designated Persons maintained by the Office of Foreign Assets Control of the U.S. Department of the Treasury or the U.S. Department of State, or by the United Nations Security Council, the European Union or any EU member state, (b) any Person operating, organized or resident in a Sanctioned Country or (c) any Person controlled by any such Person.

"Sanctions" means economic or financial sanctions or trade embargoes imposed, administered or enforced from time to time by (a) the U.S. government, including those administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury or the U.S. Department of State, or (b) the United Nations Security Council, the European Union or Her Majesty's Treasury of the United Kingdom.

"Second Amendment" means that certain Second Amendment to Loan and Security Agreement, effective as of the Second Amendment Closing Date, by and among the Borrower, Agent and the Lenders.

"Second Amendment Closing Date" means the effective date of the Project Light Agreement.

"Second Amendment Signing Date" means the date on which the Second Amendment is executed by the Borrower, Agent and the Lenders.

"Secured Obligations" means Borrower's obligations under this Agreement and any Loan Document (other than the Warrant), including any obligation to pay any amount now owing or later arising.

"Subordinated Indebtedness" means Indebtedness subordinated to the Secured Obligations in amounts and on terms and conditions satisfactory to Agent in its sole discretion and subject to a subordination agreement in form and substance satisfactory to Agent in its sole discretion.

"Subsequent Financing" means the closing of any equity financing which becomes effective after the Closing Date in which Borrower receives net cash proceeds in excess of $25,000,000 from the sale and issuance of its Equity Interests for Cash primarily for capital raising purposes and that is broadly marketed to multiple investors, which shall not include any Permitted Convertible Debt offering (or any Permitted Bond Hedge Transaction or Permitted Warrant Transaction) or any issuance or sale by

Borrower of its Equity Interests (i) pursuant to benefit plans or arrangements, including under Borrower's equity incentive plans (whether currently in effect or adopted by Borrower after the Closing Date) or otherwise as equity compensation, (ii) as dividends or distributions or upon stock splits, recapitalizations or similar transactions, (iii) pursuant to a merger, consolidation, acquisition, strategic alliance or similar business combination or acquisition, (iv) to banks, funds, equipment or real property lessors or other financial institutions pursuant to a non-convertible debt financing, equipment lease, loan or credit arrangement or commercial leasing transaction entered into for primarily non-equity financing purposes, (v) in connection with strategic transactions, including (A) joint ventures, manufacturing, marketing, OEM, sponsored research, collaboration or distribution arrangements or (B) technology transfer or development arrangements, (vi) securities issued or issuable to suppliers or third party service providers in connection with the provision of goods or services, (vii) in an at-the-market (ATM) offering, and (viii) securities issued in connection with options, warrants, convertible securities or other arrangement in existence on the Closing Date or issued in transactions excluded from the definition of Subsequent Financing pursuant to clause (i) through (vii) above; provided, however, that, if Borrower or its agents attempts to "wall-cross" the Lender or its assignee or nominee in conjunction with any Subsequent Financing and the Lender or its assignee or nominee declines to be "wall-crossed," then the issuance and sale of such equity securities shall not be considered a Subsequent Financing hereunder.

"Subsidiary" means an entity, whether a corporation, partnership, limited liability company, joint venture or otherwise, in which Borrower owns or controls 50% or more of the outstanding voting securities, including each entity listed on Schedule 1 hereto.

"Sunosi" means Borrower's solriamfetol product candidate for the treatment of excessive daytime sleepiness and other indications.

"Sunosi Business Disposition" means (i) any Sunosi Licensing and (ii) the sale or divestiture of all or any portion of Sunosi, in each case, other than any Intellectual Property, outside the United States pursuant to an arms' length transaction.

"Sunosi Licensing" has the meaning given to such term in the definition of "Forecast".

"T3M Net Product Revenue" means Borrower's net product revenue (as determined in accordance with GAAP) solely from the sale of AXS-05, AXS-07, AXS-12, AXS-14, and Sunosi (which may include royalty, profit sharing, or sales-based milestone revenue recognized in accordance with GAAP, but which shall not include any upfront or non-sales-based milestone payments under business development or licensing transactions), measured on a trailing three-month basis as of the date of the most recently delivered monthly financial statement in accordance with Section 7.1(a). For the avoidance of doubt, net product revenue shall not include any of the following to the extent not recognizable as revenue in accordance with GAAP (i) trade, quantity and cash discounts allowed by Borrower, (ii) discounts, refunds, rebates, charge backs, retroactive price adjustment and any other allowances which effectively reduce net selling price, (iii) product returns and allowances, (iv) allowances for shipping or other distribution expenses, (v) set-offs and counterclaims, and (vi) any other similar and customary deductions that are typically deducted from gross revenue and not included in net revenue in accordance with GAAP. Notwithstanding anything to the contrary herein, T3M Net Product Revenue shall not include any royalty payments associated with a Permitted Royalty Transaction or otherwise.

"T6M Net Product Revenue" means Borrower's net product revenue (as determined in accordance with GAAP) solely from the sale of AXS-05, AXS-07, and Sunosi, (which may include royalty, profit sharing, or sales-based milestone revenue recognized in accordance with GAAP, but which shall not include any upfront or non-sales-based milestone payments under business development or licensing transactions), measured on a trailing six-month basis as of the date of the most recently quarterly financial

statement filed with its most recent 10-Q filing. For the avoidance of doubt, net product revenue shall not include any of the following to the extent not recognizable as revenue in accordance with GAAP (i) trade, quantity and cash discounts allowed by Borrower, (ii) discounts, refunds, rebates, charge backs, retroactive price adjustment and any other allowances which effectively reduce net selling price, (iii) product returns and allowances, (iv) allowances for shipping or other distribution expenses, (v) set-offs and counterclaims, and (vi) any other similar and customary deductions that are typically deducted from gross revenue and not included in net revenue in accordance with GAAP.

"Taxes" means all present or future taxes, levies, imposts, duties, deductions, withholdings (including backup withholding), assessments, fees or other charges imposed by any governmental authority, including any interest, additions to tax or penalties applicable thereto.

"Term Commitment" means as to any Lender, the obligation of such Lender, if any, to make a Term Loan Advance to the Borrower in a principal amount not to exceed the amount set forth under the heading "Term Commitment" opposite such Lender's name on Schedule 1.1.

"Term Loan Advance" means each Tranche 1 Advance, Tranche 2 Advance, Tranche 3 Advance, and any other Term Loan funds advanced under this Agreement.

"Term Loan Cash Interest Rate" means for any day a per annum rate of interest equal to (a) if the prime rate as reported in The Wall Street Journal is greater than or equal to 7.00%, the greater of either (i) the prime rate as reported in The Wall Street Journal plus 2.20%, and (ii) 9.95% but in no event greater than 10.70%, and (b) if the prime rate as reported in The Wall Street Journal is less than 7.00%, 9.70%.

"Term Loan Maturity Date" means January 1, 2028; provided, however, if as of the date financial reporting is delivered for the period ending December 31, 2025 pursuant to Section 7.1 herein, the Maturity Extension Conditions are satisfied, then, January 1, 2029; provided further that if such day is not a Business Day, the Term Loan Maturity Date shall be the immediately preceding Business Day.

"Third Amendment" means that certain Third Amendment to Loan and Security Agreement, effective as of the Third Amendment Closing Date, by and among the Borrower, Agent and the Lenders.

"Third Amendment Closing Date" means January [9], 2023.

"Third Amendment Facility Charge" means Three Hundred Twelve Thousand Five Hundred Dollars ($312,500.00), which charge is payable to the Lenders in accordance with Section 4.2(k).

"Trademark License" means any written agreement granting any right to use any Trademark or Trademark registration, now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest.

"Trademarks" means all trademarks (registered, common law or otherwise) and any applications in connection therewith, including registrations, recordings and applications in the United States Patent and Trademark Office or in any similar office or agency of the United States of America, any State thereof or any other country or any political subdivision thereof.

"Tranche 1A Commitment" means as to any Lender, the obligation of such Lender, if any, to make a Term Loan Advance to Borrowers in a principal amount not to exceed the amount set forth under the heading "Tranche 1A Term Commitment" opposite such Lender's name on Schedule 1.1.

"Tranche 1B Commitment" means as to any Lender, the obligation of such Lender, if any, to make a Term Loan Advance to Borrowers in a principal amount not to exceed the amount set forth under the heading "Tranche 1B Term Commitment" opposite such Lender's name on Schedule 1.1.

"Tranche 1B Facility Charge" means three-quarter percent (0.75%) of the Tranche 1B Advances funded, which is payable to the Lenders in accordance with Section 4.2(d).

"Tranche 1C Commitment" means as to any Lender, the obligation of such Lender, if any, to make a Term Loan Advance to Borrowers in a principal amount not to exceed the amount set forth under the heading "Tranche 1C Term Commitment" opposite such Lender's name on Schedule 1.1.

"Tranche 1C Draw Period" means the period beginning on the Third Amendment Closing Date and ending on June 15, 2023.

"Tranche 1C Facility Charge" means three-quarter percent (0.75%) of the Tranche 1C Advances funded, which is payable to the Lenders in accordance with Section 4.2(e).

"Tranche 1D Commitment" means as to any Lender, the obligation of such Lender, if any, to make a Term Loan Advance to Borrowers in a principal amount not to exceed the amount set forth under the heading "Tranche 1D Term Commitment" opposite such Lender's name on Schedule 1.1.

"Tranche 1D Draw Period" means the period beginning on the earlier of (i) the full draw of the Tranche 1C Advances and (ii) the expiration of Tranche 1C Draw Period, and ending on December 15, 2023.

"Tranche 1D Facility Charge" means three-quarter percent (0.75%) of the Tranche 1D Advances funded, which is payable to the Lenders in accordance with Section 4.2(f).

"Tranche 1E Commitment" means as to any Lender, the obligation of such Lender, if any, to make a Term Loan Advance to Borrowers in a principal amount not to exceed the amount set forth under the heading "Tranche 1E Term Commitment" opposite such Lender's name on Schedule 1.1.

"Tranche 1E Draw Period" means the period beginning on the earlier of (i) the full draw of the Tranche 1D Advances and (ii) the expiration of Tranche 1D Draw Period, and ending on June 15, 2024.

"Tranche 1E Facility Charge" means three-quarter percent (0.75%) of the Tranche 1E Advances funded, which is payable to the Lenders in accordance with Section 4.2(g).

"Tranche 2 Draw Period" means, on and after Tranche 2 Draw Conditions have been met, the period beginning on the earlier of (i) the full draw of the Tranche 1E Advances and (ii) the expiration of Tranche 1E Draw Period, and ending on June 30, 2024.

"Tranche 2 Commitment" means as to any Lender, the obligation of such Lender, if any, to make a Term Loan Advance to Borrowers in a principal amount not to exceed the amount set forth under the heading "Tranche 2 Term Commitment" opposite such Lender's name on Schedule 1.1.

"Tranche 2 Draw Conditions" means (i) Borrower's achievement of T3M Net Product Revenue of at least $60,000,000 as of the most recent reporting period and (ii) no Default or Event of Default shall have occurred and be continuing.

"Tranche 2 Facility Charge" means three-quarter percent (0.75%) of the Tranche 2 Advances funded, which is payable to the Lenders in accordance with Section 4.2(h).

"Tranche 3 Commitment" means as to any Lender, the obligation of such Lender, if any, to make a Term Loan Advance to Borrowers in a principal amount not to exceed the amount set forth under the heading "Tranche 3 Term Commitment" opposite such Lender's name on Schedule 1.1.

(1) "Tranche 3 Draw Period" means the period beginning on the Third Amendment Closing Date and ending on December 31, 2025, and subject to approval by the Lenders' investment committee in its sole and unfettered discretion.

"Tranche 3 Facility Charge" means three-quarter percent (0.75%) of the Tranche 3 Advances funded, which is payable to the Lenders in accordance with Section 4.2(i).

"UCC" means the Uniform Commercial Code as the same is, from time to time, in effect in the State of California; provided, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection or priority of, or remedies with respect to, Agent's Lien on any Collateral is governed by the Uniform Commercial Code as the same is, from time to time, in effect in a jurisdiction other than the State of California, then the term "UCC" shall mean the Uniform Commercial Code as in effect, from time to time, in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority or remedies and for purposes of definitions related to such provisions.

"U.S. Person" means any Person that is a "United States person" as defined in Section 7701(a)(30) of the Code.

"Warrant" means any warrant entered into in connection with the Loan, as may be amended, restated or modified from time to time.

1.2 The following terms are defined in the Sections or subsections referenced opposite such terms:

Defined Term	Section
Agent	Preamble
Assignee	11.14
Borrower	Preamble
Claims	11.11
Collateral	3.1
Confidential Information	11.13
Current Company IP	5.10(a)
End of Term Charge	2.6
Event of Default	9
Extension End of Term Charge	2.6
Financial Statements	7.1
Indemnified Person	6.3
Initial End of Term Charge	2.6(b)
Lenders	Preamble
Liabilities	6.3

Maximum Rate	2.3
Open Source License	5.10(p)
Participant Register	11.8
Permitted License	"Permitted Transfer" clause (ii)
Prepayment Charge	2.5
Publicity Materials	11.19
Register	11.7
Rights to Payment	3.1
Specified Disputes	5.10(g)
Third Amendment End of Term Charge	2.6(c)
Third Party IP	5.10(i)
Tranche 1A Advance	2.2(a)(i)
Tranche 1A-1 Advance	2.2(a)(i)
Tranche 1A-2 Advance	2.2(a)(i)
Tranche 1B Advance	2.2(a)(ii)
Tranche 1C Advance	2.2(a)(iii)
Tranche 1D Advance	2.2(a)(iii)
Tranche 1E Advance	2.2(a)(iii)
Tranche 1 Advance	2.2(a)(iii)
Tranche 2 Advance	2.2(a)(iv)
Tranche 3 Advance	2.2(a)(v)

1.3 Unless otherwise specified, all references in this Agreement or any Annex or Schedule hereto to a "Section," "subsection," "Exhibit," "Annex," or "Schedule" shall refer to the corresponding Section, subsection, Exhibit, Annex, or Schedule in or to this Agreement. Unless otherwise specifically provided herein, any accounting term used in this Agreement or the other Loan Documents shall have the meaning customarily given such term in accordance with GAAP, and all financial computations hereunder shall be computed in accordance with GAAP, consistently applied; provided that if at any time any change in GAAP would affect the computation of any financial covenant or ratio or requirement set forth in any Loan Document, and either Borrower or Agent shall so request, Borrower, Agent and the Lenders shall negotiate in good faith to amend such ratio or requirement to preserve the original intent thereof in light of such change in GAAP; provided, further, that, until so amended, (a) such ratio or requirement shall continue to be computed in accordance with GAAP prior to such change therein and (b) Borrower shall provide Agent financial statements and other documents required under this Agreement or as reasonably requested hereunder setting forth a reconciliation between calculations of such ratio covenant or requirement made before and after giving effect to such change in GAAP. Notwithstanding the foregoing, any obligations of a Person that are or would have been treated as operating leases for purposes of GAAP prior to the issuance by the Financial Accounting Standards Board on February 25, 2016 of an Accounting Standards Update (the "ASU") shall continue to be accounted for as operating leases for purposes of all financial definitions, calculations and covenants for purpose of this Agreement (whether or not such operating lease obligations were in effect on such date) notwithstanding the fact that such obligations are required in accordance with the ASU (on a prospective or retroactive basis or otherwise) to be treated as capitalized lease obligations in accordance with GAAP (other than for purposes of the delivery of financial statements prepared in accordance with GAAP). Unless otherwise defined herein or in the other Loan Documents, terms that are used herein or in the other Loan Documents and defined in the UCC shall have the meanings given to them

in the UCC. For all purposes under the Loan Documents, in connection with any division or plan of division under Delaware law (or any comparable event under a different jurisdiction's laws): (a) if any asset, right, obligation or liability of any Person becomes the asset, right, obligation or liability of a different Person, then it shall be deemed to have been transferred from the original Person to the subsequent Person and (b) if any new Person comes into existence, such new Person shall be deemed to have been organized on the first date of its existence by the holders of its Equity Interests at such time.

1.4 Notwithstanding anything to the contrary in this Agreement or any other Loan Document, all terms of an accounting or financial nature used herein shall be construed, and all computations of amounts and ratios referred to herein shall be made without giving effect to any treatment of Indebtedness in respect of convertible debt instruments under Accounting Standards Codification 470-20 (or any other Accounting Standards Codification or Financial Accounting Standard having a similar result or effect) to value any such Indebtedness in a reduced or bifurcated manner as described therein, and such Indebtedness shall at all times be valued at the full stated principal amount thereof. For the avoidance of doubt, and without limitation of the foregoing, Permitted Convertible Debt shall at all times be valued at the full stated principal amount thereof and shall not include any reduction or appreciation in value of the shares deliverable upon conversion thereof.

SECTION 2. THE LOAN

2.1 [Reserved]

2.2 Term Loan.

(a) Advances.

(i) Subject to the terms and conditions of this Agreement, the Lenders will severally (and not jointly) make in an amount not to exceed their respective Tranche 1A Commitments, and Borrower agrees to draw, (x) a Term Loan Advance of Fifty Million Dollars ($50,000,000) on the Closing Date (the "Tranche 1A-1 Advance") and (y) a Term Loan Advance in an aggregate principal amount of Forty-Five Million Dollars ($45,000,000) on the Second Amendment Closing Date (the "Tranche 1A-2 Advance", and together with the Tranche 1A-1 Advance, collectively, the "Tranche 1A Advance").

(ii) Subject to the terms and conditions of this Agreement, Lenders will severally (and not jointly) make, in an amount not to exceed their respective Tranche 1B Commitments, an additional Term Loan Advance in an aggregate principal amount of Fifty-Five Million Dollars ($55,000,000) on or around the Third Amendment Closing Date (the "Tranche 1B Advance").

(iii) Subject to the terms and conditions of this Agreement, (A) during the Tranche 1C Draw Period, Borrower may request and the Lenders shall severally (and not jointly) make additional Term Loan Advances in an amount not to exceed their respective Tranche 1C Commitments, in an aggregate principal amount of up to Thirty Million Dollars ($30,000,000), in minimum increments of Five Million Dollars ($5,000,000) (each, a "Tranche 1C Advance") (B) during the Tranche 1D Draw Period, Borrower may request and the Lenders shall severally (and not jointly) make additional Term Loan Advances in an amount not to exceed their respective Tranche 1D Commitments, in an aggregate principal amount of up to Thirty Five Million Dollars ($35,000,000), in minimum increments of Five Million Dollars ($5,000,000) (each, a "Tranche 1D Advance"), and (C) during the Tranche 1E Draw Period, Borrower may request and the Lenders shall severally

(and not jointly) make additional Term Loan Advances in an amount not to exceed their respective Tranche 1E Commitments, in an aggregate principal amount of up to Thirty Five Million Dollars ($35,000,000), in minimum increments of Five Million Dollars ($5,000,000) (each, a "Tranche 1E Advance", and together with each Tranche 1A Advance, Tranche 1B Advance, Tranche 1C Advance, and Tranche 1D Advance, collectively, the "Tranche 1 Advance").

(iv) Subject to the terms and conditions of this Agreement, during the Tranche 2 Draw Period, and subject to the Tranche 2 Draw Conditions, Borrower may request and the Lenders shall severally (and not jointly) make an additional Term Loan Advance in an amount not to exceed their respective Tranche 2 Commitments, in an aggregate principal amount of up to Twenty-Five Million Dollars ($25,000,000) (the "Tranche 2 Advance").

(v) Subject to the terms and conditions of this Agreement, during the Tranche 3 Draw Period, subject to approval by the Lenders' investment committee in its sole and unfettered discretion, Borrower may request and the Lenders shall severally (and not jointly) make an additional Term Loan Advance in an amount not to exceed their respective Tranche 3 Commitments, in an aggregate principal amount of up to Seventy-Five Million Dollars ($75,000,000) in minimum increments of Five Million Dollars ($5,000,000) (each, a "Tranche 3 Advance").

(vi) [Reserved]

(vii) [Reserved].

(viii) [Reserved].

(ix) The aggregate outstanding Term Loan Advances may be up to the Maximum Term Loan Amount.

(b) Advance Request. To obtain a Term Loan Advance, Borrower shall complete, sign and deliver an Advance Request (at least one (1) Business Day before the Closing Date and at least five (5) Business Days before each Advance Date other than the Closing Date) to Agent. The Lenders shall fund the Term Loan Advance in the manner requested by the Advance Request provided that each of the conditions precedent to such Term Loan Advance is satisfied as of the requested Advance Date.

(c) Interest.

(i) Term Loan Cash Interest Rate. The principal balance of each Term Loan Advance shall bear interest thereon from such Advance Date at the Term Loan Cash Interest Rate based on a year consisting of 360 days, with interest computed daily based on the actual number of days elapsed. The Term Loan Cash Interest Rate will float and change on the day the prime rate changes from time to time.

(ii) [Reserved].

(iii) [Reserved].

(d) Payment. Borrower will pay interest on each Term Loan Advance on the first Business Day of each month, beginning the month after the Advance Date (each an "Interest Payment Date"). The entire Term Loan principal balance and all accrued but unpaid interest hereunder, shall be due and payable on the Term Loan Maturity Date. Borrower shall make all payments under this Agreement without setoff, recoupment or deduction and regardless of any counterclaim or defense. If a payment hereunder becomes due and payable on a day that is not a Business Day, the due date thereof shall be the immediately preceding Business Day. The Lenders will initiate debit entries to the Borrower's account as authorized on the ACH Authorization (i) on each payment date of all periodic obligations payable to the Lenders under each Term Loan Advance and (ii) reasonable, documented, out-of-pocket legal fees and costs incurred by Agent or the Lenders in connection with Section 11.12 of this Agreement; provided that, with respect to clause (i) above, in the event that the Lenders or Agent informs Borrower that the Lenders will not initiate a debit entry to Borrower's account for a certain amount of the periodic obligations due on a specific payment date, Borrower shall pay to the Lenders such amount of periodic obligations in full in immediately available funds on such payment date; provided, further, that, with respect to clause (i) above, if the Lenders or Agent informs Borrower that the Lenders will not initiate a debit entry as described above later than the date that is three (3) Business Days prior to such payment date, Borrower shall pay to the Lenders such amount of periodic obligations in full in immediately available funds on the date that is three (3) Business Days after the date on which the Lenders or Agent notifies Borrower of such; provided, further, that, with respect to clause (ii) above, in the event that the Lenders or Agent informs Borrower that the Lenders will not initiate a debit entry to Borrower's account for certain amount of such reasonable, documented out-of-pocket legal fees and costs incurred by Agent or the Lenders, Borrower shall pay to the Lenders such amount in full in immediately available funds within three (3) Business Days.

2.3Maximum Interest. Notwithstanding any provision in this Agreement or any other Loan Document, it is the parties' intent not to contract for, charge or receive interest at a rate that is greater than the maximum rate permissible by law that a court of competent jurisdiction shall deem applicable hereto (which under the laws of the State of California shall be deemed to be the laws relating to permissible rates of interest on commercial loans) (the "Maximum Rate"). If a court of competent jurisdiction shall finally determine that Borrower has actually paid to the Lenders an amount of interest in excess of the amount that would have been payable if all of the Secured Obligations had at all times borne interest at the Maximum Rate, then such excess interest actually paid by Borrower shall be applied as follows: first, to the payment of the Secured Obligations consisting of the outstanding principal; second, after all principal is repaid, to the payment of the Lenders' accrued interest, costs, expenses, professional fees and any other Secured Obligations; and third, after all Secured Obligations are repaid, the excess (if any) shall be refunded to Borrower.

2.4Default Interest. In the event any payment is not paid on the scheduled payment date (or promptly following resolution of an ACH Failure (and in no event later than three (3) Business Days of the scheduled payment date); provided that such late payment is due to an ACH Failure), an amount equal to five percent (5%) of the past due amount shall be payable on demand. In addition, upon the occurrence and during the continuation of an Event of Default hereunder, all Secured Obligations, including principal, interest, compounded interest, and professional fees, shall bear interest at a rate per annum equal to the rate set forth in Section 2.2(c) plus five percent (5%) per annum. In the event any interest is not paid when due hereunder, delinquent interest shall be added to principal and shall bear interest on interest, compounded at the rate set forth in Section 2.2(c) or Section 2.4, as applicable.

2.5Prepayment. At its option, upon at least seven (7) Business Days prior written notice to Agent (or such shorter notice period as agreed by Agent in its sole discretion), Borrower may at any time and from time to time, prepay all or a portion of the outstanding Advances by paying the entire principal balance, or such portion thereof in minimum increments of Five Million Dollars ($5,000,000), all accrued and unpaid interest thereon, together with a prepayment charge equal to the following percentage of the Advance Amount being prepaid: with respect to each Advance, if such Advance Amounts are prepaid in any of the period following the Third Amendment Closing Date but prior to February 1, 2024, 2.0%; on or after February 1, 2024, but prior to February 1, 2025, 1.5%; and on or after February 1, 2025, but prior to February 1, 2026, 1.0% (each, a "Prepayment Charge"). If at any time Borrower elects to make a prepayment, and at such time, there are outstanding Advances under multiple Tranches, the Prepayment Charge shall be determined by applying the amount of such prepayment in the following order: first, to the outstanding principal amount (and accrued but unpaid interest thereon) of Advances outstanding under the Tranche with the latest initial funding date; second, to the outstanding principal amount (and accrued but unpaid interest thereon) of Advances outstanding under the Tranche with the next latest initial funding date and so on until the entire principal balance of all Advances made hereunder (and all accrued but unpaid interest thereon) is paid in full. Borrower agrees that the Prepayment Charge is a reasonable calculation of the Lenders' lost profits in view of the difficulties and impracticality of determining actual damages resulting from an early repayment of the Advances. Borrower shall prepay the outstanding amount of all principal and accrued interest through the prepayment date and the Prepayment Charge, if any, upon the occurrence of a Change in Control or any other prepayment hereunder. Notwithstanding the foregoing, Agent and the Lenders agree to waive the Prepayment Charge if Agent and the Lenders (in their sole and absolute discretion) agree in writing to refinance the Advances prior to the Term Loan Maturity Date. Any amounts paid under this Section shall be applied by Agent to the then unpaid amount of any Secured Obligations (including principal and interest) in such order and priority as Agent may choose in its sole discretion. For the avoidance of doubt, if a payment hereunder becomes due and payable on a day that is not a Business Day, the due date thereof shall be the immediately preceding Business Day. Notwithstanding anything to the contrary contained in this Agreement, so long as Borrower provided notice to the Agent no less than seven (7) Business Days prior to the proposed prepayment date, Borrower may rescind any notice of prepayment if such prepayment would have resulted from a refinancing of all or a portion of the Term Loan Advances, which refinancing shall not be consummated or shall otherwise be delayed.

2.6End of Term Charge.

(a) Partial Prepayments. On any date that Borrower partially prepays the outstanding Secured Obligations pursuant to Section 2.5, Borrower shall pay the Lenders:

(i) with respect to any repayment of any Tranche 1A-1 Advance, a charge of:

(x) 4.85% of the principal amount of such Term Loan Advances being repaid, *plus*

(y) 1.10 % of the principal amount of such Term Loan Advances being repaid;

(ii) with respect to any repayment of any Tranche 1A-2 Advance, a charge of:

(x) 4.50% of the principal amount of such Term Loan Advances being repaid; *plus*

(y) 1.10 % of the principal amount of such Term Loan Advances being repaid;

(iii)with respect to any repayment of any Tranche 1B Advance, Tranche 1C Advance, Tranche 1D Advance, Tranche 1E Advance, Tranche 2 Advance or Tranche 3 Advance, a charge of 4.95% of the principal amount of such Term Loan Advances being repaid.

(b) Initial End of Term Charge. On the earliest to occur of (i) October 1, 2026, (ii) the date that Borrower prepays the outstanding Secured Obligations (other than any inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) in full, or (iii) the date that the Secured Obligations become due and payable in full (other than regularly scheduled interest payments), Borrower shall pay the Lenders a charge equal to (x) Four Million Four Hundred Fifty Thousand Dollars ($4,450,000) *minus* (y) the aggregate amount of payments made pursuant to Section 2.6(a)(i)(x) and Section 2.6(a)(ii)(x) (the "Initial End of Term Charge")

(c) Third Amendment End of Term Charge. On the earliest to occur of (i) January 1, 2028, (ii) the date that Borrower prepays the outstanding Secured Obligations (other than any inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) in full, or (iii) the date that the Secured Obligations become due and payable in full (other than regularly scheduled interest), Borrower shall pay the Lenders a charge equal to (x) 1.10% of the aggregate amount of all Tranche 1A Advances, plus (y) 4.95% of the aggregate amount of all Term Loan Advances (other than Tranche 1A Advances) funded, minus (z) the aggregate amount of payments made pursuant to Section 2.6(a)(i)(y), Section 2.6(a)(ii)(y), and Section 2.6(a)(iii) (the "Third Amendment End of Term Charge").

(d) Extension End of Term Charge. If the Maturity Extension Conditions are satisfied, on the earliest to occur of (i) January 1, 2029, (ii) the date that Borrower prepays the outstanding Secured Obligations (other than any inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) in full, or (iii) the date that the Secured Obligations become due and payable in full (other than regularly scheduled interest payments), Borrower shall pay the Lenders an additional charge equal to 1.00% of the aggregate amount of all Term Loan Advances outstanding as of the date on which the Maturity Extension Conditions are satisfied (the "Extension End of Term Charge", collectively with any charge made pursuant to Section 2.6(a), the Initial End of Term Charge, and the Third Amendment End of Term Charge, the "End of Term Charge").

(e) Notwithstanding the required payment date of such End of Term Charge, the applicable pro rata portion of the End of Term Charge shall be deemed earned by the Lenders as of each date a Term Loan Advance is made. For the avoidance of doubt, if a payment hereunder becomes due and payable on a day that is not a Business Day, the due date thereof shall be the immediately preceding Business Day.

2.7Pro Rata Treatment. Each payment (including prepayment) on account of any fee and any reduction of the Term Loans shall be made pro rata according to the Term Commitments of the relevant Lender.

2.8Taxes; Increased Costs. The Borrower, the Agent and the Lenders each hereby agree to the terms and conditions set forth on Addendum 1 attached hereto.

2.9Treatment of Prepayment Charge and End of Term Charge. Borrower agrees that any Prepayment Charge and any End of Term Charge payable shall be presumed to be the liquidated damages sustained by each Lender as the result of the early termination, and Borrower agrees that it is reasonable under the circumstances currently existing and existing as of the Closing Date, the Second Amendment Closing Date, and the Third Amendment Closing Date. The Prepayment Charge and the End of Term Charge shall also be payable in the event the Secured Obligations (and/or this Agreement) are satisfied or released by foreclosure (whether by power of judicial proceeding), deed in lieu of foreclosure, or by any other means. Borrower expressly waives (to the fullest extent it may lawfully do so) the provisions of any present or future statute or law that prohibits or may prohibit the collection of the foregoing Prepayment Charge and End of Term Charge in connection with any such acceleration. Borrower agrees (to the fullest extent that each may lawfully do so): (a) each of the Prepayment Charge and the End of Term Charge is reasonable and is the product of an arm's length transaction between sophisticated business people, ably represented by counsel; (b) each of the Prepayment Charge and the End of Term Charge shall be payable notwithstanding the then prevailing market rates at the time payment is made; (c) there has been a course of conduct between the Lenders and Borrower giving specific consideration in this transaction for such agreement to pay the Prepayment Charge and the End of Term Charge as a charge (and not interest) in the event of prepayment or acceleration; (d) Borrower shall be estopped from claiming differently than as agreed to in this paragraph. Borrower expressly acknowledges that their agreement to pay each of the Prepayment Charge and the End of Term Charge to the Lenders as herein described was on the Closing Date, the Second Amendment Closing Date, and the Third Amendment Closing Date, and continues to be a material inducement to the Lenders to provide the Term Loans.

SECTION 3. SECURITY INTEREST

3.1As security for the prompt and complete payment when due (whether on the payment dates or otherwise) of all the Secured Obligations, Borrower grants to Agent a security interest in all of Borrower's right, title, and interest in, to and under all of Borrower's personal property and other assets including without limitation the following (except as set forth herein) whether now owned or hereafter acquired (collectively, the "Collateral"): (a) Receivables; (b) Equipment; (c) Fixtures; (d) General Intangibles; (e) Inventory; (f) Investment Property; (g) Deposit Accounts; (h) Cash; (i) Goods; (j) the Antecip License Agreement and all proceeds thereof; and all other tangible and intangible personal property of Borrower whether now or hereafter owned or existing, leased, consigned by or to, or acquired by, Borrower and wherever located, and any of Borrower's property in the possession or under the control of Agent; and, to the extent not otherwise included, all Proceeds of each of the foregoing and all accessions to, substitutions and replacements for, and rents, profits and products of each of the foregoing.

3.2Notwithstanding the broad grant of the security interest set forth in Section 3.1, above, the Collateral shall not include (collectively, the "Excluded Property") (a) any "intent to use" trademarks at all times prior to the first use thereof, whether by the actual use thereof in commerce, the recording of a statement of use with the United States Patent and Trademark Office or otherwise, provided, that upon submission and acceptance by the United States Patent and Trademark Office of an amendment to allege use of an intent-to-use trademark application pursuant to 15 U.S.C. Section 1060(a) (or any successor provision) such intent-to-use application shall constitute Collateral, (b) non-assignable property, licenses or contracts, which by their terms require the consent of the licensor thereof or another party (but only to the extent such prohibition on transfer is enforceable under applicable law, including, without limitation, Sections 9406, 9407 and 9408 of the UCC), (c) any particular asset if the pledge thereof or the security interest therein is prohibited or restricted by applicable law, rule or regulation (including any requirement to obtain the consent

of any governmental authority, regulatory authority or third party), provided that the foregoing exclusion of this clause (c) shall in no way be construed (1) to apply to the extent that any described prohibition or restriction is unenforceable under Section 9406, 9407 or 9408 of the UCC or other applicable law or (2) to apply to the extent that any consent or waiver has been obtained, or is hereafter obtained, that would permit the Agent's security interest or Lien notwithstanding the prohibition or restriction on the pledge of such asset, (d) any Excluded Accounts, including cash pledged pursuant to Permitted Liens and any Deposit Account, securities account, commodities account or other account to the extent solely and exclusively used to hold any cash pledged as a Permitted Lien, and (e) Equipment and software (and the products and proceeds thereof) subject to Permitted Liens of the type described in clause (vii) of the definition of Permitted Liens, but only to the extent and for so long as the agreements under which the equipment is financed prohibit granting a security interest therein to Lender.

3.3 Upon termination of this Agreement and repayment if full of all Secured Obligations (other than any inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement), all security interest in the Collateral granted under this Agreement shall terminate and all rights on the Collateral shall revert to Borrower. Agent shall execute such documents and take such other steps as are reasonably necessary for Borrower to accomplish the foregoing, all at Borrower's sole cost and expense.

SECTION 4. CONDITIONS PRECEDENT TO LOAN

The obligations of the Lenders to make the Loan hereunder are subject to the satisfaction by Borrower of the following conditions:

4.1Initial Advance. On or prior to the Closing Date, Borrower shall have delivered to Agent the following:

(a)executed copies of the Loan Documents (other than the Warrant, which shall be an original), Account Control Agreements, and all other documents and instruments reasonably required by Agent to effectuate the transactions contemplated hereby or to create and perfect the Liens of Agent with respect to all Collateral, in all cases in form and substance reasonably acceptable to Agent;

(b)a legal opinion of Borrower's counsel in form and substance reasonably acceptable to Agent,

(c)certified copy of resolutions of Borrower's board of directors evidencing approval of (i) the Loan and other transactions evidenced by the Loan Documents; and (ii) the Warrant and transactions evidenced thereby;

(d)certified copies of the Certificate of Incorporation and the Bylaws, as amended through the Closing Date, of Borrower;

(e)a certificate of good standing for Borrower from its state of incorporation and similar certificates from all other jurisdictions in which it does business and where the failure to be qualified could have a Material Adverse Effect;

(f)payment of the Due Diligence Fee, Initial Facility Charge and reimbursement of Agent's and the Lenders' current expenses reimbursable pursuant to this Agreement, which amounts may be deducted from the initial Advance;

(g)all certificates of insurance and copies of each insurance policy required hereunder;

(h)executed copy of the Antecip Direct Agreement; and

(i)such other documents as Agent may reasonably request.

4.2All Advances. On each Advance Date:

(a)Agent shall have received (i) an Advance Request for the relevant Advance as required by Section 2.2(b), each duly executed by Borrower's Chief Executive Officer or Chief Financial Officer, and (ii) any other documents Agent may reasonably request.

(b)The representations and warranties set forth in this Agreement shall be true and correct in all material respects on and as of the Advance Date with the same effect as though made on and as of such date, except to the extent such representations and warranties expressly relate to an earlier date.

(c)Borrower shall be in compliance with all the terms and provisions set forth herein and in each other Loan Document on its part to be observed or performed, and at the time of and immediately after such Advance no Event of Default shall have occurred and be continuing.

(d)with respect to any Tranche 1B Advance, the Borrower shall have paid the Tranche 1B Facility Charge.

(e)with respect to any Tranche 1C Advance, the Borrower shall have paid the Tranche 1C Facility Charge.

(f)with respect to any Tranche 1D Advance, the Borrower shall have paid the Tranche 1D Facility Charge.

(g) with respect to any Tranche 1E Advance, the Borrower shall have paid the Tranche 1E Facility Charge.

(h)with respect to any Tranche 2 Advance, the Borrower shall have paid the Tranche 2 Facility Charge.

(i)with respect to any Tranche 3 Advance, the Borrower shall have paid the Tranche 3 Facility Charge.

(j)with respect to any Advance on and after the Second Amendment Closing Date, a Warrant substantially in the form of Exhibit K which shall be in form and substance satisfactory to Agent.

(k)the Borrower shall have paid the Third Amendment Facility Charge on or prior to the Third Amendment Closing Date.

(l)[Reserved].

(m)[Reserved].

(n)Each Advance Request shall be deemed to constitute a representation and warranty by Borrower on the relevant Advance Date as to the matters specified in paragraphs (b) and (c) of this Section 4.2 and as to the matters set forth in the Advance Request.

4.3No Default. As of the Closing Date and each Advance Date, (i) no fact or condition exists that could (or could, with the passage of time, the giving of notice, or both) constitute an Event of Default and (ii) no event that has had or could reasonably be expected to have a Material Adverse Effect has occurred and is continuing.

4.4Post-Close Obligations.

(a)Notwithstanding any provision herein or in any other Loan Document to the contrary, to the extent not actually delivered on or prior to the Closing Date, Borrower shall deliver to Agent (or its designated attorney or representative), within two (2) Business Days after the Closing Date, an Account Control Agreement for Borrower's accounts (other than Excluded Accounts) maintained with Silicon Valley Bank.

(b)Notwithstanding any provision herein or in any other Loan Document to the contrary, to the extent not actually delivered on or prior to the Third Amendment Closing Date, Borrower shall deliver to Agent (or its designated attorney or representative), such documents as required under Section 7 of the Third Amendment in accordance with the terms as set forth therein.

SECTION 5. REPRESENTATIONS AND WARRANTIES OF BORROWER

Borrower represents and warrants that:

5.1Corporate Status. Borrower is a corporation duly organized, legally existing and in good standing under the laws of its state of incorporation, and is duly qualified as a foreign corporation in all jurisdictions in which the nature of its business or location of its properties require such qualifications and where the failure to be qualified could reasonably be expected to have a Material Adverse Effect. Borrower's present name, former names (if any), locations, place of formation, tax identification number, organizational identification number and other information are correctly set forth in Exhibit B, as may be updated by Borrower in a written notice (including any Compliance Certificate) provided to Agent after the Closing Date.

5.2Collateral. Borrower owns the Collateral, free of all Liens, except for Permitted Liens. Borrower has the power and authority to grant to Agent a Lien in the Collateral as security for the Secured Obligations.

5.3Consents. Borrower's execution, delivery and performance of this Agreement and all other Loan Documents, and Borrower's execution of the Warrant, (i) have been duly authorized by all necessary corporate action of Borrower, (ii) will not result in the creation or imposition of any Lien upon the Collateral, other than Permitted Liens and the Liens created by this Agreement and the other Loan Documents, (iii) do not violate any provisions of Borrower's Certificate or Articles of Incorporation (as applicable), bylaws, or any, law, regulation, order, injunction, judgment, decree or writ to which Borrower is subject and (iv) except as described on Schedule 5.3, do not violate any material contract or agreement or require the consent or approval of any other Person which has not already been obtained. The individual or individuals executing the Loan Documents and the Warrant are duly authorized to do so.

5.4Material Adverse Effect. No event that has had or could reasonably be expected to have a Material Adverse Effect has occurred and is continuing. Borrower is not aware of any event likely to occur that is reasonably expected to result in a Material Adverse Effect.

5.5Actions Before Governmental Authorities. There are no actions, suits or proceedings at law or in equity or by or before any governmental authority now pending or, to the knowledge of Borrower, threatened in writing against Borrower or its property, that is reasonably expected to result in a Material Adverse Effect.

5.6Laws. Neither Borrower nor any of its Subsidiaries is in violation of any law, rule or regulation, or in default with respect to any judgment, writ, injunction or decree of any governmental authority, where such violation or default is reasonably expected to result in a Material Adverse Effect. Borrower is not in default in any manner under any provision of any agreement or instrument evidencing (i) material Indebtedness, or any other Material Agreement to which it is a party or by which it is bound or (ii) any other agreement which default is reasonably expected to result in a Material Adverse Effect.

Neither Borrower nor any of its Subsidiaries is an “investment company” or a company “controlled” by an “investment company” under the Investment Company Act of 1940, as amended. Neither Borrower nor any of its Subsidiaries is engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Borrower and each of its Subsidiaries has complied in all material respects with the Federal Fair Labor Standards Act. Neither Borrower nor any of its Subsidiaries is a “holding company” or an “affiliate” of a “holding company” or a “subsidiary company” of a “holding company” as each term is defined and used in the Public Utility Holding Company Act of 2005. Neither Borrower’s nor any of its Subsidiaries’ properties or assets has been used by Borrower or such Subsidiary or, to Borrower’s knowledge, by previous Persons, in disposing, producing, storing, treating, or transporting any hazardous substance other than in material compliance with applicable laws. Borrower and each of its Subsidiaries has obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted.

None of Borrower, any of its Subsidiaries, or any of Borrower’s or its Subsidiaries’ Affiliates or any of their respective agents acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement is (i) in violation of any Anti-Terrorism Law, (ii) engaging in or conspiring to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding or attempts to violate, any of the prohibitions set forth in any Anti-Terrorism Law, or (iii) is a Blocked Person. None of Borrower, any of its Subsidiaries, or to the knowledge of Borrower and any of their Affiliates or agents, acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement, (x) conducts any business or engages in making or receiving any contribution of funds, goods or services to or for the benefit of any Blocked Person, or (y) deals in, or otherwise engages in any transaction relating to, any property or interest in property blocked pursuant to Executive Order No. 13224, any similar executive order or other Anti-Terrorism Law. None of the funds to be provided under this Agreement will be used, directly or indirectly, (a) for any activities in violation of any applicable anti-money laundering, economic sanctions and anti-bribery laws and regulations laws and regulations or (b) for any payment to any governmental official or employee, political party, official of a political party, candidate for political office, or anyone else acting in an official capacity, in order to obtain, retain or direct business or obtain any improper advantage, in violation of the United States Foreign Corrupt Practices Act of 1977, as amended.

5.7Information Correct and Current. No information, report, Advance Request, financial statement, exhibit or schedule furnished, by or on behalf of Borrower to Agent in connection with any Loan Document or included therein or delivered pursuant thereto contained, or, when taken as a whole, contains any material misstatement of fact or, when taken together with all other such information or documents, omitted or omits to state any material fact necessary to make the statements therein, in the light of the circumstances under which they were, are or will be made, not materially misleading at the time such statement was made or deemed made. Additionally, any and all financial or business projections provided by Borrower to Agent, whether prior to or after the Closing Date, shall be (i) provided in good faith and based on the most current data and information available to Borrower and subject to normal year-end adjustments, and (ii) the most current of such projections provided to Borrower's board of directors (it being understood that such projections are subject to significant uncertainties and contingencies, many of which are beyond the control of Borrower, that no assurance is given that any particular projections will be realized, that actual results may differ).

5.8Tax Matters. Except as described on Schedule 5.8, (a) Borrower and its Subsidiaries have filed all federal and state income Tax returns and other material Tax returns that they are required to file, (b) Borrower and its Subsidiaries have duly paid all federal and state income Taxes and other material Taxes or installments thereof that they are required to pay, except Taxes being contested in good faith by appropriate proceedings and for which Borrower and its Subsidiaries maintain adequate reserves in accordance with GAAP, and (c) to the best of Borrower's knowledge, no proposed or pending Tax assessments, deficiencies, audits or other proceedings with respect to Borrower or any Subsidiary have had, or could reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect.

5.9Intellectual Property Claims. Borrower is the sole owner of, or otherwise has the right to use, the Intellectual Property material to Borrower's business. Except as described on Schedule 5.9 and as may be updated by Borrower in a written notice provided from time to time after the Closing Date, (i) each of the material Copyrights, Trademarks and Patents (other than patent applications) is valid and enforceable, (ii) no material part of the Intellectual Property has been judged invalid or unenforceable, in whole or in part, and (iii) except as set forth in the most recently delivered Compliance Certificate in accordance with Section 7.1(d), no claim has been made to Borrower in writing that any material part of the Intellectual Property violates the rights of any third party. Exhibit C (and as may be updated by Borrower in a written notice provided from time to time after the Closing Date) is a true, correct and complete list of each of Borrower's registered Patents and filed Patent applications, registered Trademarks, registered Copyrights, and Material Agreements under which Borrower licenses Intellectual Property from third parties (other than shrink-wrap software licenses, licenses that are commercially available to the public, open source licenses, licenses disclosed in writing to Agent as required under this Agreement and immaterial Intellectual Property licensed to Borrower in the ordinary course of business), together with application or registration numbers, as applicable, owned by Borrower or any Subsidiary, in each case as of the Closing Date. Borrower is not in material breach of, nor has Borrower failed to perform any material obligations under, any of the foregoing contracts, licenses or agreements and, to Borrower's knowledge, no third party to any such contract, license or agreement is in material breach thereof or has failed to perform any material obligations thereunder.

5.10Intellectual Property.

(a) A true, correct and complete list of each pending, registered, issued or in-licensed Intellectual Property that, individually or taken together with any other such Intellectual Property, is material to the business of Borrower and its Subsidiaries, taken as a whole, relating to the research,

development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of the Borrower Products, and is owned or co-owned by or exclusively or non-exclusively licensed to the Borrower or any of its Subsidiaries (collectively, the "Current Company IP"), including its name/title, current owner or co-owners (including ownership interest), registration, patent or application number, and registration or application date, issued or filed in the United States, is set forth on Schedule 5.10(a). Except as set forth on Schedule 5.10(a), (i) (A) each item of owned Current Company IP is valid, subsisting and (other than with respect to Patent applications) enforceable and no such item of Current Company IP has lapsed, expired, been cancelled or invalidated or become abandoned or unenforceable, and (B) no written notice has been received challenging the inventorship or ownership, or relating to any lapse, expiration, invalidation, abandonment or unenforceability, of any such item of Current Company IP, and (ii) (A) each such item of Current Company IP which is licensed from another Person is valid, subsisting and enforceable and no such item of Current Company IP has lapsed, expired, been cancelled or invalidated, or become abandoned or unenforceable, and (B) no written notice has been received challenging the inventorship or ownership, or relating to any lapse, expiration, invalidation, abandonment or unenforceability, of any such item of Current Company IP. To the knowledge of Borrower, there are no published patents, patent applications, articles or prior art references that would reasonably be expected to materially adversely affect the exploitation of the Borrower Products. Except as set forth on Schedule 5.10(a), (x) each Person who has or has had any rights in or to owned Current Company IP or any trade secrets owned by the Borrower or any of its Subsidiaries, including each inventor named on the Patents within such owned Current Company IP filed by the Borrower or any of its Subsidiaries, and has executed an agreement assigning his, her or its entire right, title and interest in and to such owned Current Company IP and such trade secrets, and the inventions, improvements, ideas, discoveries, writings, works of authorship, information and other intellectual property embodied, described or claimed therein, to the stated owner thereof, and (y) no such Person has any contractual or other obligation that would preclude or conflict with such assignment or the exploitation of the Borrower Products or entitle such Person to ongoing payments.

(b) (i) The Borrower or any of its Subsidiaries possesses valid title to the Current Company IP for which it is listed as the owner or co-owner, as applicable, on Schedule 5.10(a); and (ii) there are no Liens on any Current Company IP.

(c) There are no maintenance, annuity or renewal fees that are currently overdue beyond their allotted grace period for any of the Current Company IP which is owned by or exclusively licensed to the Borrower or any of its Subsidiaries, nor have any applications or registrations therefor lapsed or become abandoned, been cancelled or expired. There are no maintenance, annuity or renewal fees that are currently overdue beyond their allotted grace period for any of the Current Company IP which is non-exclusively licensed to the Borrower or any of its Subsidiaries, nor have any applications or registrations therefor lapsed or become abandoned, been cancelled or expired.

(d) There are no unpaid fees or royalties under any Material Agreements that have become due, or are expected to become overdue. Each Material Agreement is in full force and effect and is legal, valid, binding, and enforceable 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. Except as set forth on Schedule 5.10(d), neither Borrower nor any of its Subsidiaries, as applicable, is in breach of or default in any manner that could reasonably be expected to materially affect the Borrower Products under any Material Agreement to which it is a party or may otherwise be bound, and no circumstances or grounds exist that would give rise to a claim of breach or right of rescission, termination, non-renewal, revision or amendment of any of the Material Agreements, including the execution, delivery and performance of this Agreement and the other Loan Documents.

(e) No payments by the Borrower or any of its Subsidiaries are due to any other Person in respect of the Current Company IP, other than pursuant to the Material Agreements and those fees payable to patent offices in connection with the prosecution and maintenance of the Current Company IP, any applicable taxes and associated attorney fees.

(f) Neither the Borrower nor any of its Subsidiaries has undertaken or omitted to undertake any acts, and no circumstance or grounds exist that would invalidate or reduce, in whole or in part, the enforceability or scope of (i) the Current Company IP in any manner that could reasonably be expected to materially adversely affect the Borrower Products, or (ii) in the case of Current Company IP owned or co-owned or exclusively or non-exclusively licensed by the Borrower or any of its Subsidiaries, except as set forth on Schedule 5.10(f), the Borrower's or Subsidiary's entitlement to own or license and exploit such Current Company IP.

(g) Except as described on Schedule 5.9 or in the most recently delivered Compliance Certificate in accordance with Section 7.1(d), there is no requested, filed pending, decided or settled opposition, interference proceeding, reissue proceeding, reexamination proceeding, inter-partes review proceeding, post-grant review proceeding, cancellation proceeding, injunction, litigation, paragraph IV patent certification or lawsuit under the Hatch-Waxman Act, hearing, investigation, complaint, arbitration, mediation, demand, International Trade Commission investigation, decree, or any other dispute, disagreement, or claim, in each case alleged in writing to Borrower or any of its Subsidiaries (collectively referred to hereinafter as "Specified Disputes"), nor to the knowledge of Borrower, has any such Specified Dispute been threatened in writing, in each case challenging the legality, validity, enforceability or ownership of any Current Company IP, in each case that would have a material adverse effect on the Borrower Products.

(h) In each case where an issued Patent within the Current Company IP is owned or co-owned by the Borrower or any of its Subsidiaries by assignment, the assignment has been duly recorded with the U.S. Patent and Trademark Office.

(i) Except as set forth on Schedule 5.10(i) there are no pending or, to the knowledge of Borrower, threatened claims against Borrower or any of its Subsidiaries alleging (i) that any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of the Borrower Products in the United States infringes or violates (or in the past infringed or violated) the rights of any third parties in or to any Intellectual Property ("Third Party IP") or constitutes a misappropriation of (or in the past constituted a misappropriation of) any Third Party IP, or (ii) that any Current Company IP is invalid or unenforceable.

(j) Except as set forth on Schedule 5.10(j), the manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of the Borrower Products does not, to the knowledge of Borrower, infringe or violate (or in the past infringed or violated) any issued or registered Third Party IP (including any issued Patent within the Third Party IP) or constitute a misappropriation of (or in the past constituted a misappropriation of) any Third Party IP.

(k) Except as set forth on Schedule 5.10(k), there are no settlements, covenants not to sue, consents, judgments, orders or similar obligations which: (i) restrict the rights of the Borrower or any of its Subsidiaries to use any Intellectual Property relating to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of the Borrower Products (in order to accommodate any Third Party IP or otherwise), or (ii) permit any third parties to use any Company IP.

(l) Except as set forth on Schedule 5.10(l), to the knowledge of Borrower (i) there is no, nor has there been any, infringement or violation by any Person of any of the Company IP or the rights therein, and (ii) there is no, nor has there been any, misappropriation by any Person of any of the Company IP or the subject matter thereof.

(m) The Borrower and each of its Subsidiaries has taken all commercially reasonable measures customary in the biopharmaceutical industry to protect the confidentiality and value of all trade secrets owned by the Borrower or any of its Subsidiaries or used or held for use by the Borrower or any of its Subsidiaries, in each case relating to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of the Borrower Products.

(n) Except as set forth on Schedule 5.10(n), at the time of any shipment of Borrower Product in the United States occurring prior to the Closing Date, the units thereof so shipped complied with their relevant specifications and were manufactured in all material respects in accordance with current FDA Good Manufacturing Practices.

(o) Except as described on Schedule 5.10(o), Borrower has all material rights with respect to Intellectual Property necessary or material in the operation or conduct of Borrower's business as currently conducted and proposed to be conducted by Borrower. Without limiting the generality of the foregoing, and in the case of Licenses, except for restrictions that are unenforceable under Division 9 of the UCC, Borrower has the right, to the extent required to operate Borrower's business, to freely transfer, license or assign Intellectual Property necessary or material in the operation or conduct of Borrower's business as currently conducted and proposed to be conducted by Borrower, without condition, restriction or payment of any kind (other than license payments in the ordinary course of business) to any third party, and Borrower owns or has the right to use, pursuant to valid licenses, all software development tools, library functions, compilers and all other third-party software and other items that are material to Borrower's business and used in the design, development, promotion, sale, license, manufacture, import, export, use or distribution of Borrower Products that are material to Borrower's business except customary covenants in inbound license agreements and equipment leases where Borrower is the licensee or lessee. Except as has been disclosed in the Perfection Certificate or pursuant to Section 7.1(d), Borrower is not a party to, nor is it bound by, any Restricted License.

No material software or other materials used by Borrower or any of its Subsidiaries (or used in any Borrower Products or any Subsidiaries' products) are subject to an open-source or similar license (including but not limited to the General Public License, Lesser General Public License, Mozilla Public License, or Affero License) (collectively, "Open Source Licenses") in a manner that would cause such software or other materials to have to be (i) distributed to third parties at no charge or a minimal charge (royalty-free basis); (ii) licensed to third parties to modify, make derivative works based on, decompile, disassemble, or reverse engineer; or (iii) used in a manner that does could require disclosure or distribution in source code form.

5.11Borrower Products. Except as described on Schedule 5.11 or in the most recently delivered Compliance Certificate in accordance with Section 7.1(d), no material Intellectual Property owned by Borrower or Borrower Product has been or is subject to any actual or, to the knowledge of Borrower, threatened in writing litigation, proceeding (including any proceeding in the United States Patent and Trademark Office or any corresponding foreign office or agency) or outstanding decree, order, judgment, settlement agreement or stipulation that restricts in any manner Borrower's use, transfer or licensing thereof or that could reasonably be expected to affect the validity, use or enforceability thereof. Except as described in the most recently delivered Compliance Certificate in accordance with Section 7.1(d),there is no decree, order, judgment, agreement, stipulation, arbitral award or other provision entered into in connection with any

litigation or proceeding that obligates Borrower to grant licenses or ownership interest in any future Intellectual Property related to the operation or conduct of the business of Borrower or Borrower Products. Except as described in the most recently delivered Compliance Certificate in accordance with Section 7.1(d), Borrower has not received any written notice or claim, or, to the knowledge of Borrower, oral notice or claim, challenging or questioning Borrower's ownership in any Intellectual Property material to Borrower's business (or written notice of any claim challenging or questioning the ownership in any licensed Intellectual Property material to Borrower's business of the owner thereof) or suggesting that any third party has any claim of legal or beneficial ownership with respect thereto nor, to Borrower's knowledge, is there a reasonable basis for any such claim. Neither Borrower's use of its Intellectual Property material to Borrower's business nor the production and sale of Borrower Products material to Borrower's business infringes the Intellectual Property or other rights of others.

5.12Financial Accounts. Exhibit D, as may be updated by the Borrower in a written notice provided to Agent after the Closing Date, is a true, correct and complete list of (a) all banks and other financial institutions at which Borrower or any Subsidiary maintains Deposit Accounts and (b) all institutions at which Borrower or any Subsidiary maintains an account holding Investment Property, and such exhibit correctly identifies the name, address and telephone number of each bank or other institution, the name in which the account is held, a description of the purpose of the account, and the complete account number therefor.

5.13Employee Loans. Except for Permitted Investments, Borrower has no outstanding loans to any employee, officer or director of the Borrower nor has Borrower guaranteed the payment of any loan made to an employee, officer or director of the Borrower by a third party.

5.14Capitalization and Subsidiaries. Borrower's capitalization as of the Closing Date is set forth on Schedule 5.14 annexed hereto. Borrower does not own any stock, partnership interest or other securities of any Person, except for Permitted Investments. Attached as Schedule 5.14, as may be updated by Borrower in a written notice provided after the Closing Date, is a true, correct and complete list of each Subsidiary.

SECTION 6. INSURANCE; INDEMNIFICATION

6.1Coverage. Borrower shall cause to be carried and maintained commercial general liability insurance, on an occurrence form, against risks customarily insured against in Borrower's line of business. Such risks shall include the risks of bodily injury, including death, property damage, personal injury, advertising injury, and contractual liability per the terms of the indemnification agreement found in Section 6.3. Borrower must maintain a minimum of $2,000,000 of commercial general liability insurance for each occurrence. Borrower has and agrees to maintain a minimum of $2,000,000 of directors' and officers' insurance for each occurrence and $5,000,000 in the aggregate. So long as there are any Secured Obligations (other than inchoate indemnity obligations and other obligations which are expressly stated to survive termination of this Agreement) outstanding, Borrower shall also cause to be carried and maintained insurance upon the Collateral, insuring against all risks of physical loss or damage howsoever caused, in an amount not less than the full replacement cost of the Collateral; provided that such insurance may be subject to standard exceptions and deductibles. If Borrower fails to obtain the insurance called for by this Section 6.1 or fails to pay any premium thereon or fails to pay any other amount which Borrower is obligated to pay under this Agreement or any other Loan Document or which may be required to preserve the Collateral, Agent may obtain such insurance or make such payment, and all amounts so paid by Agent are immediately due and payable, bearing interest at the then highest rate applicable to the Secured Obligations, and secured by the Collateral. Agent will make reasonable efforts to

provide Borrower with notice of Agent obtaining such insurance at the time it is obtained or within a reasonable time thereafter. No payments by Agent are deemed an agreement to make similar payments in the future or Agent's waiver of any Event of Default.

6.2Certificates. Borrower shall deliver to Agent certificates of insurance that evidence Borrower's compliance with its insurance obligations in Section 6.1 and the obligations contained in this Section 6.2. Borrower's insurance certificate shall state Agent (shown as "Hercules Capital, Inc., as Agent") is an additional insured for commercial general liability, a lenders loss payable for all risk property damage insurance, subject to the insurer's approval, and a lenders loss payable for property insurance and additional insured for liability insurance for any future insurance that Borrower may acquire from such insurer. Attached to the certificates of insurance will be additional insured endorsements for liability and lender's loss payable endorsements for all risk property damage insurance. All certificates of insurance will provide for a minimum of thirty (30) days advance written notice to Agent of cancellation (other than cancellation for non-payment of premiums, for which ten (10) days' advance written notice shall be sufficient) or any other change adverse to Agent's interests. Any failure of Agent to scrutinize such insurance certificates for compliance is not a waiver of any of Agent's rights, all of which are reserved. Borrower shall provide Agent with copies of each insurance policy, and upon entering or amending any insurance policy required hereunder, Borrower shall provide Agent with copies of such policies and shall promptly deliver to Agent updated insurance certificates with respect to such policies.

6.3Indemnity. Borrower agrees to indemnify and hold Agent, the Lenders and their officers, directors, employees, agents, in-house attorneys, representatives and shareholders (each, an "Indemnified Person") harmless from and against any and all claims, costs, expenses, damages and liabilities (including such claims, costs, expenses, damages and liabilities based on liability in tort, including strict liability in tort), including reasonable, documented, out-of-pocket attorneys' fees and disbursements and other costs of investigation or defense (including those incurred upon any appeal) (collectively, "Liabilities"), that may be instituted or asserted against or incurred by such Indemnified Person as the result of credit having been extended, suspended or terminated under this Agreement and the other Loan Documents or the administration of such credit, or in connection with or arising out of the transactions contemplated hereunder and thereunder, or any actions or failures to act in connection therewith, or arising out of the disposition or utilization of the Collateral, excluding in all cases Liabilities to the extent resulting solely from any Indemnified Person's gross negligence or willful misconduct. This Section 6.3 shall not apply with respect to Taxes other than any Taxes that represent losses, claims, damages, etc. arising from any non-Tax claim. In no event shall any Indemnified Person be liable on any theory of liability for any special, indirect, consequential or punitive damages (including any loss of profits, business or anticipated savings). This Section 6.3 shall survive the repayment of indebtedness under, and otherwise shall survive the expiration or other termination of, this Agreement.

SECTION 7. COVENANTS OF BORROWER

Borrower agrees as follows:

7.1Financial Reports. Borrower shall furnish to Agent the financial statements and reports listed hereinafter (the "Financial Statements"):

(a)as soon as practicable (and in any event within thirty (30) days unless extended by Agent in connection with quarter-end closes) after the end of each month, unaudited interim and year-to-date financial statements as of the end of such month (prepared on a consolidated and consolidating basis, if applicable), including balance sheet and related statements of income and

cash flows accompanied by a report detailing any material contingencies (including the commencement of any material litigation by or against Borrower) or any other occurrence that could reasonably be expected to have a Material Adverse Effect, all certified by Borrower's Chief Executive Officer or Chief Financial Officer to the effect that they have been prepared in accordance with GAAP, except (i) for the absence of footnotes, (ii) that they are subject to normal year-end adjustments, and (iii) they do not contain certain non-cash items that are customarily included in quarterly and annual financial statements; provided, that if (x) clause (i) of the definition of "Performance Covenant A" has been achieved at all times during such reporting month and (y) no Default or Event of Default has occurred or is occurring, then Borrower shall only be required to deliver cash balances and monthly revenue during such period under this clause (a);

(b)as soon as practicable (and in any event within forty-five (45) days) after the end of each calendar quarter, unaudited interim and year-to-date financial statements as of the end of such calendar quarter (prepared on a consolidated and consolidating basis, if applicable), including balance sheet and related statements of income and cash flows accompanied by a report detailing any material contingencies (including the commencement of any material litigation by or against Borrower) or any other occurrence that could reasonably be expected to have a Material Adverse Effect, certified by Borrower's Chief Executive Officer or Chief Financial Officer to the effect that they have been prepared in accordance with GAAP, except (i) for the absence of footnotes, and (ii) that they are subject to normal year-end adjustments;

(c)as soon as practicable (and in any event within ninety (90) days) after the end of each fiscal year, unqualified audited financial statements as of the end of such year (prepared on a consolidated and consolidating basis, if applicable), including balance sheet and related statements of income and cash flows, and setting forth in comparative form the corresponding figures for the preceding fiscal year, certified by a firm of independent certified public accountants selected by Borrower and reasonably acceptable to Agent, accompanied by any management report from such accountants;

(d) as soon as practicable (and in any event within thirty (30) days unless extended by Agent in connection with quarter-end closes) after the end of each month, a Compliance Certificate in the form of Exhibit E;

(e)as soon as practicable (and in any event within thirty (30) days unless extended by Agent in connection with quarter-end closes) after the end of each month, a report showing agings of accounts receivable and accounts payable;

(f)promptly and in any event within 5 days after the sending or filing thereof, as the case may be, copies of any proxy statements, financial statements or reports that Borrower has made generally available to holders of its Common Stock and copies of any regular, periodic and special reports or registration statements that Borrower files with the Securities and Exchange Commission or any governmental authority that may be substituted therefor, or any national securities exchange;

(g)[Reserved];

(h)financial and business projections promptly following their approval by Borrower's board of directors, and in any event, within sixty (60) days after the end of Borrower's fiscal year, as well as budgets, operating plans and other financial information reasonably requested by Agent; and

(i)prompt notice if Borrower or any Subsidiary has knowledge that Borrower, or any Subsidiary or Affiliate of Borrower, is listed on the OFAC Lists or (a) is convicted on, (b) pleads *nolo contendere* to, (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering.

Borrower shall not (without the consent of Agent, such consent not to be unreasonably withheld or delayed), make any change in its (a) accounting policies or reporting practices, except as required by GAAP or (b) fiscal years or fiscal quarters, unless Borrower shall have notified Agent in writing within thirty (30) days in advance of such change. The fiscal year of Borrower shall end on December 31.

The executed Compliance Certificate, and all Financial Statements required to be delivered pursuant to clauses (a), (b), (c) and (d) shall be sent via e-mail to financialstatements@htgc.com with a copy to legal@htgc.com and mdutra@htgc.com provided, that if e-mail is not available or sending such Financial Statements via e-mail is not possible, they shall be faxed to Agent at: (650) 473-9194, attention Account Manager: Axsome Therapeutics, Inc.

Notwithstanding the foregoing, documents required to be delivered under Sections 7.1(a), (b), (c) or (f) pursuant to the terms hereof (to the extent any such documents are included in materials otherwise filed with the SEC) may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower emails a link thereto to Agent.

7.2Management Rights. Borrower shall permit any representative that Agent or the Lenders authorizes, including its attorneys and accountants, to inspect the Collateral and examine and make copies and abstracts of the books of account and records of Borrower at reasonable times and upon reasonable notice during normal business hours; provided, however, that so long as no Event of Default has occurred and is continuing, such examinations shall be limited to no more often than twice per fiscal year. In addition, any such representative shall have the right to meet with management and officers of Borrower to discuss such books of account and records in connection with such examinations. In addition, Agent or the Lenders shall be entitled at reasonable times and intervals to consult with and advise the management and officers of Borrower concerning significant business issues affecting Borrower. Such consultations shall not unreasonably interfere with Borrower's business operations. The parties intend that the rights granted Agent and the Lenders shall constitute "management rights" within the meaning of 29 C.F.R. Section 2510.3- 101(d)(3)(ii), but that any advice, recommendations or participation by Agent or the Lenders with respect to any business issues shall not be deemed to give Agent or the Lenders, nor be deemed an exercise by Agent or the Lenders of, control over Borrower's management or policies.

7.3Further Assurances. Borrower shall from time to time following Agent's written request execute, deliver and file, alone or with Agent, any financing statements, security agreements, collateral assignments, notices, control agreements, or other documents to perfect, give the highest priority to Agent's Lien on the Collateral (subject to Permitted Liens) or otherwise evidence Agent's rights herein. Borrower shall from time to time procure any instruments or documents as may be reasonably requested by Agent, and take all further action that may be necessary, or that Agent may reasonably request, to perfect and protect the Liens granted hereby and thereby. In addition, and for such purposes only, Borrower hereby authorizes Agent to execute and deliver on behalf of Borrower and to file such financing statements (including an indication that the financing statement covers

"all assets or all personal property" of Borrower in accordance with Section 9-504 of the UCC), collateral assignments, notices, control agreements, security agreements and other documents without the signature of Borrower either in Agent's name or in the name of Agent as agent and attorney-in-fact for Borrower. Borrower shall protect and defend Borrower's title to the Collateral and Agent's Lien thereon against all Persons claiming any interest adverse to Borrower or Agent other than Permitted Liens.

7.4Indebtedness. Borrower shall not create, incur, assume, guarantee or be or remain liable with respect to any Indebtedness, or permit any Subsidiary so to do, other than Permitted Indebtedness, or prepay any Indebtedness or take any actions which impose on Borrower an obligation to prepay any Indebtedness, except for (a) the conversion of Indebtedness into equity securities and the payment of cash in lieu of fractional shares in connection with such conversion, (b) payment and prepayment of purchase money Indebtedness and capital leases pursuant to its then applicable payment schedule, (c) prepayment by any Subsidiary of (i) inter-company Indebtedness owed by such Subsidiary to any Borrower, or (ii) if such Subsidiary is not a Borrower, intercompany Indebtedness owed by such Subsidiary to another Subsidiary that is not a Borrower or (d) as otherwise permitted hereunder or approved in writing by Agent.

Notwithstanding anything to the contrary in the foregoing, the issuance of, performance of obligations under (including any payments of interest), and conversion, exchange, exercise, repurchase, redemption (including, for the avoidance of doubt, a required repurchase in connection with the redemption of Permitted Convertible Debt upon satisfaction of a condition related to the stock price of the Common Stock), settlement or early termination or cancellation of (whether in whole or in part and including by netting or set-off) (in each case, whether in cash, Common Stock, following a merger event or other change of the Common Stock, other securities or property), or the satisfaction of any condition that would permit or require any of the foregoing, any Permitted Convertible Debt shall not constitute a prepayment of Indebtedness by Borrower for the purposes of this Section 7.4; *provided* that principal payments in cash (other than cash in lieu of fractional shares) shall only be allowed if the Redemption Conditions are satisfied in respect of such payment and at all times after such payment; *provided* further that, to the extent both (a) the aggregate amount of cash payable upon conversion or payment of any Permitted Convertible Debt (excluding any required payment of interest with respect to such Permitted Convertible Debt and excluding any payment of cash in lieu of a fractional share due upon conversion thereof) exceeds the aggregate principal amount thereof and (b) such conversion or payment does not trigger or correspond to an exercise or early unwind or settlement of a corresponding portion of the Permitted Bond Hedge Transactions relating to such Permitted Convertible Debt (including, for the avoidance of doubt, the case where there is no Permitted Bond Hedge Transaction relating to such Permitted Convertible Debt), the payment of such excess cash shall not be permitted by the preceding sentence.

Notwithstanding the foregoing, Borrower may repurchase, exchange or induce the conversion of Permitted Convertible Debt by delivery of shares of Common Stock and/or a different series of Permitted Convertible Debt and/or by payment of cash (in an amount that does not exceed the proceeds received by Borrower from the substantially concurrent issuance of Common Stock and/or Permitted Convertible Debt plus the net cash proceeds, if any, received by Borrower pursuant to the related exercise or early unwind or termination of the related Permitted Bond Hedge Transactions and Permitted Warrant Transactions, if any, pursuant to the immediately following proviso); provided that, substantially concurrently with, or a commercially reasonable period of time before or after, the related settlement date for the Permitted Convertible Debt that is so repurchased, exchanged or converted, Borrower shall exercise or unwind or terminate early (whether in cash, shares or any combination thereof) the portion of the Permitted Bond Hedge Transactions and Permitted Warrant Transactions, if any, corresponding to such Permitted Convertible Debt that are so repurchased, exchanged or converted.

7.5Collateral. Borrower shall at all times keep the Collateral and all other property and assets used in Borrower's business or in which Borrower now or hereafter holds any interest free and clear from any legal process or Liens whatsoever (except for Permitted Liens), and shall give Agent prompt written notice of any legal process affecting the Collateral, such other property and assets, or any Liens thereon, provided however, that the Collateral and such other property and assets may be subject to Permitted Liens. Borrower shall not enter into or suffer to exist or become effective any agreement that prohibits or limits the ability of any Borrower to create, incur, assume or suffer to exist any Lien upon any of its property (including Intellectual Property), whether now owned or hereafter acquired, to secure its obligations under the Loan Documents to which it is a party other than (a) this Agreement and the other Loan Documents, (b) any agreements governing any purchase money Liens or capital lease obligations otherwise permitted hereby (in which case, any prohibition or limitation shall only be effective against the assets financed thereby) and (c) customary restrictions on the assignment of leases, licenses and other agreements. Borrower shall cause its Subsidiaries to protect and defend such Subsidiary's title to its assets from and against all Persons claiming any interest adverse to such Subsidiary, and Borrower shall cause its Subsidiaries at all times to keep such Subsidiary's property and assets free and clear from any legal process or Liens whatsoever (except for Permitted Liens), and shall give Agent prompt written notice of any legal process affecting such Subsidiary's assets.

7.6Investments. Borrower shall not directly or indirectly acquire or own, or make any Investment in or to any Person, or permit any of its Subsidiaries to do so, other than Permitted Investments.

Notwithstanding the foregoing, and for the avoidance of doubt, this Section 7.6 shall not prohibit the conversion by holders of (including any payment upon conversion, whether in cash, Common Stock or a combination thereof), or required payment of any principal or premium on (including, for the avoidance of doubt, in respect of a required repurchase in connection with the redemption of Permitted Convertible Debt upon satisfaction of a condition related to the stock price of the Common Stock) or required payment of any interest with respect to, any Permitted Convertible Debt in each case, in accordance with the terms of the indenture governing such Permitted Convertible Debt; provided that principal payments in cash (other than cash in lieu of fractional shares) shall only be allowed if the Redemption Conditions are satisfied in respect of such payment and at all times after such payment; provided further that, to the extent both (a) the aggregate amount of cash payable upon conversion or payment of any Permitted Convertible Debt (excluding any required payment of interest with respect to such Permitted Convertible Debt and excluding any payment of cash in lieu of a fractional share due upon conversion thereof) exceeds the aggregate principal amount thereof and (b) such conversion or payment does not trigger or correspond to an exercise or early unwind or settlement of a corresponding portion of the Permitted Bond Hedge Transactions relating to such Permitted Convertible Debt (including, for the avoidance of doubt, the case where there is no Permitted Bond Hedge Transaction relating to such Permitted Convertible Debt), the payment of such excess cash shall not be permitted by the preceding sentence.

Notwithstanding the foregoing, Borrower may repurchase, exchange or induce the conversion of Permitted Convertible Debt by delivery of Common Stock and/or a different series of Permitted Convertible Debt and/or by payment of cash (in an amount that does not exceed the proceeds received by Borrower from the substantially concurrent issuance of Common Stock and/or Permitted Convertible Debt plus the net cash proceeds, if any, received by Borrower pursuant to the related exercise or early unwind or termination of the related Permitted Bond Hedge Transactions and Permitted Warrant Transactions, if any, pursuant to the immediately following proviso); provided that, substantially concurrently with, or a commercially reasonable period of time before or after, the related settlement date for the Permitted Convertible Debt that is so repurchased, exchanged or

converted, Borrower shall exercise or unwind or terminate early (whether in cash, shares or any combination thereof) the portion of the Permitted Bond Hedge Transactions and Permitted Warrant Transactions, if any, corresponding to such Permitted Convertible Debt that are so repurchased, exchanged or converted.

7.7Distributions. Borrower shall not, and shall not allow any Subsidiary to, (a) repurchase or redeem any class of stock or other Equity Interest other than pursuant to employee, director or consultant repurchase plans or other similar agreements that are Permitted Investments or the conversion of any of its convertible securities pursuant to the terms of such convertible securities; provided, however, in each case the repurchase or redemption price does not exceed the original consideration paid for such stock or Equity Interest unless required by the terms of such agreement or plan, or pursuant to a public repurchase of securities in compliance with the requirements of SEC Rule 10b-18, or (b) declare or pay any cash dividend or make any other cash distribution on any class of stock or other Equity Interest, except that a Subsidiary may pay dividends or make other distributions to Borrower or any Subsidiary of Borrower, (c) except for Permitted Investments, lend money to any employees, officers or directors or guarantee the payment of any such loans granted by a third party in excess of $100,000 in the aggregate or (d) waive, release or forgive any Indebtedness owed by any employees, officers or directors in excess of $100,000 in the aggregate other than cancellation of Indebtedness in connection with the repurchase of Equity Interests permitted under clause (a) above. Notwithstanding the foregoing, Borrower may redeem or repurchase stock and other Equity Interests and may declare and pay dividends and make distributions in any amount, so long as the Redemption Conditions (as applied to such redemption, repurchase, dividend or distribution) are satisfied.

Notwithstanding the foregoing, and for the avoidance of doubt, this Section 7.7 shall not prohibit the conversion by holders of (including any payment upon conversion, whether in cash, Common Stock or a combination thereof), or required payment of any principal or premium on (including, for the avoidance of doubt, in respect of a required repurchase in connection with the redemption of Permitted Convertible Debt upon satisfaction of a condition related to the stock price of the Common Stock) or required payment of any interest with respect to, any Permitted Convertible Debt in each case, in accordance with the terms of the indenture governing such Permitted Convertible Debt; provided that principal payments in cash (other than cash in lieu of fractional shares) shall only be allowed if the Redemption Conditions are satisfied in respect of such payment and at all times after such payment; provided further that, to the extent both (a) the aggregate amount of cash payable upon conversion or payment of any Permitted Convertible Debt (excluding any required payment of interest with respect to such Permitted Convertible Debt and excluding any payment of cash in lieu of a fractional share due upon conversion thereof) exceeds the aggregate principal amount thereof and (b) such conversion or payment does not trigger or correspond to an exercise or early unwind or settlement of a corresponding portion of the Permitted Bond Hedge Transactions relating to such Permitted Convertible Debt (including, for the avoidance of doubt, the case where there is no Permitted Bond Hedge Transaction relating to such Permitted Convertible Debt), the payment of such excess cash shall not be permitted by the preceding sentence.

Notwithstanding the foregoing, Borrower may repurchase, exchange or induce the conversion of Permitted Convertible Debt by delivery of Common Stock and/or a different series of Permitted Convertible Debt and/or by payment of cash (in an amount that does not exceed the proceeds received by Borrower from the substantially concurrent issuance of Common Stock and/or Permitted Convertible Debt plus the net cash proceeds, if any, received by Borrower pursuant to the related exercise or early unwind or termination of the related Permitted Bond Hedge Transactions and Permitted Warrant Transactions, if any, pursuant to the immediately following proviso); provided that, substantially concurrently with, or a commercially reasonable period of time before or after,

the related settlement date for the Permitted Convertible Debt that is so repurchased, exchanged or converted, Borrower shall exercise or unwind or terminate early (whether in cash, shares or any combination thereof) the portion of the Permitted Bond Hedge Transactions and Permitted Warrant Transactions, if any, corresponding to such Permitted Convertible Debt that are so repurchased, exchanged or converted.

Notwithstanding anything to the contrary set forth in this Section 7, and for the avoidance of doubt:

(i) Borrower may make any required payment of premium to a counterparty thereunder due in connection with entering into any Permitted Bond Hedge Transaction;

(ii) Borrower may make any payment in connection with any Permitted Warrant Transaction by (i) delivery of shares of the Borrower's Common Stock (together with cash in lieu of fractional shares) upon net share settlement thereof, (ii) set-off, netting and/or payment of an early termination payment or other payment thereunder, in each case, in the Borrower's Common Stock and (iii) solely to the extent the Borrower does not have the option of satisfying such payment obligations through the delivery of shares of the Borrower's Common Stock or is otherwise required to satisfy such payment obligations in cash, set-off, netting and/or payment of an early termination payment or other payment thereunder, in each case, in cash (it being understood and agreed that any payment made in cash in connection with Permitted Warrant Transactions by set-off, netting and/or payment of an early termination payment or similar payment thereunder, in each case, after using commercially reasonable efforts to satisfy such obligation (or the portion thereof remaining after giving effect to any netting or set-off against termination or similar payments under an applicable Permitted Bond Hedge Transaction) by delivery of shares of the Borrower's Common Stock shall be deemed to be a payment obligation required to be satisfied in cash); and

(iii)Borrower may acquire shares or other Equity Interests or cash or a combination thereof under the terms of any Permitted Bond Hedge Transaction or Permitted Warrant Transaction.

7.8Transfers. Except for Permitted Transfers, Borrower shall not, and shall not allow any Subsidiary to, voluntarily or involuntarily transfer, sell, lease, license, lend or in any other manner convey any equitable, beneficial or legal interest in any material portion of its assets; provided that with respect to any Auvelity Licensing or Sunosi Licensing, as applicable, upon the Borrower's reasonable request, Agent shall use commercially reasonable efforts to execute a non-disturbance agreement (a "Non-Disturbance Agreement"), among the Agent (on behalf of itself and the Lenders), Borrower, and any counterparty to the Auvelity Licensing or Sunosi Licensing, as applicable, in a form and substance satisfactory to Agent, which shall provide, among other things, (a) an acknowledgement by Agent that Borrower and/or its Subsidiaries has out-licensed Intellectual Property pursuant to the Auvelity Licensing or Sunosi Licensing, as applicable (such licensed Intellectual Property, the "Licensed Intellectual Property"), (b) notwithstanding anything to the contrary in this Agreement or any other Loan Document, the Agent nor any Lender shall exercise any rights or remedies it has with respect to the Licensed Intellectual Property (including, but not limited to, the ability terminate the Auvelity Licensing or Sunosi Licensing, as applicable, or foreclose on the Licensed Intellectual Property) unless a default has occurred and is continuing under the agreement evidencing the Auvelity Licensing or Sunosi Licensing, as applicable, which would permit the Borrower to terminate such agreement and (c) an acknowledgement by Borrower and the applicable counterparty to the Auvelity Licensing or Sunosi Licensing that the proceeds of any Auvelity Licensing or Sunosi Licensing, as applicable, constitute and remain Collateral, notwithstanding the execution of the Non-Disturbance Agreement.

7.9Mergers and Consolidations. Except for Permitted Acquisitions, Borrower shall not merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with or into any other business organization (other than mergers or consolidations of (a) a Subsidiary which is not a Borrower into another Subsidiary or into Borrower or (b) a Borrower into another Borrower).

7.10Taxes. Borrower shall, and shall cause each of its Subsidiaries to, pay when due all material Taxes of any nature whatsoever now or hereafter imposed or assessed against Borrower or the Collateral or upon Borrower's ownership, possession, use, operation or disposition thereof or upon Borrower's rents, receipts or earnings arising therefrom. Borrower shall, and shall cause each of its Subsidiaries to, accurately file on or before the due date therefor (taking into account proper extensions) all federal and state income Tax returns and other material Tax returns required to be filed. Notwithstanding the foregoing, Borrower and its Subsidiaries may contest, in good faith and by appropriate proceedings diligently conducted, Taxes for which Borrower and its Subsidiaries maintain adequate reserves in accordance with GAAP.

7.11Corporate Changes. Neither Borrower nor any Subsidiary shall change its corporate name, legal form or jurisdiction of formation without twenty (20) days' prior written notice to Agent. Neither Borrower nor any Subsidiary shall suffer a Change in Control. Neither Borrower nor any Subsidiary shall relocate its chief executive office or its principal place of business unless: (i) it has provided prior written notice to Agent; and (ii) such relocation shall be within the continental United States of America. Neither Borrower nor any Subsidiary shall relocate any item of Collateral (other than (u) sales of Inventory in the ordinary course of business and Permitted Transfers, (v) relocations of Equipment and other property having an aggregate value of up to $250,000 in any fiscal year, (w) relocations of Collateral from a location described on Exhibit B to another location described on Exhibit B, (x) locations of mobile equipment, including phones, tablets and computers with employees and consultants in the ordinary course of business, (y) locations where Collateral may be temporarily located for sales, testing or demonstration purposes in the ordinary course of business, (z) locations where biopharmaceutical compounds and therapeutic materials are located in the ordinary course of business in connection with clinical trials and development arrangements) unless (i) it has provided prompt written notice to Agent, (ii) such relocation is within the continental United States of America and, (iii) if such relocation is to a third party bailee, it has delivered a bailee agreement in form and substance reasonably acceptable to Agent.

7.12Deposit Accounts. Neither Borrower nor any Subsidiary (other than Excluded Subsidiaries) shall maintain any Deposit Accounts, or accounts holding Investment Property, except with respect to which Agent has an Account Control Agreement; provided that no Account Control Agreement shall be required for Excluded Accounts. No Excluded Subsidiary shall maintain any Deposit Accounts, or accounts holding Investment Property holding more than Five Hundred Thousand Dollars ($500,000) in the aggregate for all such Accounts of all Excluded Subsidiaries at any time.

7.13Borrower shall notify Agent of each Subsidiary formed or acquired subsequent to the Closing Date and, at within 20 days such formation or acquisition (including, without limitation, pursuant to a division), as applicable, unless otherwise approved in writing by Agent in its sole discretion, shall cause any such Subsidiary (other than Excluded Subsidiaries) to execute and deliver to Agent a Joinder Agreement. If at any time, the Excluded Subsidiary Condition is not satisfied, Borrower shall promptly cause one or more Subsidiaries to execute and deliver to Agent a Joinder Agreement such that, after giving effect to such Joinder Agreement, the Excluded Subsidiary Conditions is satisfied.

7.14Excluded Subsidiaries. Borrower shall not permit the Excluded Subsidiaries to: (a) have outstanding liabilities in excess of $750,000 in the aggregate at any time, or (b) own any Intellectual Property material to the business of Borrower or Borrower and its Subsidiaries, taken as a whole.

7.15Notification of Event of Default. Borrower shall notify Agent immediately of the occurrence of any Event of Default.

7.16Regulatory and Product Notices. The Borrower shall promptly (but in any event within three (3) days) after the receipt or occurrence thereof notify Agent of:

(i) any written notice received by Borrower or its Subsidiaries alleging potential or actual violations of any Public Health Law by Borrower or its Subsidiaries,

(ii) any written notice that the FDA (or international equivalent) is limiting, suspending or revoking any Registration (including, but not limited to, by the issuance of a clinical hold),

(iii)any written notice that Borrower or its Subsidiaries has become subject to any Regulatory Action,

(iv)the exclusion or debarment from any governmental healthcare program or debarment or disqualification by FDA (or international equivalent) of Borrower or its Subsidiaries or its or their authorized officers,

(v) any notice that a Borrower or any Subsidiary, or any of their licensees or sublicensees (including licensees or sublicensees under any Material Agreement), is being investigated or is the subject of any allegation of potential or actual violations of any Federal Health Care Program Laws,

(vi)any written notice that any product of Borrower or its Subsidiaries has been seized, withdrawn, recalled, detained, or subject to a suspension of manufacturing, or the commencement of any proceedings in the United States or any other jurisdiction seeking the withdrawal, recall, suspension, import detention, or seizure of any Borrower Product are pending or threatened in writing against Borrower or its Subsidiaries,

(vii)changing the scope of marketing authorization or the labeling of the products of Borrower and its Subsidiaries under any such Registration, or

(viii)considering or implementing any other such regulatory action,

except, in each case of (i) through (viii) above, where such action would not reasonably be expected to have, either individually or in the aggregate, Material Regulatory Liabilities.

7.17Use of Proceeds. Borrower agrees that the proceeds of the Loans shall be used solely to refinance existing indebtedness, to pay related fees and expenses in connection with this Agreement and for working capital and general corporate purposes. The proceeds of the Loans will not be used in violation of Anti-Corruption Laws or applicable Sanctions.

7.18Material Agreement. The Borrower shall not, without the consent of the Agent, materially amend or terminate the Antecip License Agreement. The Borrower shall give prompt written notice to the Agent of entering into a Material Agreement or materially amending or terminating a Material Agreement.

7.19Compliance with Laws.

Borrower shall maintain, and shall cause its Subsidiaries to maintain, compliance in all material respects with all applicable laws, rules or regulations (including any law, rule or regulation with respect to the making or brokering of loans or financial accommodations), and shall, or cause its Subsidiaries to, obtain and maintain all required governmental authorizations, approvals, licenses, franchises, permits or registrations reasonably necessary in connection with the conduct of Borrower's business except where a failure to do so could not reasonably be expected to have a Material Adverse Effect.

Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries permit any Affiliate controlled by Borrower to, directly or indirectly, knowingly enter into any documents, instruments, agreements or contracts with any Person listed on the OFAC Lists. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries, permit any Affiliate controlled by Borrower to, directly or indirectly, (i) conduct any business or engage in any transaction or dealing with any Blocked Person, including, without limitation, the making or receiving of any contribution of funds, goods or services to or for the benefit of any Blocked Person, (ii) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to Executive Order No. 13224 or any similar executive order or other Anti-Terrorism Law, or (iii) engage in or conspire to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in Executive Order No. 13224 or other Anti-Terrorism Law.

Borrower has implemented and maintains in effect policies and procedures designed to ensure compliance by the Borrower, its Subsidiaries and their respective directors, officers, employees and agents with Anti-Corruption Laws and applicable Sanctions, and Borrower, its Subsidiaries and their respective officers and employees and to the knowledge of Borrower its directors and agents, are in compliance with Anti-Corruption Laws and applicable Sanctions in all material respects.

None of Borrower, any of its Subsidiaries or any of their respective directors, officers or employees, or to the knowledge of Borrower, any agent for Borrower or its Subsidiaries that will act in any capacity in connection with or benefit from the credit facility established hereby, is a Sanctioned Person. No Loan, use of proceeds or other transaction contemplated by this Agreement will violate Anti-Corruption Laws or applicable Sanctions.

7.20Financial Covenants.

(a) Minimum Cash.

(i) Upon the Third Amendment Closing Date, Borrower shall thereafter maintain Qualified Cash in an amount greater than or equal to the sum of Thirty Million Dollars ($30,000,000) *plus* the Qualified Cash A/P Amount at all times.

(ii) If Borrower makes any payment in respect to the last sentence of the first paragraph of Section 7.7 or makes any other cash payment in respect of Permitted Convertible Debt, subject to satisfaction of the Redemption Conditions, Borrower shall, at all times thereafter, maintain Qualified Cash in the amount required by the defined term "Redemption Conditions".

(b) Performance Covenant. Beginning with the reporting period ending June 30, 2023, and all times thereafter, Borrower shall satisfy either of (i) Performance Covenant A or Performance Covenant B, tested at all times, or (ii) Performance Covenant C, tested quarterly.

7.21Intellectual Property. Each Borrower shall (i) protect, defend and maintain the validity and enforceability of its Intellectual Property that is material to the conduct of Borrower's business; (ii) promptly advise Agent in writing of material infringements of its Intellectual Property; and (iii) not allow any Intellectual Property material to Borrowers' business to be abandoned, forfeited or dedicated to the public without Agent's written consent. If a Borrower (a) obtains any Patent, registered Trademark, registered Copyright, registered mask work, or any pending application for any of the foregoing, whether as owner, licensee or otherwise, or (b) applies for any Patent or the registration of any Trademark, then such Borrower shall concurrently with the delivery of the next Compliance Certificate required under Section 7.1(d), provide written notice thereof to Agent and shall execute such intellectual property security agreements and other documents and take such other actions as Agent may request in its good faith business judgment to perfect and maintain a first priority perfected security interest in favor of Agent in such property. If a Borrower decides to register any Copyrights or mask works in the United States Copyright Office, such Borrower shall: (x) provide Agent with at least fifteen (15) days prior written notice of such Borrower's intent to register such Copyrights or mask works together with a copy of the application it intends to file with the United States Copyright Office (excluding exhibits thereto); (y) execute an intellectual property security agreement and such other documents and take such other actions as Agent may request in its good faith business judgment to perfect and maintain a first priority perfected security interest in favor of Agent in the Copyrights or mask works intended to be registered with the United States Copyright Office; and (z) record such intellectual property security agreement with the United States Copyright Office contemporaneously with filing the Copyright or mask work application(s) with the United States Copyright Office. Except as set forth in the most recently delivered Compliance Certificate in accordance with Section 7.1(d), provide to Agent (x) copies of all applications that it files for Patents or for the registration of Trademarks, Copyrights or mask works, or (y) evidence that it has acquired any registered Trademarks, in each case, together with evidence of the recording of the intellectual property security agreement required for Agent to perfect and maintain a first priority perfected security interest in such property. Borrower shall, together with the delivery of the next Compliance Certificate referred to in Section 7.01(d), provide written notice to Agent of entering into or becoming bound by any Restricted License (other than over-the-counter software that is commercially available to the public). Borrower shall use its commercially reasonable efforts take such steps as Agent reasonably requests to obtain the consent of, or waiver by, any person whose consent or waiver is necessary for (1) any Restricted License to be deemed "Collateral" and for Agent to have a security interest in it that might otherwise be restricted or prohibited by law or by the terms of any such Restricted License, whether now existing or entered into in the future, and (2) Agent to have the ability in the event of a liquidation of any Collateral to dispose of such Collateral in accordance with Agent's rights and remedies under this Agreement and the other Loan Documents.

7.22Transactions with Affiliates. Borrower shall not and shall not permit any Subsidiary to, directly or indirectly, enter into or permit to exist any transaction of any kind with any Affiliate of Borrower or such Subsidiary except for (a) transactions on terms that are not less favorable to Borrower or such Subsidiary, as the case may be, than those that might be obtained in an arm's length transaction from a Person who is not an Affiliate of Borrower or such Subsidiary, (b) transactions between or among the Borrowers not involving any other Affiliate, (c) any Permitted Investment, (d) any Permitted Indebtedness, (e) any Distributions permitted by Section 7.7, (f) any Permitted Transfers, (g) to the extend approved by the Borrower's board of directors, the payment of reasonable fees to directors of Borrower who are not employees of Borrower or any Subsidiary,

and compensation and employee benefit arrangements paid to, and indemnities provided for the benefit of, directors, officers or employees of Borrower or its Subsidiaries in the ordinary course of business, and (h) any contribution to the capital of Borrower or any purchase of Equity Interests of Borrower, in each case solely to the extent such transaction does not cause a Change in Control to occur.

7.23Malta Subsidiary. The Malta Subsidiary shall not hold Cash outside of the United States in excess of $3,000,000 in the aggregate at any time outstanding.

SECTION 8. RIGHT TO INVEST

8.1Borrower shall provide (or in the case of a Subsequent Financing that is a registered offering, the Borrower shall use its commercially reasonable efforts to provide) the Lenders or their permitted assignees or nominees, designated as such in writing to Borrower, the opportunity, in their discretion, to participate in each Subsequent Financing in an amount of up to Five Million Dollars ($5,000,000), in the aggregate for all Lenders and their permitted assignees or nominees, in such Subsequent Financing on substantially the same terms, conditions and pricing afforded to other investors participating in such Subsequent Financing. If the Lenders (or their permitted assignees or nominees) elect to participate in any Subsequent Financing, the Lenders (or their permitted assignees or nominees, as applicable) participating in such Subsequent Financing agree to become a party to the agreements executed by the other investors participating in such Subsequent Financing, including with respect to obligations of confidentiality or as may otherwise be required by the Securities Act of 1933, as amended, and the rules and regulations promulgated by the Securities and Exchange Commission thereunder. Borrower, or an investment bank or underwriter engaged on Borrower's behalf, shall provide the Lenders or their permitted assignees or nominees at least three (3) Business Days' written notice of any planned Subsequent Financing and the opportunity to exercise the right to invest under this Section 8.1 with respect to any such Subsequent Financing. This Section 8.1, and all rights and obligations hereunder, shall terminate upon the earliest to occur of (a) termination of this Agreement or (b) such time that the Lenders or their permitted assignees or nominees have purchased $5,000,000 of Borrower's Equity Interests in the aggregate in Subsequent Financings.

8.2In addition to the foregoing provision, upon the Second Amendment Closing Date, the Lenders have agreed to purchase between $5,000,000 and $8,000,000 of unregistered Common Stock of the Borrower at a share price equal to the lesser of (a) the three-day volume weighted average price as of the Second Amendment Signing Date or (b) the three-day volume weighted average price as of the Second Amendment Closing Date; provided that in no case shall the share price be less than a 20% discount to the three-day volume weighted average price of Borrower's Common Stock at the time of the purchase. Prior to the Second Amendment Closing Date, the parties will execute a mutually agreed upon stock purchase agreement with customary terms and provisions. For the avoidance of doubt, this investment will not count towards Lender's existing $5,000,000 Right to Invest provided above.

SECTION 9. EVENTS OF DEFAULT

The occurrence of any one or more of the following events shall be an Event of Default:

9.1Payments. Borrower fails to pay any amount due under this Agreement or any of the other Loan Documents (other than the Warrant) on the due date; provided, however, that an Event of Default shall not occur on account of a failure to pay due solely to an administrative or operational error of Agent or the Lenders or Borrower's bank if Borrower had the funds to make the payment when due and makes the payment within three (3) Business Days following Borrower's knowledge of such failure to pay; or

9.2Covenants. Borrower breaches or defaults in the performance of any covenant or Secured Obligation under this Agreement, or any of the other Loan Documents or any other agreement among Borrower, Agent and the Lenders, and (a) with respect to a default under any covenant under this Agreement (other than under Sections 4.4 , 6, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9, 7.15, 7.17, 7.18, 7.19, 7.20. 7.21, 7.22 and 7.23), any other Loan Document, or any other agreement among Borrower, Agent and the Lenders, such default continues for more than ten (10) days after the earlier of the date on which (i) Agent or the Lenders has given notice of such default to Borrower and (ii) Borrower has actual knowledge of such default or (b) with respect to a default under any of Sections 4.4, 6, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9, 7.15, 7.17, 7.18, 7.19, 7.20. 7.21, 7.22 and 7.23, the occurrence of such default; or

9.3Material Adverse Effect. A circumstance has occurred that could reasonably be expected to have a Material Adverse Effect; provided that, solely for purposes of this Section 9.3, the occurrence of any of the following, in and of itself, shall not constitute a Material Adverse Effect: (a) [reserved], (b) [reserved], or (c) adverse results or delays in any nonclinical or clinical trial, (d) the denial, delay or limitation of approval of the FDA with respect to any drug.

9.4Representations. Any representation or warranty made by Borrower in any Loan Document or in the Warrant shall have been false or misleading in any material respect when made or when deemed made; or

9.5Insolvency. Borrower (A) (i) shall make an assignment for the benefit of creditors; or (ii) shall be unable to pay its debts as they become due, or be unable to pay or perform under the Loan Documents, or shall become insolvent; or (iii) shall file a voluntary petition in bankruptcy; or (iv) shall file any petition, answer, or document seeking for itself any reorganization, arrangement, composition, readjustment, liquidation, dissolution or similar relief under any present or future statute, law or regulation pertinent to such circumstances; or (v) shall seek or consent to or acquiesce in the appointment of any trustee, receiver, or liquidator of Borrower or of all or any substantial part (i.e., 33-1/3% or more) of the assets or property of Borrower; or (vi) shall cease its operations of its business as its business has normally been conducted, or terminate substantially all of its employees; or (vii) Borrower or its directors or majority stockholders shall take any action initiating any of the foregoing actions described in clauses (i) through (vi); or (B) either (i) forty-five (45) days shall have expired after the commencement of an involuntary action against Borrower seeking reorganization, arrangement, composition, readjustment, liquidation, dissolution or similar relief under any present or future statute, law or regulation, without such action being dismissed or all orders or proceedings thereunder affecting the operations or the business of Borrower being stayed; or (ii) a stay of any such order or proceedings shall thereafter be set aside and the action setting it aside shall not be timely appealed; or (iii) Borrower shall file any answer admitting or not contesting the material allegations of a petition filed against Borrower in any such proceedings; or (iv) the court in which such proceedings are pending shall enter a decree or order granting the relief sought in any such proceedings; or (v) forty-five (45) days shall have expired after the appointment, without the consent or acquiescence of Borrower, of any trustee, receiver or liquidator of Borrower or of all or any substantial part of the properties of Borrower without such appointment being vacated; or

9.6Attachments; Judgments. Any portion of Borrower’s assets is attached or seized, or a levy is filed against any such assets, or a judgment or judgments is/are entered for the payment of money (not covered by independent third party insurance as to which liability has not been rejected by such insurance carrier), individually or in the aggregate, of at least $500,000, or Borrower is enjoined or in any way prevented by court order from conducting any part of its business as its business has normally been conducted and such attachment, seizure, levy, judgment or injunction is not, within fifteen (15) days after the occurrence thereof, satisfied, discharged, paid or stayed (whether through the posting of a bond or otherwise); or

9.7Other Obligations.

(a)The occurrence of any default in the payment of any Indebtedness under any agreement or obligation of Borrower involving Indebtedness in excess of $1,000,000, beyond the period of grace if any, provided in the instrument or agreement under which such Indebtedness was created; or

(b)There is, under any agreement to which Borrower is a party with a third party or parties, any default resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount individually or in the aggregate in excess of One Million Dollars ($1,000,000); or

(c)The occurrence of any early payment is required or unwinding or termination occurs with respect to any Permitted Bond Hedge Transaction or Permitted Warrant Transaction, or any condition giving rise to the foregoing is met, in each case, with respect to which Borrower or its Affiliate is the "affected party" or "defaulting party" under the terms of such Permitted Bond Hedge Transaction or Permitted Warrant Transaction, if a Material Adverse Effect could reasonably be expected to result from such default, early payment, unwinding or termination; or

(d)The occurrence of any default under, (i) subject to the Antecip Direct Agreement, the Antecip License Agreement that permits the counterparty thereto to terminate such agreement or (ii) any other Material Agreement that permits the counterparty thereto to terminate such Material Agreement or accelerate payments in excess of $5,000,000 owed thereunder.

9.8Stop Trade. At any time, an SEC stop trade order or NASDAQ market trading suspension of the Common Stock shall be in effect for five (5) consecutive days or five (5) days during a period of ten (10) consecutive days, excluding in all cases a suspension of all trading on a public market; provided that Borrower shall not have been able to cure such trading suspension within thirty (30) days of the notice thereof or list the Common Stock on another public market within sixty (60) days of such notice.

SECTION 10. REMEDIES

10.1General. Upon the occurrence and during the continuation of any one or more Events of Default, Agent may, and at the direction of the Required Lenders shall, accelerate and demand payment of all or any part of the Secured Obligations together with a Prepayment Charge and declare them to be immediately due and payable (provided, that upon the occurrence of an Event of Default of the type described in Section 9.5, all of the Secured Obligations (including, without limitation, the Prepayment Charge and the End of Term Charge) shall automatically be accelerated and made due and payable, in each case without any further notice or act). Borrower hereby irrevocably appoints Agent as its lawful attorney-in-fact to: (a) exercisable following the occurrence and during the continuation of an Event of Default, (i) sign Borrower's name on any invoice or bill of lading for any account or drafts against account debtors; (ii) demand, collect, sue, and give releases to any account debtor for monies due, settle and adjust disputes and claims about the accounts directly with account debtors, and compromise, prosecute, or defend any action, claim, case, or proceeding about any Collateral (including filing a claim or voting a claim in any bankruptcy case in Agent's or Borrower's name, as Agent may elect); (iii) make, settle, and adjust all claims under Borrower's insurance policies; (iv) pay, contest or settle any Lien, charge, encumbrance, security interest, or other claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; (v) transfer the Collateral into the name of Agent or a third party as the UCC permits; and (vi) receive, open and dispose of mail addressed to Borrower; and (b)

regardless of whether an Event of Default has occurred, (i) endorse Borrower's name on any checks, payment instruments, or other forms of payment or security; and (ii) notify all account debtors to pay Agent directly. Borrower hereby appoints Agent as its lawful attorney-in-fact to sign Borrower's name on any documents necessary to perfect or continue the perfection of Agent's security interest in the Collateral regardless of whether an Event of Default has occurred until all Secured Obligations (other than any inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been satisfied in full and the Loan Documents (other than the Warrant) have been terminated. Agent's foregoing appointment as Borrower's attorney in fact, and all of Agent's rights and powers, coupled with an interest, are irrevocable until all Secured Obligations (other than any inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been fully repaid and performed and the Loan Documents (other than the Warrant) have been terminated. Agent may, and at the direction of the Required Lenders shall, exercise all rights and remedies with respect to the Collateral under the Loan Documents or otherwise available to it under the UCC and other applicable law, including the right to release, hold, sell, lease, liquidate, collect, realize upon, or otherwise dispose of all or any part of the Collateral and the right to occupy, utilize, process and commingle the Collateral. All Agent's rights and remedies shall be cumulative and not exclusive.

10.2Collection; Foreclosure. Upon the occurrence and during the continuance of any Event of Default, Agent may, and at the direction of the Required Lenders shall, at any time or from time to time, apply, collect, liquidate, sell in one or more sales, lease or otherwise dispose of, any or all of the Collateral, in its then condition or following any commercially reasonable preparation or processing, in such order as Agent may elect. Any such sale may be made either at public or private sale at its place of business or elsewhere. Borrower agrees that any such public or private sale may occur upon ten (10) calendar days' prior written notice to Borrower. Agent may require Borrower to assemble the Collateral and make it available to Agent at a place designated by Agent that is reasonably convenient to Agent and Borrower. The proceeds of any sale, disposition or other realization upon all or any part of the Collateral shall be applied by Agent in the following order of priorities:

First, to Agent and the Lenders in an amount sufficient to pay in full Agent's and the Lenders' reasonable costs and professionals' and advisors' fees and expenses as described in Section 11.12;

Second, to the Lenders in an amount equal to the then unpaid amount of the Secured Obligations (including principal, interest, and the Default Interest pursuant to Section 2.4), in such order and priority as Agent may choose in its sole discretion; and

Finally, after the full and final payment in Cash of all of the Secured Obligations (other than inchoate obligations), to any creditor holding a junior Lien on the Collateral, or to Borrower or its representatives or as a court of competent jurisdiction may direct.

Agent shall be deemed to have acted reasonably in the custody, preservation and disposition of any of the Collateral if it complies with the obligations of a secured party under the UCC.

10.3No Waiver. Agent shall be under no obligation to marshal any of the Collateral for the benefit of Borrower or any other Person, and Borrower expressly waives all rights, if any, to require Agent to marshal any Collateral.

10.4Cumulative Remedies. The rights, powers and remedies of Agent hereunder shall be in addition to all rights, powers and remedies given by statute or rule of law and are cumulative. The exercise of any one or more of the rights, powers and remedies provided herein shall not be construed as a waiver of or election of remedies with respect to any other rights, powers and remedies of Agent.

SECTION 11. MISCELLANEOUS

11.1Severability. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement shall be prohibited by or invalid under such law, such provision shall be ineffective only to the extent and duration of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Agreement.

11.2Notice. Except as otherwise provided herein, any notice, demand, request, consent, approval, declaration, service of process or other communication (including the delivery of Financial Statements) that is required, contemplated, or permitted under the Loan Documents or with respect to the subject matter hereof shall be in writing, and shall be deemed to have been validly served, given, delivered, and received upon the earlier of: (i) the day of transmission by electronic mail or hand delivery or delivery by an overnight express service or overnight mail delivery service; or (ii) the third calendar day after deposit in the United States of America mails, with proper first class postage prepaid, in each case addressed to the party to be notified as follows:

(a) If to Agent:
HERCULES CAPITAL, INC.
Legal Department
Attention: Chief Legal Officer and Michael Dutra
400 Hamilton Avenue, Suite 310
Palo Alto, CA 94301
email: legal@htgc.com and mdutra@htgc.com
Telephone: 650-289-3060

(b) If to the Lenders:
HERCULES CAPITAL, INC.
Legal Department
Attention: Chief Legal Officer and Michael Dutra
400 Hamilton Avenue, Suite 310
Palo Alto, CA 94301
email: legal@htgc.com and mdutra@htgc.com
Telephone: 650-289-3060

(c) If to Borrower:
22 Cortlandt Street, 16th Floor
New York, NY, 10007
Attention: Nick Pizzie, Chief Financial Officer
email: npizzie@axsome.com
Telephone: +1-646-844-6270

or to such other address as each party may designate for itself by like notice.

11.3Entire Agreement; Amendments.

(a)This Agreement and the other Loan Documents constitute the entire agreement and understanding of the parties hereto in respect of the subject matter hereof and thereof, and supersede and replace in their entirety any prior proposals, term sheets, non-disclosure or confidentiality agreements, letters, negotiations or other documents or agreements, whether written or oral, with respect to the subject matter hereof or thereof (including Agent's revised proposal letter dated September 2, 2020 and the Non-Disclosure Agreement).

(b)Neither this Agreement, any other Loan Document (other than the Warrant which is subject to the amendment provisions therein), nor any terms hereof or thereof may be amended, supplemented or modified except in accordance with the provisions of this Section 11.3(b). The Required Lenders and Borrower party to the relevant Loan Document may, or, with the written consent of the Required Lenders, the Agent and the Borrower party to the relevant Loan Document may, from time to time, (i) enter into written amendments, supplements or modifications hereto and to the other Loan Documents for the purpose of adding any provisions to this Agreement or the other Loan Documents or changing in any manner the rights of the Lenders or of the Borrower hereunder or thereunder or (ii) waive, on such terms and conditions as the Required Lenders or the Agent, as the case may be, may specify in such instrument, any of the requirements of this Agreement or the other Loan Documents or any default or Event of Default and its consequences; provided, however, that no such waiver and no such amendment, supplement or modification shall (A) forgive the principal amount or extend the final scheduled date of maturity of any Loan, extend the scheduled date of any amortization payment in respect of any Term Loan, reduce the stated rate of any interest (or fee payable hereunder) or extend the scheduled date of any payment thereof, in each case without the written consent of each Lender directly affected thereby; (B) eliminate or reduce the voting rights of any Lender under this Section 11.3(b) without the written consent of such Lender; (C) reduce any percentage specified in the definition of Required Lenders, consent to the assignment or transfer by the Borrower of any of its rights and obligations under this Agreement and the other Loan Documents, release all or substantially all of the Collateral or release a Borrower from its obligations under the Loan Documents, in each case without the written consent of all Lenders; or (D) amend, modify or waive any provision of Section 11.18 or Addendum 3 without the written consent of the Agent. Any such waiver and any such amendment, supplement or modification shall apply equally to each Lender and shall be binding upon Borrower, the Lender, the Agent and all future holders of the Loans. Notwithstanding the foregoing, the Warrant may be amended in accordance with its terms, and this Section 11.3(b) shall not apply to such amendments.

11.4No Strict Construction. The parties hereto have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the parties hereto and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any provisions of this Agreement.

11.5No Waiver. The powers conferred upon Agent and the Lenders by this Agreement are solely to protect its rights hereunder and under the other Loan Documents and its interest in the Collateral and shall not impose any duty upon Agent or the Lenders to exercise any such powers. No omission or delay by Agent or the Lenders at any time to enforce any right or remedy reserved to it, or to require performance of any of the terms, covenants or provisions hereof by Borrower at any time designated, shall be a waiver of any such right or remedy to which Agent or the Lenders is entitled, nor shall it in any way affect the right of Agent or the Lenders to enforce such provisions thereafter.

11.6Survival. All agreements, representations and warranties contained in this Agreement and the other Loan Documents or in any document delivered pursuant hereto or thereto shall be for the benefit of Agent and the Lenders and shall survive the execution and delivery of this Agreement. Sections 6.3, 11.15 and 11.18 shall survive the termination of this Agreement.

11.7Successors and Assigns. The provisions of this Agreement and the other Loan Documents shall inure to the benefit of and be binding on Borrower and its permitted assigns (if any). Borrower shall not assign its obligations under this Agreement or any of the other Loan Documents (other than the Warrant which may be assigned in accordance with its terms) without Agent's express prior written consent, and any such attempted assignment shall be void and of no effect. Agent and the Lenders may assign, transfer, or endorse its rights hereunder and under the other Loan Documents without prior notice to Borrower (provided that any assignment, transfer or endorsement of the Warrant shall be subject to the terms thereof), and all of such rights shall inure to the benefit of Agent's and the Lenders' successors and assigns; provided that as long as no Event of Default has occurred and is continuing, neither Agent nor any Lender may assign, transfer or endorse its rights hereunder or under the Loan Documents to any party that is a direct competitor of Borrower or any "vulture fund" "distressed debt fund" or similar entity (in each case, as reasonably determined by Agent in good faith), it being acknowledged that in all cases, any transfer to an Affiliate of any Lender or Agent shall be allowed. Notwithstanding the foregoing, (x) in connection with any assignment by a Lender as a result of a forced divestiture at the request of any regulatory agency, the restrictions set forth herein shall not apply and Agent and the Lenders may assign, transfer or indorse its rights hereunder and under the other Loan Documents to any Person or party (provided that any assignment, transfer or endorsement of the Warrant shall be subject to the terms thereof) and (y) in connection with a Lender's own financing or securitization transactions, the restrictions set forth herein shall not apply and Agent and the Lenders may assign, transfer or indorse its rights hereunder and under the other Loan Documents to any Person or party providing such financing or formed to undertake such securitization transaction and any transferee of such Person or party upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction (provided that any assignment, transfer or endorsement of the Warrant shall be subject to the terms thereof); provided that no such sale, transfer, pledge or assignment under this clause (y) shall release such Lender from any of its obligations hereunder or substitute any such Person or party for such Lender as a party hereto until Agent shall have received and accepted an effective assignment agreement from such Person or party in form satisfactory to Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such assignee as Agent reasonably shall require. The Agent, acting solely for this purpose as an agent of the Borrower, shall maintain at one of its offices in the United States a register for the recordation of the names and addresses of the Lender(s), and the Term Commitments of, and principal amounts (and stated interest) of the Loans owing to, each Lender pursuant to the terms hereof from time to time (the "Register"). The entries in the Register shall be conclusive absent manifest error, and the Borrower, the Agent and the Lender(s) shall treat each Person whose name is recorded in the Register pursuant to the terms hereof as a Lender hereunder for all purposes of this Agreement. The Register shall be available for inspection by the Borrower and any Lender, at any reasonable time and from time to time upon reasonable prior notice.

11.8Participations. Each Lender that sells a participation shall, acting solely for this purpose as a non-fiduciary agent of the Borrower, maintain a register on which it enters the name and address of each participant and the principal amounts (and stated interest) of each participant's interest in the Loans or other obligations under the Loan Documents (the "Participant Register"); provided that no Lender shall have any obligation to disclose all or any portion of the Participant Register (including the identity of any participant or any information relating to a participant's interest in any commitments, loans, its other obligations under any Loan Document) to any Person

except to the extent that such disclosure is necessary to establish that such commitment, loan, letter of credit or other obligation is in registered form under Section 5f.103-1(c) of the United States Treasury Regulations. The entries in the Participant Register shall be conclusive absent manifest error, and such Lender shall treat each Person whose name is recorded in the Participant Register as the owner of such participation for all purposes of this Agreement notwithstanding any notice to the contrary. For the avoidance of doubt, the Agent (in its capacity as Agent) shall have no responsibility for maintaining a Participant Register. Borrower agrees that each participant shall be entitled to the benefits of the provisions in Addendum 1 attached hereto (subject to the requirements and limitations therein, including the requirements under Section 7 of Addendum 1 attached hereto (it being understood that the documentation required under Section 7 of Addendum 1 attached hereto shall be delivered to the participating Lender)) to the same extent as if it were a Lender and had acquired its interest by assignment pursuant to Section 11.7; provided that such participant shall not be entitled to receive any greater payment under Addendum 1 attached hereto, with respect to any participation, than its participating Lender would have been entitled to receive, except to the extent such entitlement to receive a greater payment results from a change in law that occurs after the participant acquired the applicable participation.

11.9Governing Law. This Agreement and the other Loan Documents have been negotiated and delivered to Agent and the Lenders in the State of California, and shall have been accepted by Agent and the Lenders in the State of California. Payment to Agent and the Lenders by Borrower of the Secured Obligations is due in the State of California. This Agreement and the other Loan Documents shall be governed by, and construed and enforced in accordance with, the laws of the State of California, excluding conflict of laws principles that would cause the application of laws of any other jurisdiction.

11.10Consent to Jurisdiction and Venue. All judicial proceedings (to the extent that the reference requirement of Section 11.11 is not applicable) arising in or under or related to this Agreement or any of the other Loan Documents may be brought in any state or federal court located in the State of California. By execution and delivery of this Agreement, each party hereto generally and unconditionally: (a) consents to nonexclusive personal jurisdiction in Santa Clara County, State of California; (b) waives any objection as to jurisdiction or venue in Santa Clara County, State of California; (c) agrees not to assert any defense based on lack of jurisdiction or venue in the aforesaid courts; and (d) irrevocably agrees to be bound by any judgment rendered thereby in connection with this Agreement or the other Loan Documents. Service of process on any party hereto in any action arising out of or relating to this Agreement shall be effective if given in accordance with the requirements for notice set forth in Section 11.2, and shall be deemed effective and received as set forth in Section 11.2. Nothing herein shall affect the right to serve process in any other manner permitted by law or shall limit the right of either party to bring proceedings in the courts of any other jurisdiction.

11.11Mutual Waiver of Jury Trial / Judicial Reference.

(a)Because disputes arising in connection with complex financial transactions are most quickly and economically resolved by an experienced and expert Person and the parties wish applicable state and federal laws to apply (rather than arbitration rules), the parties desire that their disputes be resolved by a judge applying such applicable laws. EACH OF BORROWER, AGENT AND THE LENDERS SPECIFICALLY WAIVES ANY RIGHT IT MAY HAVE TO TRIAL BY JURY OF ANY CAUSE OF ACTION, CLAIM, CROSS-CLAIM, COUNTERCLAIM, THIRD PARTY CLAIM OR ANY OTHER CLAIM (COLLECTIVELY, “CLAIMS”) ASSERTED BY BORROWER AGAINST AGENT, THE LENDERS OR THEIR RESPECTIVE ASSIGNEE OR BY AGENT, THE LENDERS OR THEIR RESPECTIVE ASSIGNEE AGAINST BORROWER.

This waiver extends to all such Claims, including Claims that involve Persons other than Agent, Borrower and the Lenders; Claims that arise out of or are in any way connected to the relationship among Borrower, Agent and the Lenders; and any Claims for damages, breach of contract, tort, specific performance, or any equitable or legal relief of any kind, arising out of this Agreement, any other Loan Document.

(b)If the waiver of jury trial set forth in Section 11.11(a) is ineffective or unenforceable, the parties agree that all Claims shall be resolved by reference to a private judge sitting without a jury, pursuant to Code of Civil Procedure Section 638, before a mutually acceptable referee or, if the parties cannot agree, a referee selected by the Presiding Judge of the Santa Clara County, California. Such proceeding shall be conducted in Santa Clara County, California, with California rules of evidence and discovery applicable to such proceeding.

(c)In the event Claims are to be resolved by judicial reference, either party may seek from a court identified in Section 11.10, any prejudgment order, writ or other relief and have such prejudgment order, writ or other relief enforced to the fullest extent permitted by law notwithstanding that all Claims are otherwise subject to resolution by judicial reference.

11.12Professional Fees. Borrower promises to pay Agent's and the Lenders' reasonable, documented out-of-pocket fees and expenses necessary to finalize the loan documentation, including but not limited to reasonable, documented attorneys' fees, UCC searches, filing costs, and other miscellaneous expenses. In addition, Borrower promises to pay any and all reasonable, documented out-of-pocket attorneys' and other professionals' fees and expenses incurred by Agent after the Closing Date in connection with or related to: (a) the Loan; (b) the administration, collection, or enforcement of the Loan; (c) the amendment or modification of the Loan Documents; (d) any waiver, consent, release, or termination under the Loan Documents; (e) the protection, preservation, audit, field exam, sale, lease, liquidation, or disposition of Collateral or the exercise of remedies with respect to the Collateral; (f) any legal, litigation, administrative, arbitration, or out of court proceeding in connection with or related to Borrower or the Collateral, and any appeal or review thereof; and (g) any bankruptcy, restructuring, reorganization, assignment for the benefit of creditors, workout, foreclosure, or other action related to Borrower, the Collateral, the Loan Documents, including representing Agent or the Lenders in any adversary proceeding or contested matter commenced or continued by or on behalf of Borrower's estate, and any appeal or review thereof.

11.13Confidentiality. Agent and the Lenders acknowledge that certain items of Collateral and information provided to Agent and the Lenders by Borrower, including items provided in connection with the Non-Disclosure Agreement, are confidential and proprietary information of Borrower, if and to the extent such information either (x) is marked as confidential by Borrower at the time of disclosure, or (y) should reasonably be understood to be confidential (the "Confidential Information"). Accordingly, Agent and the Lenders agree that any Confidential Information it may obtain in the course of acquiring, administering, or perfecting Agent's security interest in the Collateral shall not be disclosed to any other Person or entity in any manner whatsoever, in whole or in part, without the prior written consent of Borrower, except that Agent and the Lenders may disclose any such information: (a) to its Affiliates and its partners, investors, lenders, directors, officers, employees, agents, advisors, counsel, accountants, counsel, representative and other professional advisors if Agent or the Lenders in their sole discretion determines that any such party should have access to such information in connection with such party's responsibilities in connection with the Loan or this Agreement and; provided that such recipient of such Confidential Information either (i) agrees to be bound by the confidentiality provisions of this paragraph or (ii) is otherwise subject to confidentiality restrictions that reasonably protect against the disclosure of Confidential

Information; (b) if such information is generally available to the public through no fault of Agent or any Lender; (c) if required or appropriate in any report, statement or testimony submitted to any governmental authority having or claiming to have jurisdiction over Agent or the Lenders and any rating agency; (d) if required or appropriate in response to any summons or subpoena or in connection with any litigation, to the extent permitted or deemed advisable by Agent's or the Lenders' counsel; (e) to comply with any legal requirement or law applicable to Agent or the Lenders or demanded by any governmental authority; (f) to the extent reasonably necessary in connection with the exercise of, or preparing to exercise, or the enforcement of, or preparing to enforce, any right or remedy under any Loan Document (including Agent's sale, lease, or other disposition of Collateral after default), or any action or proceeding relating to any Loan Document; (g) to any participant or assignee of Agent or the Lenders or any prospective participant or assignee, provided, that such participant or assignee or prospective participant or assignee is subject to confidentiality restrictions no less stringent than this Section 11.13 and in any event that reasonably protect against the disclosure of Confidential Information; (h) otherwise to the extent consisting of general portfolio information that does not identify Borrower; or (i) otherwise with the prior consent of Borrower; provided, that any disclosure made in violation of this Agreement shall not affect the obligations of Borrower or any of its Affiliates or any guarantor under this Agreement or the other Loan Documents. Agent's and the Lenders' obligations under this Section 11.13 shall supersede all of their respective obligations under the Non-Disclosure Agreement.

11.14Assignment of Rights. Borrower acknowledges and understands that Agent or the Lenders may, subject to Section 11.7, sell and assign all or part of its interest hereunder and under the Loan Documents (other than the Warrant which is subject to any assignment, transfer or endorsement provisions therein) to any Person or entity (an "Assignee"). After such assignment the term "Agent" or "Lender" as used in the Loan Documents (other than the Warrant which is subject to any assignment, transfer or endorsement provisions therein) shall mean and include such Assignee, and such Assignee shall be vested with all rights, powers and remedies of Agent and the Lenders hereunder with respect to the interest so assigned; but with respect to any such interest not so transferred, Agent and the Lenders shall retain all rights, powers and remedies hereby given. No such assignment by Agent or the Lenders shall relieve Borrower of any of its obligations hereunder. the Lenders agrees that in the event of any transfer by it of the promissory note(s) (if any), it will endorse thereon a notation as to the portion of the principal of the promissory note(s), which shall have been paid at the time of such transfer and as to the date to which interest shall have been last paid thereon.

11.15Revival of Secured Obligations. This Agreement and the Loan Documents shall remain in full force and effect and continue to be effective if any petition is filed by or against Borrower for liquidation or reorganization, if Borrower becomes insolvent or makes an assignment for the benefit of creditors, if a receiver or trustee is appointed for all or any significant part of Borrower's assets, or if any payment or transfer of Collateral is recovered from Agent or the Lenders. The Loan Documents and the Secured Obligations and Collateral security shall continue to be effective, or shall be revived or reinstated, as the case may be, if at any time payment and performance of the Secured Obligations or any transfer of Collateral to Agent, or any part thereof is rescinded, avoided or avoidable, reduced in amount, or must otherwise be restored or returned by, or is recovered from, Agent, the Lenders or by any obligee of the Secured Obligations, whether as a "voidable preference," "fraudulent conveyance," or otherwise, all as though such payment, performance, or transfer of Collateral had not been made. In the event that any payment, or any part thereof, is rescinded, reduced, avoided, avoidable, restored, returned, or recovered, the Loan Documents and the Secured Obligations shall be deemed, without any further action or documentation, to have been revived and reinstated except to the extent of the full, final, and indefeasible payment to Agent or the Lenders in Cash.

11.16Counterparts. This Agreement and any amendments, waivers, consents or supplements hereto may be executed in any number of counterparts, and by different parties hereto in separate counterparts, each of which when so delivered shall be deemed an original, but all of which counterparts shall constitute but one and the same instrument.

11.17No Third-Party Beneficiaries. No provisions of the Loan Documents are intended, nor will be interpreted, to provide or create any third-party beneficiary rights or any other rights of any kind in any Person other than Agent, the Lenders and Borrower unless specifically provided otherwise herein, and, except as otherwise so provided, all provisions of the Loan Documents will be personal and solely among Agent, the Lenders and the Borrower.

11.18Agency. Agent and each Lender hereby agree to the terms and conditions set forth on Addendum 3 attached hereto. Borrower acknowledges and agrees to the terms and conditions set forth on Addendum 3 attached hereto.

11.19Publicity. None of the parties hereto nor any of its respective member businesses and Affiliates shall, without the other parties' prior written consent (which shall not be unreasonably withheld or delayed), publicize or use (a) the other party's name (including a brief description of the relationship among the parties hereto), logo or hyperlink to such other parties' web site, separately or together, in written and oral presentations, advertising, promotional and marketing materials, client lists, public relations materials or on its web site (together, the "Publicity Materials"); (b) the names of officers of such other parties in the Publicity Materials; and (c) such other parties' name, trademarks, servicemarks in any news or press release concerning such party; provided however, notwithstanding anything to the contrary herein, no such consent shall be required (i) to the extent necessary to comply with the requests of any regulators, legal requirements or laws applicable to such party, pursuant to any listing agreement with any national securities exchange (so long as such party provides prior notice to the other party hereto to the extent reasonably practicable) and (ii) to comply with Section 11.13.

11.20Electronic Execution of Certain Other Documents. The words "execution," "execute", "signed," "signature," and words of like import in or related to any document to be signed in connection with this Agreement and the transactions contemplated hereby (including without limitation assignments, assumptions, amendments, waivers and consents) shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by the Agent, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the California Uniform Electronic Transaction Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

(SIGNATURES TO FOLLOW)

IN WITNESS WHEREOF, Borrower, Agent and the Lenders have duly executed and delivered this Loan and Security Agreement as of the day and year first above written.

BORROWER:

AXSOME THERAPEUTICS, INC.

Signature: _____

Print Name: _____

Title: _____

Accepted in Palo Alto, California:

AGENT:

HERCULES CAPITAL, INC.

Signature: _____

Print Name: _____

Title: _____

LENDERS:

HERCULES CAPITAL, INC.

Signature: _____

Print Name: _____

Title: _____

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ADDENDUM 1 to LOAN AND SECURITY AGREEMENT

TAXES; INCREASED COSTS

1. **Defined Terms**. For purposes of this Addendum 1:

   a. "**Connection Income Taxes**" means Other Connection Taxes that are imposed on or measured by net income (however denominated) or that are franchise Taxes or branch profits Taxes.

   b. "**Excluded Taxes**" means any of the following Taxes imposed on or with respect to a Recipient or required to be withheld or deducted from a payment to a Recipient, (i) Taxes imposed on or measured by net income (however denominated), franchise Taxes, and branch profits Taxes, in each case, (A) imposed as a result of such Recipient being organized under the laws of, or having its principal office or, in the case of any Lender, its applicable lending office located in, the jurisdiction imposing such Tax (or any political subdivision thereof) or (B) that are Other Connection Taxes, (ii) in the case of a Lender, U.S. federal withholding Taxes imposed on amounts payable to or for the account of such Lender with respect to an applicable interest in a Loan or Term Commitment pursuant to a law in effect on the date on which (A) such Lender acquires such interest in the Loan or Term Commitment or (B) such Lender changes its lending office, except in each case to the extent that, pursuant to Section 2 or Section 4 of this Addendum 1, amounts with respect to such Taxes were payable either to such Lender's assignor immediately before such Lender became a party hereto or to such Lender immediately before it changed its lending office, (iii) Taxes attributable to such Recipient's failure to comply with Section 7 of this Addendum 1 and (iv) any withholding Taxes imposed under FATCA.

   c. "**FATCA**" means Sections 1471 through 1474 of the Code, as of the date of this Agreement (or any amended or successor version that is substantively comparable and not materially more onerous to comply with), any current or future regulations or official interpretations thereof, any agreements entered into pursuant to Section 1471(b)(1) of the Code, and any fiscal or regulatory legislation, rules or practices adopted pursuant to any intergovernmental agreement, treaty or convention among governmental authorities and implementing such Sections of the Code.

   d. "**Foreign Lender**" means a Lender that is not a U.S. Person.

   e. "**Indemnified Taxes**" means (i) Taxes, other than Excluded Taxes, imposed on or with respect to any payment made by or on account of any obligation of the Borrower under any Loan Document and (ii) to the extent not otherwise described in clause (i), Other Taxes.

   f. "**Other Connection Taxes**" means, with respect to any Recipient, Taxes imposed as a result of a present or former connection between such Recipient and the jurisdiction imposing such Tax (other than connections arising from such Recipient having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to or enforced any Loan Document, or sold or assigned an interest in any Loan or Loan Document).

g. "**Other Taxes**" means all present or future stamp, court or documentary, intangible, recording, filing or similar Taxes that arise from any payment made under, from the execution, delivery, performance, enforcement or registration of, from the receipt or perfection of a security interest under, or otherwise with respect to, any Loan Document, except any such Taxes that are Other Connection Taxes imposed with respect to an assignment.

h. "**Recipient**" means the Agent or any Lender, as applicable.

i. "**Withholding Agent**" means the Borrower and the Agent.

2. **Payments Free of Taxes**. Any and all payments by or on account of any obligation of the Borrower under any Loan Document (other than the Warrant) shall be made without deduction or withholding for any Taxes, except as required by applicable law. If any applicable law (as determined in the good faith discretion of an applicable Withholding Agent) requires the deduction or withholding of any Tax from any such payment by a Withholding Agent, then the applicable Withholding Agent shall be entitled to make such deduction or withholding and shall timely pay the full amount deducted or withheld to the relevant governmental authority in accordance with applicable law and, if such Tax is an Indemnified Tax, then the sum payable by the Borrower shall be increased as necessary so that after such deduction or withholding has been made (including such deductions and withholdings applicable to additional sums payable under this Section 2 or Section 4 of this Addendum 1) the applicable Recipient receives an amount equal to the sum it would have received had no such deduction or withholding been made.

3. **Payment of Other Taxes by Borrower**. The Borrower shall timely pay to the relevant governmental authority in accordance with applicable law, or at the option of the Agent timely reimburse it for the payment of, any Other Taxes.

4. **Indemnification by Borrower**. The Borrower shall indemnify each Recipient, within 10 days after demand therefor, for the full amount of any Indemnified Taxes (including Indemnified Taxes imposed or asserted on or attributable to amounts payable under Section 2 of this Addendum 1 or this Section 4) payable or paid by such Recipient or required to be withheld or deducted from a payment to such Recipient and any reasonable expenses arising therefrom or with respect thereto, whether or not such Indemnified Taxes were correctly or legally imposed or asserted by the relevant governmental authority. A certificate as to the amount of such payment or liability delivered to the Borrower by a Lender (with a copy to the Agent), or by the Agent on its own behalf or on behalf of a Lender, shall be conclusive absent manifest error.

5. **Indemnification by the Lenders**. Each Lender shall severally indemnify the Agent, within 10 days after demand therefor, for (a) any Indemnified Taxes attributable to such Lender (but only to the extent that the Borrower has not already indemnified the Agent for such Indemnified Taxes and without limiting the obligation of the Borrower to do so), (b) any Taxes attributable to such Lender's failure to comply with the provisions of Section 11.8 of the Agreement relating to the maintenance of a Participant Register and (c) any Excluded Taxes attributable to such Lender, in each case, that are payable or paid by the Agent in connection with any Loan Document, and any reasonable expenses arising therefrom or with respect thereto, whether or not such Taxes were correctly or legally imposed or asserted by the relevant governmental authority. A certificate as to the amount of such payment or liability delivered to any Lender by the Agent shall be conclusive absent manifest error. Each Lender hereby authorizes the Agent to set off and apply any and all amounts at any time owing to such Lender under any Loan Document or otherwise payable by the Agent to the Lender from any other source against any amount due to the Agent under this Section 5.

6. **Evidence of Payments**. As soon as practicable after any payment of Taxes by the Borrower to a governmental authority pursuant to the provisions of this Addendum 1, the Borrower shall deliver to the Agent the original or a certified copy of a receipt issued by such governmental authority evidencing such payment, a copy of the return reporting such payment or other evidence of such payment reasonably satisfactory to the Agent.

7. **Status of Lenders**.

   a. Any Lender that is entitled to an exemption from or reduction of withholding Tax with respect to payments made under any Loan Document shall deliver to the Borrower and the Agent, at the time or times reasonably requested by the Borrower or the Agent, such properly completed and executed documentation reasonably requested by the Borrower or the Agent as will permit such payments to be made without withholding or at a reduced rate of withholding. In addition, any Lender, if reasonably requested by the Borrower or the Agent, shall deliver such other documentation prescribed by applicable law or reasonably requested by the Borrower or the Agent as will enable the Borrower or the Agent to determine whether or not such Lender is subject to backup withholding or information reporting requirements. Notwithstanding anything to the contrary in the preceding two sentences, the completion, execution and submission of such documentation (other than such documentation set forth in Sections 7(b)(i), 7(b)(ii) and 7(b)(iv) of this Addendum 1) shall not be required if in the Lender's reasonable judgment such completion, execution or submission would subject such Lender to any material unreimbursed cost or expense or would materially prejudice the legal or commercial position of such Lender.

   b. Without limiting the generality of the foregoing, in the event that the Borrower is a U.S. Person,

      i. any Lender that is a U.S. Person shall deliver to the Borrower and the Agent on or prior to the date on which such Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of the Borrower or the Agent), executed copies of IRS Form W-9 certifying that such Lender is exempt from U.S. federal backup withholding tax;

      ii. any Foreign Lender shall, to the extent it is legally entitled to do so, deliver to the Borrower and the Agent (in such number of copies as shall be requested by the recipient) on or prior to the date on which such Foreign Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of the Borrower or the Agent), whichever of the following is applicable:

         A. in the case of a Foreign Lender claiming the benefits of an income tax treaty to which the United States is a party (x) with respect to payments of interest under any Loan Document, executed copies of IRS Form W-8BEN or IRS Form W-8BEN-E establishing an exemption from, or reduction of, U.S. federal withholding Tax pursuant to the "interest" article of such tax treaty and (y) with respect to any other applicable payments under any Loan Document, IRS Form W-8BEN or IRS Form W-8BEN-E establishing an exemption from, or reduction of, U.S. federal withholding Tax pursuant to the "business profits" or "other income" article of such tax treaty;

         B. executed copies of IRS Form W-8ECI;

C. in the case of a Foreign Lender claiming the benefits of the exemption for portfolio interest under Section 881(c) of the Code, (x) a certificate substantially in the form of Exhibit J-1 to the effect that such Foreign Lender is not a "bank" within the meaning of Section 881(c)(3)(A) of the Code, a "10 percent shareholder" of the Borrower within the meaning of Section 871(h)(3)(B) of the Code, or a "controlled foreign corporation" related to the Borrower as described in Section 881(c)(3)(C) of the Code (a "**U.S. Tax Compliance Certificate**") and (y) executed copies of IRS Form W-8BEN or IRS Form W-8BEN-E; or

D. to the extent a Foreign Lender is not the beneficial owner, executed copies of IRS Form W-8IMY, accompanied by IRS Form W-8ECI, IRS Form W-8BEN, IRS Form W-8BEN-E, a U.S. Tax Compliance Certificate substantially in the form of Exhibit J-2 or Exhibit J-3, IRS Form W-9, and/or other certification documents from each beneficial owner, as applicable; provided that if the Foreign Lender is a partnership and one or more direct or indirect partners of such Foreign Lender are claiming the portfolio interest exemption, such Foreign Lender may provide a U.S. Tax Compliance Certificate substantially in the form of Exhibit J-4 on behalf of each such direct and indirect partner;

iii. any Foreign Lender shall, to the extent it is legally entitled to do so, deliver to the Borrower and the Agent (in such number of copies as shall be requested by the recipient) on or prior to the date on which such Foreign Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of the Borrower or the Agent), executed copies of any other form prescribed by applicable law as a basis for claiming exemption from or a reduction in U.S. federal withholding Tax, duly completed, together with such supplementary documentation as may be prescribed by applicable law to permit the Borrower or the Agent to determine the withholding or deduction required to be made; and

iv. if a payment made to a Lender under any Loan Document would be subject to U.S. federal withholding Tax imposed by FATCA if such Lender were to fail to comply with the applicable reporting requirements of FATCA (including those contained in Section 1471(b) or 1472(b) of the Code, as applicable), such Lender shall deliver to the Borrower and the Agent at the time or times prescribed by law and at such time or times reasonably requested by the Borrower or the Agent such documentation prescribed by applicable law (including as prescribed by Section 1471(b)(3)(C)(i) of the Code) and such additional documentation reasonably requested by the Borrower or the Agent as may be necessary for the Borrower and the Agent to comply with their obligations under FATCA and to determine that such Lender has complied with such Lender's obligations under FATCA or to determine the amount, if any, to deduct and withhold from such payment. Solely for purposes of this clause (iv), "FATCA" shall include any amendments made to FATCA after the date of this Agreement.

c. Each Lender agrees that if any form or certification it previously delivered expires or becomes obsolete or inaccurate in any respect, it shall update such form or certification or promptly notify the Borrower and the Agent in writing of its legal inability to do so.

8. **Treatment of Certain Refunds**. If any party determines, in its sole discretion exercised in good faith, that it has received a refund of any Taxes as to which it has been indemnified pursuant to the provisions

of this Addendum 1 (including by the payment of additional amounts pursuant to the provisions of this Addendum 1), it shall pay to the indemnifying party an amount equal to such refund (but only to the extent of indemnity payments made under the provisions of this Addendum 1 with respect to the Taxes giving rise to such refund), net of all out-of-pocket expenses (including Taxes) of such indemnified party and without interest (other than any interest paid by the relevant governmental authority with respect to such refund). Such indemnifying party, upon the request of such indemnified party, shall repay to such indemnified party the amount paid over pursuant to this Section 8 (plus any penalties, interest or other charges imposed by the relevant governmental authority) in the event that such indemnified party is required to repay such refund to such governmental authority. Notwithstanding anything to the contrary in this Section 8, in no event will the indemnified party be required to pay any amount to an indemnifying party pursuant to this Section 8 the payment of which would place the indemnified party in a less favorable net after-Tax position than the indemnified party would have been in if the Tax subject to indemnification and giving rise to such refund had not been deducted, withheld or otherwise imposed and the indemnification payments or additional amounts with respect to such Tax had never been paid. This Section 8 shall not be construed to require any indemnified party to make available its Tax returns (or any other information relating to its Taxes that it deems confidential) to the indemnifying party or any other Person.

9. **Increased Costs**. If any change in applicable law shall subject any Recipient to any Taxes (other than (A) Indemnified Taxes, (B) Taxes described in clauses (ii) through (iv) of the definition of Excluded Taxes and (C) Connection Income Taxes) on its loans, loan principal, commitments, or other obligations, or its deposits, reserves, other liabilities or capital attributable thereto, and the result shall be to increase the cost to such Recipient of making, converting to, continuing or maintaining any Term Loan or of maintaining its obligation to make any such Loan, or to reduce the amount of any sum received or receivable by such Recipient (whether of principal, interest or any other amount), then, upon the request of such Recipient, the Borrower will pay to such Recipient such additional amount or amounts as will compensate such Recipient for such additional costs incurred or reduction suffered.

10. **Mitigation**. If any Lender requires the Borrower to pay any Indemnified Taxes or additional amounts pursuant to this Addendum, then such Lender shall (at the request of the Borrower) use reasonable efforts to designate a different lending office for funding or booking its Loans hereunder or to assign its rights and obligations hereunder to another of its branches, offices, or affiliates, if, in the judgment of such Lender, such designation or assignment: (i) would eliminate or reduce amounts payable pursuant to this Addendum in the future, and (ii) would not subject such Lender to any unreimbursed cost or expense and would not otherwise be disadvantageous to such Lender. The Borrower hereby agrees to pay all reasonable costs and expenses incurred by any Lender in connection with such designation or assignment.

11. **Survival**. Each party's obligations under the provisions of this Addendum 1 (including any inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of the Loan Documents) shall survive the resignation or replacement of the Agent or any assignment of rights by, or the replacement of, a Lender, the termination of the Term Commitments and the repayment, satisfaction or discharge of all obligations under any Loan Document (other than the Warrant).

ADDENDUM 2 to LOAN AND SECURITY AGREEMENT

[Reserved.]

ADDENDUM 3 to LOAN AND SECURITY AGREEMENT

Agent and Lender Terms

(a) Each Lender hereby irrevocably appoints Hercules Capital, Inc. to act on its behalf as the Agent hereunder and under the other Loan Documents (other than the Warrant) and authorizes the Agent to take such actions on its behalf and to exercise such powers as are delegated to the Agent by the terms hereof or thereof, together with such actions and powers as are reasonably incidental thereto.

(b) Each Lender agrees to indemnify the Agent in its capacity as such (to the extent not reimbursed by Borrower and without limiting the obligation of Borrower to do so), according to its respective Term Commitment percentages (based upon the total outstanding Term Commitments) in effect on the date on which indemnification is sought under this Addendum 3, from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, costs, expenses or disbursements of any kind whatsoever that may at any time be imposed on, incurred by or asserted against the Agent in any way relating to or arising out of, this Agreement, any of the other Loan Documents (other than the Warrant) or any documents contemplated by or referred to herein or therein (other than the Warrant) or the transactions contemplated hereby or thereby or any action taken or omitted by the Agent under or in connection with any of the foregoing; The agreements in this Section shall survive the payment of the Loans and all other amounts payable hereunder.

(c) Agent in Its Individual Capacity. The Person serving as the Agent hereunder shall have the same rights and powers in its capacity as a Lender as any other Lender and may exercise the same as though it were not the Agent and the term "Lender" shall, unless otherwise expressly indicated or unless the context otherwise requires, include each such Person serving as Agent hereunder in its individual capacity.

(d) Exculpatory Provisions. The Agent shall have no duties or obligations except those expressly set forth herein and in the other Loan Documents. Without limiting the generality of the foregoing, the Agent shall not:

(i) be subject to any fiduciary or other implied duties, regardless of whether any default or any Event of Default has occurred and is continuing;

(ii) have any duty to take any discretionary action or exercise any discretionary powers, except discretionary rights and powers expressly contemplated hereby or by the other Loan Documents that the Agent is required to exercise as directed in writing by the Lenders; provided that the Agent shall not be required to take any action that, in its opinion or the opinion of its counsel, may expose the Agent to liability or that is contrary to any Loan Document or applicable law; and

(iii) except as expressly set forth herein and in the other Loan Documents, have any duty to disclose, and the Agent shall not be liable for the failure to disclose, any information relating to the Borrower or any of its Affiliates that is communicated to or obtained by any Person serving as the Agent or any of its Affiliates in any capacity.

(e) The Agent shall not be liable for any action taken or not taken by it (i) with the consent or at the request of the Lenders or as the Agent shall believe in good faith shall be necessary, under the circumstances or (ii) in the absence of its own gross negligence or willful misconduct.

(f) The Agent shall not be responsible for or have any duty to ascertain or inquire into (i) any statement, warranty or representation made in or in connection with this Agreement or any other Loan Document, (ii) the contents of any certificate, report or other document delivered hereunder or thereunder or in connection herewith or therewith, (iii) the performance or observance of any of the covenants, agreements or other terms or conditions set forth herein or therein or the occurrence of any default or Event of Default, (iv) the validity, enforceability, effectiveness or genuineness of this Agreement, any other Loan Document or any other agreement, instrument or document or (v) the satisfaction of any condition set forth in Section 4 or elsewhere herein, other than to confirm receipt of items expressly required to be delivered to the Agent. Reliance by Agent. Agent may rely, and shall be fully protected in acting, or refraining to act, upon, any resolution, statement, certificate, instrument, opinion, report, notice, request, consent, order, bond or other paper or document that it has no reason to believe to be other than genuine and to have been signed or presented by the proper party or parties or, in the case of cables, telecopies and telexes, to have been sent by the proper party or parties. In the absence of its gross negligence or willful misconduct, Agent may conclusively rely, as to the truth of the statements and the correctness of the opinions expressed therein, upon any certificates or opinions furnished to Agent and conforming to the requirements of this Agreement or any of the other Loan Documents. Agent may consult with counsel, and any opinion or legal advice of such counsel shall be full and complete authorization and protection in respect of any action taken, not taken or suffered by Agent hereunder or under any Loan Documents in accordance therewith. Agent shall have the right at any time to seek instructions concerning the administration of the Collateral from any court of competent jurisdiction. Agent shall not be under any obligation to exercise any of the rights or powers granted to Agent by this Agreement and the other Loan Documents at the request or direction of the Lenders unless Agent shall have been provided by the Lenders with adequate security and indemnity against the costs, expenses and liabilities that may be incurred by it in compliance with such request or direction.

EXHIBIT B

[Exhibit B intentionally omitted. It is not material and would be competitively harmful if publicly disclosed.]

Exhibit 10.3

SUBLEASE
(One World Trade Center, 22nd Floor)

This SUBLEASE, dated as of February 21, 2023 (the "**Effective Date**"), between ADVANCE MAGAZINE PUBLISHERS INC. D/B/A CONDÉ NAST, a New York corporation, having an office at One World Trade Center, New York, New York 10007 ("**Sublandlord**") and AXSOME THERAPEUTICS, INC., having offices up until the Commencement Date at 22 Cortlandt St 16th floor, New York, NY 10007, Attn: General Counsel ("**Subtenant**").

W I T N E S S E T H:

WHEREAS, Sublandlord, is the tenant under a certain Lease, dated May 25, 2011, (the "**Original Lease**"), with WTC Tower 1 LLC, as landlord ("**Prime Landlord**"), and Sublandlord, as tenant, as amended by the First Amendment to Lease, dated as of March 19, 2012 (the "**First Amendment**"; the Original Lease, as heretofore amended, the "**Lease**"), which Lease demises the premises (the "**Prime Leased Premises**") covering the entire 20th through 44th floors and certain below grade space in the building known as One World Trade Center or 1 World Trade Center, New York, New York (the "**Building**");

WHEREAS, Subtenant desires to sublet the entire 22nd floor of the Building, as more particularly shown on Exhibit A annexed hereto (the "**Premises**") from Sublandlord, and Sublandlord is willing to sublet the same to Subtenant, on the terms and conditions hereinafter set forth; and

WHEREAS, terms used but not otherwise defined herein shall have the meanings ascribed thereto in the Lease.

NOW, THEREFORE, in consideration of the mutual covenants herein contained, Sublandlord and Subtenant agree as follows:

1. Demise; Term.

(a) Sublandlord hereby subleases to Subtenant, and Subtenant hereby hires from Sublandlord, the Premises for a term (the "**Term**") to commence (subject to the provisions of Section 17 entitled "Landlord's Consents" and Section 18 entitled "Delivery of Possession" hereof) on the later to occur of (a) the full execution and delivery of this Sublease by both Sublandlord and Subtenant, (b) the date Sublandlord receives Prime Landlord's written consent to this Sublease and (c) the date on which Sublandlord's Work (as hereinafter defined) is deemed to have been substantially completed and Sublandlord has delivered the Premises to Subtenant in the Premises Condition, as hereinafter defined (the later of such dates is called the "**Commencement Date**") and to expire (unless sooner terminated in accordance with applicable Legal Requirements or pursuant to Section 26 hereof or extended pursuant to Section 27 hereof) on the day immediately preceding the 10th anniversary of the Rent Commencement Date (as hereinafter defined the "**Expiration Date**") both dates inclusive. Sublandlord shall provide Subtenant with 5 Business

Days' advance notice of the Commencement Date. Sublandlord estimates that the Commencement Date will occur on or about two (2) weeks from the date Prime Landlord executes the Landlord's Consent (as defined in Section 17 hereof) to this Sublease. Notwithstanding the foregoing, in the event the Rent Commencement Date is not the first day of a month, the Expiration Date will be the last day of the month in which the 10th anniversary of the Rent Commencement Date occurs.

(b) Promptly after the occurrence of the Commencement Date, Sublandlord and Subtenant shall confirm the occurrence thereof, as well as the Rent Commencement Date and Expiration Date, by executing an instrument reasonably satisfactory to Sublandlord and Subtenant; provided that failure by Sublandlord or Subtenant to execute such instrument shall not affect the occurrence of the Commencement Date in accordance with Section 1(a) hereof.

(c) Notwithstanding the foregoing, Subtenant and any of Subtenant's contractors shall have access to the Premises up to thirty (30) days prior to the Commencement Date for the sole purpose of installing its equipment, IT equipment and furniture in connection with Subtenant's initial occupancy of the Premises (collectively, the "**Early Access**"); provided that (A) all of the terms and conditions of this Sublease shall apply to such Early Access (notwithstanding that the Commencement Date has not yet occurred), except Subtenant's obligation to pay monthly Fixed Rent and Additional Rent under Sections 2 and 3 hereof; (B) Subtenant and Subtenant's contractors shall not interfere with Sublandlord's performance of any work (including, without limitation, Sublandlord's Work); (C) Subtenant shall provide Sublandlord with 1 Business Day's (as defined in the Lease) prior notice of each intended Early Access (which may be by email to [*****], along with evidence of insurance required under Section 13 hereof entitled "Insurance"; (D) such Early Access shall be at Subtenant's own risk (subject to clause (E) below); and (E) such Early Access shall not subject Sublandlord to any liability or responsibility for injury or damages to persons or property or to any liability for any cause whatsoever, except to the extent caused by the negligence or willful misconduct of Sublandlord, its agents, employees or contractors in the Premises. Sublandlord shall in all events have priority access to the Premises for the performance of Sublandlord's Work.

(d) If, in Sublandlord's sole reasonable discretion (but not acting in an arbitrary or capricious manner), any Early Access shall interfere with or delay (in each case to more than a de minimis extent) the performance Sublandlord's Work or otherwise violate the terms of this Sublease or the Lease, then upon Sublandlord's request, all Early Access shall immediately cease and Subtenant shall cause all Subtenant's contractors to immediately cease any Early Access until Sublandlord reasonably determines such interference does not exist. In connection with any Early Access, Subtenant shall comply, and cause Subtenant's contractors to comply, promptly with all procedures and regulations reasonably prescribed by Sublandlord from time to time for coordinating any Early Access with any other activity or work in the Premises, including, without limitation, the use of compatible labor.

(e) The subleasing of the Premises by Subtenant shall include the right of Subtenant to (a) access the Building Common Areas in common with other tenants in the Building (subject to the terms of Original Lease Article 43), (b) use the Subgrade Lobby upon and subject to the terms of Original Lease Article 43 and (c) use all fixtures, improvements and betterments owned or leased by Prime Landlord or Sublandlord which, at any time during the term of this Sublease, are attached to or installed in the Premises, all subject to such restrictions, rules, regulations, security arrangements and charges (if any) as are provided for in the Lease and this Sublease.

2. Fixed Rent. Subtenant shall pay to Sublandlord a fixed basic rent ("**Fixed Rent**") as follows:

(1) for the period commencing on the Commencement Date (as defined below) and ending on the day immediately preceding the fifth (5th) anniversary of the Rent Commencement Date, at the rate of $2,521,272.00 per annum, payable in equal monthly installments of $210,106.00; and

(2) for the period commencing on the fifth (5th) anniversary of the Rent Commencement Date and ending on the day immediately preceding the tenth (10th) anniversary of the Rent Commencement Date, at the rate of $2,763,702.00 per annum, payable in equal monthly installments of $230,308.50.

(b) Subtenant shall pay the Fixed Rent in equal monthly installments in advance commencing on the Rent Commencement Date and with each monthly installment to be received by Sublandlord not later than the first Business Day of each month thereafter during the Term. Subtenant shall make all payments of Fixed Rent and all other sums of money as shall become due and payable by Subtenant to Sublandlord under this Sublease ("**Additional Rent**") to Sublandlord by ACH transfer or wire transfer of immediately available Federal Reserve Funds to an account at a bank specified in a written notice to Subtenant, containing all necessary wiring instructions, or at such other place as Sublandlord may designate in writing, without demand, abatement, set-off or deduction whatsoever (except as expressly provided herein).

(c) If the Rent Commencement Date occurs on a day other than the 1st day of a calendar month or the Expiration Date occurs on a day other than the last day of a calendar month, the Fixed Rent and any Additional Rent for any such partial calendar month shall be prorated.

(d) *Rent Commencement Date*. Provided Subtenant is not then in monetary or material non-monetary default beyond any applicable notice and cure periods under this Sublease (and if such a default exists, then as soon as such default is cured) and this Sublease is in full force and effect, Subtenant shall be entitled to an abatement of Fixed Rent for the period commencing on the Commencement Date to and including the day immediately preceding the date occurring in the [*****] after the Commencement Date which is the same numerical date in the month as the Commencement Date (except that if there is no same numerical date in such [*****], then the last day of such [*****]) (the "**Free Rent Period**"). The day immediately following the expiration of the Free Rent Period is herein referred to as the "**Rent Commencement Date**". The day following the foregoing Free Rent Period, provided Subtenant is not then in monetary or material non-monetary default beyond any applicable notice and cure periods under this Sublease (and if such a default exists, then as soon as such default is cured) and this Sublease is in full force and effect, Subtenant shall be entitled to a partial abatement of Fixed Rent for the following [*****] period (commencing on the Rent Commencement Date) on [*****] rentable square feet ("**Partial Free Rent Period**") in the amount of [*****] per month so that Subtenant's Fixed Rent for such period shall be [*****] per month during the Partial Free Rent Period. If Subtenant does not exercise the Termination Option (as hereinafter defined), then, provided that (i) Subtenant is not then in monetary or material non-monetary default beyond any applicable notice and cure periods under this Sublease (and if such a default exists, then as soon as such default is cured), and (ii) this Sublease is in full force and effect, and (iii) Subtenant is Axsome Therapeutics, Inc., or its

successors or assigns then Subtenant shall be entitled to an abatement of the then Fixed Rent for a [*****] period commencing on the first full month after the 5th anniversary of the Rent Commencement Date.

3. Additional Rent. Subtenant shall pay to Sublandlord, as Additional Rent, from and after the Rent Commencement Date, each of the following:

(1) *Sublease Pilot/Real Estate Taxes.* Commencing on January 1, 2024, Subtenant's Share (as hereinafter defined) of all amounts which are payable by Sublandlord pursuant to Article 4.05 of the Original Lease, but only to the extent such amounts, on a 12-month basis, exceed the amounts finally determined to be payable under Article 4.05 of the Original Lease for calendar year 2023 (the "**PILOT Base Year**") (i.e., the sum of (x) the aggregate amount payable by Sublandlord with respect to the PILOT Semi-Annual Period (as defined in the Lease) commencing on January 1, 2023 and (y) the aggregate amount payable by Sublandlord with respect to the PILOT Semi-Annual Period commencing on July 1, 2023); provided that no Additional Rent under this Section 3(a)(1) shall be due and payable by Subtenant until (and for the period prior to) the Rent Commencement Date;

(2) *Sublease Operating Expense.* Commencing on January 1, 2024, Subtenant's Share of all amounts which are payable by Sublandlord for the Premises pursuant to Article 4.03 of the Original Lease (the "**Expense Payments**"), but only to the extent such amounts exceed the amounts finally determined to be payable under Article 4.03 of the Original Lease for the calendar year 2023 (the "**Sublease Operating Expense Base Year**"); provided that no Additional Rent under this Section 3(a)(2) shall be due and payable by Subtenant until (and for the period prior to) the Rent Commencement Date;

(3) *Sublease CAM Base Year*. Commencing on January 1, 2024, Subtenant's Share of all amounts which are payable by Sublandlord for the Premises pursuant to Article 4.04 of the Original Lease (the "**CAM Payments**"), but only to the extent such amounts exceed the amounts finally determined to be payable under Article 4.04 of the Original Lease for the calendar year 2023 (the "**Sublease CAM Base Year**"); provided that no Additional Rent under this Section 3(a)(3) shall be due and payable by Subtenant until (and for the period prior to) the Rent Commencement Date;

(4) *Electricity and Submetering.* All amounts which are payable by Sublandlord pursuant to Article 7 of the Original Lease or otherwise on account of electricity supplied to the Premises during the Term (it being acknowledged that prior to the Commencement Date, a submeter has or will be installed by Sublandlord (at no additional cost to Subtenant) to separately submeter the Premises), without markup or supplementary charges imposed by Sublandlord. Subtenant acknowledges that the electricity consumed in connection with providing HVAC to the Premises will be included in the electricity supplied to the Premises, measured by the submeter and paid by Subtenant;

(5) *Condenser Water and other Costs.* All amounts which are payable by Sublandlord pursuant to Article 6.06 of the Original Lease on account of condenser water supplied to any Supplemental HVAC System (as defined in the Lease) serving the Premises during the Term and

(6) *Services provided at Subtenant's Request.* The full amount of any other charge, fee, cost, sum or expense which Sublandlord pays or incurs on or after the Commencement Date or in connection with, any services or supplies provided to or for the Premises (or any part thereof) during the Term at the request of Subtenant and/or as may be required pursuant to the terms and provisions of the Lease with respect to the Premises during the Term.

(b) *Subtenant's Share.* "**Subtenant's Share**" means, from time to time during the term of this Sublease, the fraction (expressed as a percentage) having as its numerator the rentable square feet comprising the Premises (which shall be deemed to be 48,486 rentable square feet on the Effective Date) and as its denominator the rentable square feet then comprising the Prime Leased Premises (which is currently deemed to be 1,194,633 rentable square feet on the Effective Date). As of the Effective Date, Subtenant's Share is 4.05865%.

(c) *Rent or Occupancy Tax*. Subtenant shall pay any commercial rent or occupancy tax due from Subtenant with regard to this Sublease or the Premises either to the taxing authority or, if appropriate, to Sublandlord, as Additional Rent, at least five (5) Business Days before the due date of each and every such tax payment to the taxing authority.

(d) *Payment of Additional Rent.* All payments of Additional Rent shall be paid by Subtenant to Sublandlord within ten (10) Business Days after Sublandlord's request and an invoice therefor; provided that if the Lease requires the making of payments on account of any item of Additional Rent, Subtenant shall make such payments at least five (5) Business Days prior to its respective due date under the Lease (provided such due date in set forth in the invoice delivered to Subtenant). Sublandlord shall provide Subtenant with (1) copies of all statements, bills and back-up documentation received from Prime Landlord applicable to Additional Rent payable by Subtenant hereunder with submission of invoices or requests for payment by Sublandlord, or if such documentation is neither required nor actually provided, then by appropriate reference to the applicable obligation giving rise to such invoice or request for payment, as identified by Sublandlord, and, (2) where the billing requires calculations by Sublandlord, a reasonably detailed breakdown of such calculations with reasonably supporting documentation.

(e) Within ten (10) days of receipt of request from Subtenant, Sublandlord shall deliver to Subtenant, if Sublandlord has received or promptly after Sublandlord's receipt of the same, a copy of each Expense Statement (as defined in the Lease) received by Sublandlord for an Expense Year (as defined in the Lease) occurring during the Term commencing with the 2023 Expense Year. Provided that Subtenant is not in default under this Sublease, upon the written request of Subtenant, given no later than twenty (20) days after Subtenant's receipt of a copy of an Expense Statement, Sublandlord shall reasonably consult with Subtenant regarding any Expenses or Tenant's CAM Payment (as both terms are defined in the Lease) set forth in the Expense Statement of which Subtenant has a reasonable basis for concern. If, after consulting with Subtenant, Sublandlord (in Sublandlord's sole but reasonable discretion) determines to exercise its rights set forth in Section 4.03E(iii) of the Lease to (i) dispute the applicable Expense Statement and examine Prime Landlord's books and records and/or (ii) commence arbitration with respect to the applicable Expense Statement, then (i) subject to Subtenant's delivery of a confidentiality agreement to Sublandlord and Prime Landlord with respect to such dispute and such examination substantially in the form attached as Exhibit O to the Lease, Sublandlord shall promptly share the results of such examination with Subtenant; and (ii) Subtenant shall pay to Sublandlord, as

Additional Rent, Subtenant's Share of Sublandlord's reasonable costs and expenses incurred in connection with such examination and any arbitration. Notwithstanding the foregoing, in no event shall Sublandlord be required to take any step that may, in Sublandlord's sole judgment, have an adverse effect on its relationship with Prime Landlord.

4. Use. The Premises shall be used and occupied only for general and executive offices, and for uses incidental thereto permitted under the terms of the Lease and for no other purpose. Notwithstanding anything in this Sublease to the contrary, no noise which disturbs Sublandlord, other subtenants, or tenants in the Building shall be made or permitted by Subtenant in the Premises. Additionally, and without limitation, Subtenant will not permit any odors or dust emanating within the Premises to seep into other portions of the Building.

5. Incorporation of the Lease. Except as may be inconsistent or inapplicable with the terms of this Sublease, all of the terms, covenants and conditions of the Lease are hereby made a part of this Sublease with the same force and effect as if fully set forth at length herein, except that, unless the context requires otherwise, references in the Lease to (i) "Lease" shall mean this Sublease, (ii) the "Demised Premises" or "Premises" shall mean the Premises defined herein, (iii) "Landlord" shall mean Sublandlord herein, (iv) the term "Tenant" in the Lease shall mean Subtenant herein, (v) "Initial Term" shall mean the Term hereof, (vi) "Expiration Date" shall mean the Expiration Date defined herein, and (vii) "subleases", "sublettings", "sublets" or "subtenants" (or of like import) shall mean sub-subleases, sub-sublettings, sub-sublets or sub-subtenants hereunder, respectively. In the event of any conflict between this Sublease and the Lease (as incorporated herein), such conflict shall be resolved in favor of this Sublease; provided same shall not be a default under the Lease. Without limiting the generality of the foregoing, Sublandlord and Subtenant acknowledge that the provisions of the Lease set forth on Exhibit B attached hereto and made a part hereof (as well as such other terms of the Lease that do not relate to the Premises), are inconsistent, inapplicable or contrary with the terms of this Sublease and therefore are excluded from the incorporation by reference of the Lease into this Sublease or modified as described thereon. For the avoidance of doubt, this Sublease is subject in all respects to the terms of the Lease and is subject to the restrictions contained in the Lease, whether or not such terms or restrictions are incorporated by reference herein. In any case where the consent or approval of Prime Landlord under the Lease is required, Sublandlord's consent shall also be required hereunder. Subtenant represents to Sublandlord that it has read and is familiar with the terms of the Lease (excluding redacted terms not relevant to Subtenant) provided by Sublandlord to Subtenant.

(a) *Time Limits for Notices.* Except as otherwise provided herein, the time limits contained in the Lease for the giving of notices, making payments or demands or performing of any act, condition or covenant on Sublandlord's part, as tenant thereunder, are changed for the purposes of incorporation herein by reference by shortening same in each instance by three (3) days (except as specifically provided herein), so that Subtenant shall have a lesser time to observe or perform under this Sublease than Sublandlord has under the Lease. In no event, however, shall Subtenant have less than three (3) Business Days to so observe or perform. If Sublandlord or Subtenant receives any notice or demand from Prime Landlord relating to this Sublease or the Premises or Subtenant receives any notice or demand from Prime Landlord under the Lease, said party shall promptly give a copy thereof to the other. In the case of any time limit described above which is one (1) or two (2) days after the giving of the notice applicable thereto, such notice shall be delivered personally as provided in Section 16 hereof.

(b) *Subtenant Compliance with Lease*. Subject to the provisions of Section 5(a) of this Sublease and other than the payment of Rent Subtenant shall comply with all of the terms, covenants and conditions of the Lease on the part of tenant therein named to be performed thereunder.

(c) *Sublandlord Not Responsible for Prime Landlord Performance*. Performance by Prime Landlord under the Lease shall be deemed and accepted by Subtenant as performance by Sublandlord under this Sublease. Sublandlord shall not be responsible for any breach of the Lease by Prime Landlord or any nonperformance or noncompliance with any provision thereof by Prime Landlord, including, without limitation, the failure of Prime Landlord to provide any services, utilities and/or repairs. Sublandlord makes no representation that Prime Landlord will provide any or all of the services, utilities and/or repairs referred to and incorporated by reference into this Sublease, but Sublandlord shall comply with the provisions of Section 10 hereof. Sublandlord shall duly observe and perform all of the terms and conditions of the Lease that are required to be performed or observed by Sublandlord as the tenant thereunder with respect to the Prime Leased Premises other than the Premises and are not required to be performed or observed by Subtenant under this Sublease. Other than the payment of Rent and except as otherwise expressly provided in this Sublease, including to the extent certain Lease provisions are not incorporated herein by reference, Subtenant acknowledges that Subtenant is obligated to perform all of Sublandlord's obligations, as tenant, for the Premises. Furthermore, Subtenant shall not be liable for: (a) complying with provisions of the Lease with respect to the Prime Leased Premises, other than the Premises, (b) curing any default under the Lease with respect to the Prime Leased Premises, other than the Premises, or prior to the Commencement Date, (c) repairing damage to the Premises directly caused by Sublandlord, (d) removing any improvements installed by Prime Landlord or Sublandlord, and (e) removing mechanics liens caused by Sublandlord.

(d) *No Violations of the Lease*. Subtenant shall not do nor permit anything to be done which would violate or breach the terms and provisions of the Lease or cause the Lease to be terminated or forfeited by reason of any right of termination or forfeiture reserved or vested in Prime Landlord under the Lease.

(e) *"Sublandlord" includes Tenant Guarantor for Indemnity Purposes*. Notwithstanding anything in the Lease or this Sublease to the contrary, whenever the Lease or the Sublease provides that Subtenant indemnify Sublandlord, the term "**Sublandlord**" shall be deemed to include Tenant Guarantor.

(f) *Consents*. Whenever in this Sublease it is provided that either party will not unreasonably withhold its consent to any matter, such party shall also be deemed to have agreed not to unreasonably delay or condition such consent. If and when Subtenant shall so reasonably request in writing, Sublandlord will use commercially reasonable efforts to obtain Prime Landlord's consent on Subtenant's behalf (at Subtenant's cost, unless otherwise expressly provided in this Sublease, and in any event with no representation, warranty or covenant that Prime Landlord's consent will be given). Sublandlord shall not be deemed to have unreasonably withheld or delayed its consent to any matter if Prime Landlord's consent to the matter requested is required by the Lease or this Sublease and if Prime Landlord shall have withheld or delayed its consent to such matter. If either party shall request the other's consent and such consent is withheld, conditioned or delayed, such party shall not be entitled to any damages by reason thereof, it being

intended that the sole remedy therefor shall be an action for specific performance or injunction and that such remedy shall only be available where a party has agreed herein not to unreasonably withhold, condition or delay such consent or where, as a matter of law, such consent may not be unreasonably withheld, conditioned or delayed.

6. Remedies. *Same Remedies as Prime Landlord*. Sublandlord shall have the same rights and remedies with respect to a breach of this Sublease by Subtenant as Prime Landlord has with respect to a breach of a similar obligation of Sublandlord as tenant under the Lease, as if the same were more fully set forth at length herein and Sublandlord shall have, with respect to Subtenant this Sublease and the Premises, all of the rights, powers, privileges and immunities as are had by Prime Landlord under the Lease to the extent incorporated herein.

(a) *Cease Default Activities*. If Prime Landlord, in writing, shall claim or otherwise allege that a use of, action or inaction involving, or other circumstances concerning, the Premises is in violation of any provision of, or may become a default under, the Lease, in addition to Sublandlord's other rights hereunder and at law, Subtenant, promptly after notice from Sublandlord, shall cease such use or action, take such action or cause such circumstance to be changed so that the basis or alleged basis for such claim or allegation shall no longer exist.

(b) *Summary Proceeding.* In supplementing Article 32.04 of the Original Lease, if Sublandlord commences any summary proceeding against Subtenant, Subtenant will not interpose any counterclaim of whatever nature or description in any such proceeding (unless failure to impose such counterclaim would preclude Subtenant from asserting in a separate action the claim which is the subject of such counterclaim) and will not seek to consolidate such proceeding with any other action which may have been or will be brought in any other court by Subtenant.

7. Intentionally Omitted.

8. Subordination. *Sublease Subordination*. This Sublease is subject and subordinate to (i) the Lease, (ii) any and all amendments or modifications to the Lease, and supplemental agreements relating thereto, hereafter made between the Prime Landlord and Sublandlord which do not in any respect contravene any express rights granted to or impose further obligations on Subtenant hereunder (except to a de minimis extent) and (iii) to all other matters and interests to which the Lease is or shall be subordinate. Subject to the terms of any Subtenant SNDA (as defined in the Lease) between Subtenant and Prime Landlord in the event of termination, re-entry or dispossession by Prime Landlord under the Lease, Prime Landlord may, at its option, either terminate this Sublease or take over all of the right, title and interest of Sublandlord under this Sublease and Subtenant shall, at Prime Landlord's option, attorn to Prime Landlord pursuant to the then executory provisions of this Sublease. Sublandlord shall deliver to Subtenant copies of all future executed amendments, modifications and supplements to the Lease which affect the Premises and which Prime Landlord has given a copy thereof to Sublandlord. In accordance with the requirements of Article 47 of the Lease, Subtenant hereby agrees to comply with (and to (a) instruct all of its employees to comply with and (b) include in each sublease and other occupancy agreement an express obligation that all subtenants and other occupants of any portion of the Premises must comply with) the Information Security Handbook issued by the Port Authority, as the same may be modified or supplemented from time to time without the approval of Subtenant,

provided that each of such modifications or supplements shall be generally applicable to all office tenants of the World Trade Center and all other rules and regulations of the Building.

(a) *Sublandlord Request for SNDA for Subtenant*. At Subtenant's request, Sublandlord shall request for Subtenant from Prime Landlord, a non-disturbance and attornment agreement in such Prime Landlord's then standard form (an "**SNDA**"). Sublandlord and Subtenant acknowledge and agree that the provision of an SNDA by Prime Landlord is subject to the satisfaction of specified conditions set forth in the Lease. Accordingly, if Sublandlord is unable to obtain an SNDA by making such a request, Sublandlord shall have no liability to Subtenant, it being intended that Sublandlord's sole obligation shall be to request that the Prime Landlord enter into such SNDA and, in no event shall Sublandlord be required to (i) expend any sums in its effort to obtain such SNDA, (ii) commence any litigation in order to obtain an SNDA or (iii) take any step (other than making a request for an SNDA) that may, in Sublandlord's sole reasonable judgment, have an adverse effect on its relationship with the Prime Landlord.

(b) *Information Security Handbook.* In accordance with the requirements of Article 47 of the Original Lease, Subtenant hereby agrees to comply with (and to (a) instruct all of its employees to comply with and (b) include in each sublease and other occupancy agreement an express obligation that all subtenants and other occupants of any portion of the Premises must comply with) the Information Security Handbook issued by the Port Authority, as the same may be modified or supplemented from time to time without the approval of Subtenant, provided that each of such modifications or supplements shall be generally applicable to all office tenants of the World Trade Center and all other rules and regulations of the Building.

9. Assignment and Subleasing.

(a) *General Clause*. Notwithstanding anything contained in the Lease to the contrary and subject to the further provisions of this Section 9, neither this Sublease nor the term and estate hereby granted, nor any part hereof or thereof, shall be assigned, mortgaged, pledged, encumbered or otherwise transferred voluntarily, involuntarily, by operation of law or otherwise by Subtenant, and neither the Premises, nor any part thereof, shall be subleased, be licensed, be used or occupied by any person or entity other than Subtenant or be encumbered in any manner by reason of any act or omission on the part of Subtenant, and no rents or other sums receivable by Subtenant under any sublease of all or any part of the Premises shall be assigned or otherwise encumbered, without the prior consent of Sublandlord and Prime Landlord (to the extent required under the Lease). Except as otherwise set forth in this Section 9, the dissolution or direct or indirect transfer of control of Subtenant or withdrawal of existing partners or members, shall be deemed an assignment of this Sublease regardless of whether the transfer is made by one or more transactions, if one or more persons or entities hold the controlling interest prior to the transfer or afterwards. An agreement under which another person or entity becomes responsible for all or a portion of Subtenant's obligations under this Sublease shall be deemed an assignment of this Sublease; provided, however, that in no event shall receipt of funds by Subtenant from common funding sources or sponsors of Subtenant in the ordinary course of its business, such as a governmental authority, be deemed an assignment or a violation of this Sublease. No assignment or other transfer of this Sublease and the term and estate hereby granted, and no subletting of all or any portion of the Premises shall relieve Subtenant of its liability under this Sublease or of the obligation to obtain Sublandlord's and Prime Landlord's prior consent (to the extent required under

the Lease) to any further assignment, other transfer or subletting. Notwithstanding anything contained herein to the contrary, any proposed assignment, further subletting or other transfer of this Sublease, or the term and estate hereby granted remain subject to all rights and restrictions under Article 8 of the Original Lease (whether or not such terms thereof are incorporated herein). Any attempt to assign this Sublease or sublet all or any portion of the Premises in violation of this Section 9 shall be null and void.

(1) *No Sublandlord Consent Required for Mergers and Certain Purchases.* Notwithstanding Section 9(a)(1), without the consent of Sublandlord (and without Prime Landlord's consent if not required under the Lease) this Sublease may be assigned to (A) an entity created by merger, reorganization or recapitalization of or with Subtenant or (B) a purchaser of all or substantially all of Subtenant's assets or ownership interests; provided, in the case of both clause (A) and clause (B), that (i) Sublandlord shall have received a notice of such assignment from Subtenant (if Subtenant is prohibited from disclosing such transaction by confidentiality agreement, then Subtenant shall advise Sublandlord as soon as reasonably practicable once it is permitted to disclose); (ii) the assignee assumes by written instrument reasonably satisfactory to Sublandlord all of Subtenant's obligations under this Sublease from and after such assignment (provided, however, to the extent Additional Rent has not been billed yet, the assignee shall assume payment for same), (iii) such assignment is for a valid business purpose and not to avoid any obligations under this Sublease, (iv) the assignee shall not have or enjoy diplomatic immunity, (v) in Sublandlord's reasonable judgement, the assignee is a reputable entity of good character, and (vi) the assignee shall have, immediately after giving effect to such assignment, an aggregate net worth (computed in accordance with GAAP) at least equal to Subtenant's aggregate net worth (taking into account the percentage of the Premises the assignee will be taking); and the assignee shall have, immediately after giving effect to such assignment, at least [*****] in cash and liquidity (which [*****] threshold shall be reduced proportionately if the assignee is not taking the full Premises). It is agreed that no such assignment shall relieve Subtenant of its liability under this Sublease.

(2) *No Sublandlord Consent Required for Transfers to Affiliates*. Notwithstanding Section 9(a)(1), without the consent of Sublandlord (and without Prime Landlord's consent to the extent not required under the Lease) Subtenant may assign this Sublease or sublet or permit the occupancy of all or part of the Premises to an Affiliate of Subtenant; provided, that (A) Sublandlord shall have received a notice of such assignment or sublease from Subtenant (if Subtenant is prohibited from disclosing such transaction by confidentiality agreement, then Subtenant shall advise Sublandlord as soon as reasonably practicable once it is permitted to disclose); and (B) in the case of any such assignment or sublease, (i) the assignment or sublease is for a valid business purpose and not to avoid any obligations under this Sublease, (ii) the assignee assumes by written instrument reasonably satisfactory to Sublandlord all of Subtenant's obligations under this Sublease from and after the date of the assignment, (iii) in Sublandlord's reasonable judgment, the assignee or sublessee is a reputable entity of good character, (iv) the assignee or sublessee shall not have or enjoy diplomatic immunity, (v) the assignee or sublessee shall have, immediately after giving effect to such assignment or sublease, an aggregate net worth (computed in accordance with GAAP) at least equal to the Subtenant's aggregate net worth (taking into account the percentage of the Premises the assignee or subtenant will be taking), and (vi) the assignee or sublessee shall have, immediately after giving effect to such assignment or sublease, at least [*****] in cash and liquidity, which [*****] threshold shall be reduced proportionately if the assignee or subtenant is not taking the full Premises. "**Affiliate**"

means, as to any designated person or entity, any other person or entity which controls, is controlled by, or is under common control with, such designated person or entity. "**Control**" (and with correlative meaning, "controlled by" and "under common control with") means the ownership, directly or indirectly, of at least fifty-one (51%) percent or more of the outstanding stock if a corporation, or other equity interest if not a corporation, or the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such entity, whether through the ownership of voting securities or by contract or otherwise. It is agreed that no such assignment or sublease shall relieve Subtenant of its liability under this Sublease.

(3) Notwithstanding the foregoing, no assignment or sublease referred to in Section 9(a)(2) and (3) shall be effective if Subtenant is then in default under this Sublease beyond any applicable notice, grace and/or cure period.

(4) Intentionally Omitted.

(5) Sublandlord agrees to request Prime Landlord's consent to an assignment, sub-sublease or license affirmatively.

(6) Intentionally omitted.

(b) *Sublandlord's Rights*. Anything contained in the Lease to the contrary notwithstanding, if Subtenant desires to assign this Sublease or sublet all or substantially all of the Premises for all or substantially all of the balance of the Sublease Term (other than in accordance with Section 9(a)(2) and (3)), prior to requesting Prime Landlord or Sublandlord's consent, as applicable, Subtenant shall give to Sublandlord notice ("**Subtenant's Offer Notice**") thereof, and Sublandlord agrees to keep such potential assignment or subletting confidential (other than with respect to Sublandlord's officers, directors, counsel, consultants, lenders and other advisors who need to know such terms for purposes of evaluating the proposed assignment or sublease) if so requested by Subtenant. The Subtenant's Offer Notice shall specify (A) in the case of a proposed subletting, (i) the term of the subletting of such space, (ii) the fixed annual rent which Subtenant desires to receive for such proposed subletting and, (iii) the proposed commencement date, and (B) in the case of a proposed assignment, (i) Subtenant's good faith offer of the consideration Subtenant desires to receive or pay for such assignment and (ii) the proposed assignment commencement date.

(1) Subtenant's Offer Notice shall be deemed an offer from Subtenant to Sublandlord whereby Sublandlord may, at Sublandlord's sole option, terminate this Sublease. Said option may be exercised by Sublandlord by delivery of an irrevocable notice to Subtenant within thirty (30) days after Sublandlord's receipt of Subtenant's Offer Notice. If Sublandlord fails to exercise the option to terminate within such thirty (30) day period, time being of the essence, Sublandlord shall be deemed to have waived its right to terminate.

(2) If Sublandlord exercises its option under Section 9(b)(2) to terminate this Sublease, this Sublease shall be deemed to have been terminated as of the proposed commencement date set forth in Subtenant's Offer Notice as if such date were the Expiration Date and all Fixed Rent and Additional Rent owed by Subtenant hereunder shall be paid and apportioned as of such date.

(3) In the event Sublandlord does not exercise its option to terminate under Section 9(b) hereof or is deemed to have waived same, in the case of a proposed sublease of all or substantially all of the Premises for all or substantially all of the balance of the Sublease Term, Subtenant shall not sublet any space at a rental which is less (on a per rentable square foot basis) than [*****] of the net effective rental specified in Subtenant's Offer Notice with respect to such space, without complying once again with the provisions of Section 9(b)(1) and (2). In the case of a proposed assignment, Subtenant shall not assign this Sublease where the total consideration paid for such assignment is less than [*****] of the total consideration specified in Subtenant's Offer Notice. If Sublandlord does not timely exercise its option or is deemed to have waived such option set forth in Section 9(b)(2), and Subtenant fails to execute and deliver an assignment or sublease within 180 days after the giving of the relevant Subtenant's Offer Notice, then Subtenant shall again comply with Section 9(b)(1) and (2) before assigning this Sublease or subletting all or substantially all of the Premises for all or substantially all of the balance of the Sublease Term.

(c) *Assignment and Subletting Procedures*. (1) If (1) Subtenant delivers to Sublandlord a Subtenant's Offer Notice with respect to any proposed assignment of this Sublease or subletting of all or substantially all of the Premises for all or substantially all of the balance of the Sublease Term and Sublandlord does not timely exercise its option to terminate or is deemed to have waived such option under Section 9(b)(2), and Subtenant thereafter desires to assign this Sublease or sublet the Premises or any portion thereof, or (2) Subtenant desires to assign this Sublease or sublet the Premises or any portion thereof where no Subtenant's Offer Notice is required (other than with respect to an assignment or sublease pursuant to Section 9(a)(1) or (2) or (3)), Subtenant shall notify Sublandlord (a "**Transfer Notice**") of such desire, which notice shall be accompanied by (A) a copy of either, at Subtenant's option, (v) an agreed upon term sheet containing all of the material business terms of the proposed assignment or sublease and all related agreements, or (w) the proposed assignment or sublease and all related agreements, and in the case of (v) or (w), the effective date of which shall be at least thirty (30) days after the giving of the Transfer Notice, (B) the identity of the proposed assignee or subtenant, the nature of its business and its proposed use of the Premises, (C) current financial information with respect to the proposed assignee or subtenant, including without limitation, its most recent financial reports, (and Sublandlord agrees to sign a Non-Disclosure Agreement in form reasonably acceptable to Sublandlord and such assignee or sublessee with respect to such financial reports) and (D) such other information as Sublandlord may reasonably request, which Subtenant shall provide within five (5) days of such request, and Sublandlord's consent to the proposed assignment or sublease shall not be unreasonably withheld, conditioned or delayed (said option may be exercised by Sublandlord by delivery of an irrevocable notice to Subtenant within thirty (30) days after Sublandlord's receipt of Subtenant's Transfer Notice; provided Subtenant has delivered all additional information Sublandlord has requested within the aforementioned five (5) day period). If Sublandlord fails to consent or deny consent within such thirty (30) day period, Subtenant shall send Sublandlord a second Transfer Notice, which shall include, in 12 point capital letters, a statement that if Sublandlord does not respond within ten (10) days of the receipt of the Second Transfer Notice, time being of the essence, Sublandlord's consent shall be deemed given. The parties agree that Subtenant shall have the right to simultaneously submit a Subtenant's Offer

Notice and Transfer Notice. If Sublandlord does not respond within such ten (10) day period, Sublandlord shall be deemed to have consented thereto, provided that:

(i) Subtenant is not then in monetary default under this Sublease in the payment of Fixed Rent or Additional Rent beyond any applicable notice and cure period (and if such a default exists, then as soon as such default is cured).

(ii) Such Transfer Notice shall be delivered to Sublandlord within six (6) months after the delivery to Sublandlord of any applicable Subtenant's Offer Notice.

(iii) In Sublandlord's reasonable judgment, the proposed assignee or subtenant will use the Premises in a manner that (x) is in keeping with the then standards of the Building, and (y) is limited to the use expressly permitted under this Sublease.

(iv) The proposed assignee or subtenant is, in Sublandlord's reasonable judgment, a reputable person or entity of good character and with sufficient financial worth to make the required payments under such assignment or sublease.

(v) Neither the proposed assignee or subtenant, nor any Affiliate of such assignee or subtenant, is then an occupant of any part of the Prime Leased Premises or the Building provided that Sublandlord has comparable space available in the Prime Leased Premises for a comparable term or Prime Landlord has comparable space available in the Building for a comparable term.

(vi) The proposed assignee or subtenant is not a person with whom Sublandlord or Prime Landlord is then negotiating or has within the prior six (6) months negotiated to lease comparable space for a comparable term in the Prime Leased Premises or the Building.

(vii) Neither the proposed assignee or subtenant is a Specific Competitor as listed on the attached Exhibit G.

(viii) The form of the proposed assignment or sublease shall comply with the applicable provisions of this Section 9 and Subtenant shall deliver a fully executed copy of the Sublease to Sublandlord within ten (10) days of the full execution.

(ix) There shall not be more than four (4) rental units in the Premises.

(x) Subtenant shall promptly reimburse Sublandlord for any actual reasonable out-of-pocket costs actually incurred by Sublandlord in connection with Sublandlord's review of said proposed assignment or sublease, including, without limitation, the costs of making investigations as to the acceptability of the proposed assignee or subtenant, and reasonable legal costs incurred in connection with the granting of any requested consent.

(xi) The proposed assignee or subtenant shall not have or enjoy diplomatic immunity.

(2) Intentionally Omitted.

(3) If Sublandlord consents and Subtenant fails to execute and deliver the assignment or sublease to which Sublandlord consented within one hundred twenty (120) days after the giving of such consent, then Subtenant shall again comply with this Section 9 before assigning this Sublease or subletting all or part of the Premises.

(d) *General Provisions*. If this Sublease is assigned, whether or not in violation of this Sublease, Sublandlord may collect rent from the assignee. If the Premises or any part thereof is sublet or occupied by anybody other than Subtenant, whether or not in violation of this Sublease, Sublandlord may, after default by Subtenant, and expiration of Subtenant's time to cure such default, collect rent from the subtenant or occupant. In either event, Sublandlord shall apply the net amount collected against Fixed Rent, but no such assignment, subletting, occupancy or collection shall be deemed a waiver of any of the provisions of Section 9(a)(1), or the acceptance of the assignee, subtenant or occupant as tenant, or a release of Subtenant from the performance of Subtenant's obligations under this Sublease.

(1) No assignment or transfer (other than as provided in Section 9(a)(2) and (3) hereof) shall be effective (unless by operation of law) until the assignee delivers to Sublandlord (A) evidence that the assignee, as Subtenant hereunder, has complied with the requirements of Section 13 (Insurance) hereof, and (B) an agreement in form and substance reasonably satisfactory to Sublandlord whereby the assignee assumes Subtenant's obligations under this Sublease from and after the date of the assignment (except as specifically set forth above).

(2) Notwithstanding any assignment or transfer, whether or not in violation of this Sublease, and notwithstanding the acceptance of any Fixed Rent or Additional Rent, by Sublandlord from an assignee, transferee, or any other party, the original named Subtenant and each permitted assignee or transferee shall remain fully liable for the payment of the Rent and the performance of all of Subtenant's other obligations under this Sublease. The joint and several liability of Subtenant and any immediate or remote successor in interest of Subtenant shall not be discharged, released or impaired in any respect by any agreement made by Sublandlord extending the time to perform, or otherwise modifying, any of the obligations of Subtenant under this Sublease, or by any waiver or failure of Sublandlord to enforce any of the obligations of Subtenant under this Sublease. If any such amendment between Sublandlord and a sub-subtenant or assignee to this Sublease operates to increase the obligations or liabilities of Subtenant under this Sublease, the liability under this Section 9(d)(3) of the assigning Subtenant shall continue to be no greater than if such amendment had not been made (unless such party shall have expressly consented in writing to such amendment, or the assignee shall be an Affiliate of Subtenant).

(3) Each subletting by Subtenant shall be subject to the following:

(A) No subletting shall be for a term (including any renewal or extension options contained in the sublease) ending later than one day prior to the Expiration Date.

(B) No sublease shall be valid (other than as provided in Section 9(a)(2) and (3) hereof), and no subtenant shall take possession of the Premises or any part thereof, until there has been delivered to Sublandlord, both (i) an executed counterpart of such sublease, and (ii) a certificate of insurance evidencing that (x)

Sublandlord is an additional insured under the insurance policies required to be maintained by occupants of the Premises pursuant to Section 13 of this Sublease, and (y) there is in full force and effect, the insurance otherwise required pursuant to Section 13 of this Sublease.

(C) Subject to any SNDA, each sublease shall provide that it is subject and subordinate to this Sublease and the matters to which this Sublease is or shall be subordinate to, and that in the event of termination, reentry or dispossess by Sublandlord under this Sublease Sublandlord may, at its option, either terminate such sublease or take over all of the right, title and interest of Subtenant, as sublessor, under such sublease, and such subtenant shall, at Sublandlord's option, attorn to Sublandlord pursuant to the then executory provisions of such sublease

(D) Each sublease shall include an express obligation that all subtenants and other occupants of any portion of the Premises must comply with the Information Security Handbook issued by the Port Authority, as the same may be modified or supplemented from time to time and all rules and regulations of the Building.

(4) Each sublease shall provide that the subtenant may not assign its rights thereunder or further sublet the space demised under the sublease, in whole or in part, without Sublandlord's consent and without complying with all of the terms and conditions of this Section 9.

(5) Subtenant shall not advertise (but may list with brokers) its space for assignment or subletting at a rental rate lower than the then Building rental rate for such space.

(6) Subject to the terms of Original Lease Section 8.01B and Sublease Sections 9(a)(2) and (3) hereof, Subtenant shall not, without the consent of Prime Landlord and Sublandlord (to be granted or denied in accordance with Original Lease Article 8 and Sublease Section 9), transfer a majority of its issued and outstanding capital stock (if a corporation) or a majority of its total equity interest (if a partnership or limited liability company) (not including transfers to a Successor), however accomplished, and whether in a single transaction or in a series of related or unrelated transactions, if the primary purpose of such transfer is to transfer this Sublease or the use of the Premises. The transfer of outstanding capital stock of any corporate subtenant, for purposes of this Section, shall not include (and such transaction shall not be deemed an assignment of this Sublease or a sub-sublease) any sale of such stock which is effected through "over-the-counter market" or through any recognized stock exchange or any sale of such stock pursuant to the registration requirements of the Securities Act of 1933, as amended or any exemption therefrom (such sales of stock hereinafter referred to as "**Permitted Stock Transfers**"). Sublandlord and Prime Landlord shall not be entitled to recapture the Premises covered by such Permitted Stock Transfers nor to receive any portion of any profits received by Subtenant in connection with Permitted Stock Transfers.

(e) *Assignment and Sublease Profits*. If the aggregate of the amounts payable as fixed rent and as additional rent on account of PILOT expenses, CAM Expenses, Expenses and electricity by a subtenant under a sublease of all or any part of the Premises and the amount of any

Other Sublease Consideration payable to Subtenant by such subtenant, whether received in a lump-sum payment or otherwise shall be in excess of Subtenant's Basic Cost therefor at that time then, after deducting Subtenant's Basic Costs on a "first out" basis with respect to such sublease, promptly after the collection thereof, Subtenant shall pay to Sublandlord in monthly installments as and when collected, as Additional Rent, [*****] of such excess. In addition to the foregoing, if Subtenant assigns this Sublease or sub-subleases all or any portion of the Premises during the Free Rent Period and/or up to [*****] RSF in the aggregate during the Partial Free Rent Period, in calculating [*****] of the excess as set forth above, during the (i) Free Rent Period of the Term, the amount of Fixed Rent paid by Subtenant shall be [*****] and (ii) during the Partial Free Rent Period of the Term, the amount of Fixed Rent paid by Subtenant shall be [*****] for the first [*****] rentable square feet subleased or assigned space. Upon request of Sublandlord (no more frequently than once per calendar year), Subtenant shall deliver to Sublandlord within 60 days of such request, a statement specifying each sublease in effect during such calendar year or partial calendar, the rentable area demised thereby, the term thereof and a computation in reasonable detail showing the calculation of the amounts paid and payable by the subtenant to Subtenant, and by Subtenant to Sublandlord, with respect to such sublease for the period covered by such statement. "**Subtenant's Basic Cost**" for sublet space at any time means the sum of (A) the portion of the Fixed Rent, PILOT payments, Expense payments and CAM payments which is attributable to the sublet space, plus (B) the amount payable by Subtenant on account of electricity in respect of the sublet space, plus (C) the amount of any costs reasonably incurred by Subtenant in making changes in the layout and finish of the sublet space for the subtenant and/or all rent concessions and work allowances paid or incurred in connection with such sublease, plus (D) the amount of any advertising expenses, customary brokerage commissions and reasonable legal fees paid by Subtenant in connection with the sublease. "**Other Sublease Considerations**" means all sums paid for the furnishing of services by Subtenant, after deducting the reasonable costs actually incurred by Subtenant to deliver such services, and the sale or rental of Subtenant's fixtures, leasehold improvements, equipment, furniture or other personal property less, in the case of the sale thereof, the then net unamortized or undepreciated cost thereof determined on the basis of Subtenant's federal income tax returns. Upon any assignment of this Sublease, Subtenant shall pay to Sublandlord [*****] of the Assignment Consideration received by Subtenant for such assignment, after deducting therefrom customary and reasonable closing expenses. "**Assignment Consideration**" means an amount equal to all sums and other considerations paid to Subtenant by the assignee for or by reason of such assignment (including, without limitation, sums paid for the furnishing of services by Subtenant, after deducting the reasonable costs actually incurred by Subtenant to deliver such services), and the sale or rental of Subtenant's fixtures, leasehold improvements, equipment, furniture, furnishings or other personal property, less, (i) in the case of a sale thereof, the then net unamortized or undepreciated cost thereof determined on the basis of Subtenant's federal income tax returns and (ii) the cost of any reasonable advertising expenses, brokerage fees, legal fees and any other concessions or fees actually incurred by Subtenant in connection with such assignment.

(f) *Subleasing or Assignment to Competitors of Sublandlord.* Notwithstanding anything contained in this Sublease to the contrary, Subtenant shall not be permitted to sublease the Premises or assign this Sublease to a Specific Competitor of Sublandlord as defined in Exhibit G.

(g) *Permitted Occupants*. In addition to the space occupied by the entities described in Section 9(a)(2) and (3) hereof, to the extent permitted under the Lease, Subtenant may permit up to [*****] in the aggregate of the Premises to be occupied on a temporary basis, at any time and from time to time, by any clients, agents, guests, or independent contractors of Subtenant (such persons who shall be permitted to occupy portions of the Premises pursuant to this Section 9(g) being hereinafter referred to as "**Permitted Occupant**," or collectively as the "**Permitted Occupants**"), without the consent, recapture and profit splitting rights of Sublandlord and Prime Landlord, provided that (i) the portion of the Premises occupied by any such occupant and the portion of the Premises occupied by Subtenant shall not be separated by demising walls , (ii) there shall be no separate identification of such Permitted Occupants in the Main Lobby, the Below Grade Public Lobby or the Subgrade Lobby, (iii) Subtenant shall receive no rent, payment or other consideration in connection with such occupancy in excess of the pro rata portion of the rent payable by Subtenant hereunder in respect of such space other than any nominal rent payments or other consideration for actual services rendered or provided by or for such occupant, (iv) the Permitted Occupants shall use the Premises in conformity with all of the applicable provisions of this Sublease and (v) Subtenant shall send written notice to Sublandlord prior to any occupancy that will exceed three (3) continuous days.

10. Subtenant to look to Prime Landlord for All Services. (a) Notwithstanding anything contained in this Sublease to the contrary (including, without limitation, any provision of the Lease incorporated herein by reference), Sublandlord shall have no obligation to (1) perform or provide any services under this Sublease (including, without limitation, the providing of electrical energy, condenser water or other utilities, passenger and freight elevator and loading dock service, window washing, HVAC, cleaning, rubbish removal, hot and cold water, security, fire protection and life safety and sprinkler services), (2) make any repairs or restorations to the Premises, (3) comply with any laws or requirements of any governmental authorities, (4) provide any insurance with respect to the Building, the Premises, or the improvements therein, (5) remove, encapsulate or otherwise treat any asbestos-containing materials or other Hazardous Materials located in the Premises and/or the Building (unless Sublandlord has breached the Lease regarding same), or (5) take any other action that Prime Landlord is obligated to provide, make, comply with or take, or cause to be done, under the Lease (collectively, "**Services**") and the only Services or rights to which Subtenant is entitled under this Sublease, including, without limitation, any right to repairs, electrical energy, condenser water or other utilities, passenger and freight elevator and loading dock service, window washing, HVAC, cleaning, rubbish removal, hot and cold water, security, fire protection and life safety and sprinkler services, are those to which Sublandlord is entitled as the tenant under the Lease, and for all such Services and rights, Subtenant will look solely to Prime Landlord, subject to the terms and conditions of the Lease (and it being understood and agreed that the provisions of Section 10(b) of this Sublease shall apply to the enforcement of the Lease). Sublandlord assumes no liability for any covenants, representations or warranties made by Prime Landlord under the Lease. Sublandlord hereby grants to Subtenant Sublandlord's rights under the Lease with respect to Services provided by Prime Landlord to the extent that Sublandlord is entitled to receive same under the Lease and to grant same to Subtenant. Sublandlord shall take all reasonable steps to assist Subtenant as Subtenant may from time-to-time request, at Subtenant's sole cost and expense (and provided Subtenant indemnifies Sublandlord in connection therewith and in connection with the enforcement of this indemnity) and without liability to Sublandlord in seeking Services from Prime Landlord (including, without limitation, forwarding any requests for Services to Prime Landlord if Prime Landlord will not accept such requests from Subtenant

directly), subject to Section 10(b) hereof. Except as provided in this Section 10, under no circumstances, shall Sublandlord be required to bring or cooperate with any action or proceeding against Prime Landlord. Nothing contained in this Sublease shall be deemed a waiver of Sublandlord's rights to receive Services from Prime Landlord. Sublandlord shall in no event be liable to Subtenant for any failure to render any of the Services, nor shall any such failure entitle Subtenant to any abatement or reduction in Fixed Rent or Additional Rent payable under this Sublease or to any right to terminate this Sublease, except to the extent (if any) that (i) the same results primarily or proximately from Sublandlord's willful misconduct, negligence or default under the Lease, or (ii) there is an abatement of rent under the Lease with respect to the Premises, or (iii) except as otherwise expressly provided herein (e.g., Sublandlord's indemnity). Sublandlord consents to Subtenant's making requests for overtime services and standard building services for or in respect of all or any portion of the Premises directly to Prime Landlord, provided that Subtenant delivers a notice concurrently to Sublandlord (and that Subtenant pays for such services in accordance with Section 3 hereof).

(b) *Enforcement of Prime Lease.* If the Prime Landlord shall default in any of its obligations to Sublandlord with respect to the Premises, Sublandlord shall not, except as and to the extent hereinafter set forth, be obligated to bring any action or proceeding or to take any steps to enforce Sublandlord's rights against Prime Landlord other than, upon the written request of Subtenant, making a demand upon the Prime Landlord to perform its obligations under the Lease with respect to the Premises. If following the making of such demand and the expiration of any applicable grace period granted to Prime Landlord under the Lease, Prime Landlord shall fail to perform its obligations under the Lease, or Sublandlord shall fail or refuse to take appropriate action for the enforcement of Sublandlord's rights against Prime Landlord with respect to the Premises within a reasonable period of time (considering, inter alia, the nature of Prime Landlord's default), then Subtenant shall have the right to take such action in its own name, and for that purpose and only to such extent, all of the rights of Sublandlord under the Lease hereby are conferred upon and assigned to Subtenant and Subtenant hereby is subrogated to such rights to the extent that the same shall apply to the Premises. If (a) any such action against the Prime Landlord in Subtenant's name is barred by reason of lack of privity, non-assignability or otherwise, and (b) the failure of Prime Landlord to perform its obligations under the Lease has, or may have, an adverse effect upon the Premises or Subtenant's permitted use thereof, then subject to and upon the following terms, Subtenant may bring such action in Sublandlord's name and Sublandlord shall execute all documents reasonably required in connection therewith, provided (i) the same is without cost and expense to Sublandlord, (ii) Subtenant shall provide the indemnification to Sublandlord required pursuant to Section 13 hereof, and (iii) Subtenant is not in default hereunder beyond applicable notice and cure periods, (iv) Subtenant shall use legal counsel reasonably acceptable to Sublandlord and all documents or other filings shall be subject to Sublandlord's approval and (v) Subtenant has obtained the prior written consent of Sublandlord, which consent shall not be unreasonably withheld, conditioned, or delayed.

11. Broker. Subtenant and Sublandlord each represent to the other that it has dealt with no broker in connection with this transaction except Jones Lang LaSalle Brokerage, Inc. ("**JLL**" "**Broker**"). Subtenant shall indemnify and hold Sublandlord and Prime Landlord harmless from all costs, liabilities and expenses (including, without limitation, reasonable attorney's fees and disbursements and the enforcement of this indemnity) arising from any claim for brokerage commission made by any party other than Broker claiming to act for or on behalf of Subtenant in

this transaction. Sublandlord shall indemnify and hold Subtenant and Prime Landlord harmless from all costs, liabilities and expenses (including, without limitation, reasonable attorney's fees and disbursements and the enforcement of this indemnity) arising from any claim for brokerage commission made by any party including Broker claiming to act for or on behalf of Sublandlord in connection with this transaction. Subtenant shall not be liable for payment of the commission due to Broker in connection with this transaction which commission shall be payable pursuant to a separate agreement by Sublandlord. Sublandlord shall not be liable for any commission payable with respect to Subtenant's lease of the Premises or leasing of any other space in the Building from Prime Landlord subsequent to the term. The provisions of this Section 11 shall survive the termination of this Sublease.

12. Holdover. *Holdover Rental Rate*. Upon the expiration or other termination of the Term, including the early termination of the Term pursuant to Subtenant exercising its Termination Option (as hereinafter defined), Subtenant shall quit and surrender the Premises, (i) and remove all Alterations, including Specialty Alterations installed by Subtenant in compliance with Section 21(a) and (h) hereof, repair any damage caused thereby and otherwise restore the Premises to its condition before such Alterations were made, and (ii) as otherwise provided in the Lease. Subject to Section 21(a) and (h) hereof and the Lease, Subtenant acknowledges that it shall be required to remove all Specialty Alterations installed by Subtenant and to repair any damage caused thereby. Alterations installed by Subtenant shall be required to be removed and restored by the Expiration Date pursuant to the terms of the Lease and Section 21(a) and (h) hereof. Notwithstanding the foregoing, Subtenant shall not be required to remove any Alteration (i) if it is a Decorative Alteration or (ii) if Sublandlord, at the time Subtenant requested consent to make such Alteration, agreed that Subtenant need not remove such Alteration. The parties recognize and agree that the damage to Sublandlord resulting from any failure by Subtenant to timely surrender possession of the Premises as aforesaid will be substantial and will exceed the amount of monthly rent theretofore payable hereunder and will be impossible to accurately measure. Subtenant agrees that if possession of the Premises is not surrendered to Sublandlord upon the expiration or sooner termination of the Term, then notwithstanding anything to the contrary contained in this Sublease, Subtenant shall be considered a tenant at sufferance and shall pay as a holdover rental (1) for the first month of the holdover month-to-month tenancy, an amount equal to 150% of the Fixed Rent which Subtenant was obligated to pay for the month immediately preceding the end of the Term plus one-twelfth (1/12) of all items of annual Additional Rent which would have been payable monthly pursuant to this Sublease had its term not expired or been terminated, (2) for the second and third months of the holdover month-to-month tenancy, an amount equal to 175% of the Fixed Rent which Subtenant was obligated to pay for the month immediately preceding the end of the Term plus one-twelfth (1/12) of all items of annual Additional Rent which would have been payable monthly pursuant to this Sublease had its term not expired or been terminated, and (3) for all other months of the holdover month-to-month tenancy thereafter, an amount equal to 200% of the Fixed Rent which Subtenant was obligated to pay for the month immediately preceding the end of the Term plus one-twelfth (1/12) of all items of annual Additional Rent which would have been payable monthly pursuant to this Sublease had its term not expired or been terminated.

(a) *Subtenant Indemnity*. Furthermore, if Subtenant holds over beyond the termination of the Term, then Subtenant shall be liable for all holdover rent, charges, fees, indemnities, holdover damages and other amounts owed by Sublandlord to Prime Landlord in

respect of such holding over pursuant to the Lease or otherwise, including, without limitation, pursuant to Article 22.02 of the Original Lease, but only to the extent such amounts exceed the amounts due and payable under clause (a) above. In addition to the amounts described above, if Subtenant holds over beyond the termination of the Term, Subtenant shall be liable to Sublandlord for and indemnify and hold Sublandlord harmless against (i) any payment or rent concession that Sublandlord may be required to make to any subtenant obtained by Sublandlord for all or any part of the Premises (a "**New Subtenant**") by reason of the late delivery of space to the New Subtenant as a result of Subtenant's holding over or in order to induce such New Subtenant not to terminate its sublease by reason of the holding over by Subtenant, (ii) the loss of the benefit of the bargain if any New Subtenant shall terminate its sublease by reason of the holding over by Subtenant and (iii) any claim for damages by any New Subtenant. Subtenant shall defend, indemnify and hold Sublandlord harmless from and against all losses, costs, (including reasonable attorney's fees and the enforcement of this indemnity) and damages (including consequential damages and lost profits) arising out of or relating solely to the holding over by the Subtenant in the Premises and arising after the earlier of (1) November 30, 2039, (2) the termination of this Sublease as a result of a default by Subtenant hereunder and (3) the date that is six (6) months after the date a notice of termination is delivered to Subtenant pursuant to the provisions of Section 12(c) below. Notwithstanding anything to the contrary contained herein, if Sublandlord or Sublandlord's other subtenants (if any) are also holding over in portions of the Prime Leased Premises and such holdover also delays delivery to Prime Landlord or another subtenant, then the indemnity under this Section 12(a) and (b) shall take such concurrent holdover into account (as applicable) for so long as it shall exist, based on the duration thereof and the relative sizes of spaces in which such concurrent holdover is occurring (but, in the case of holdover by other subtenants, such taking into account shall apply only to the extent of amounts actually collected from such other subtenants).

(b) *Holdover upon Casualty*. In the event of a casualty or condemnation for which Sublandlord or Prime Landlord has the right under the Lease to terminate the Lease in its entirety or with respect to the Premises and Sublandlord or Prime Landlord elects to so terminate, Sublandlord shall deliver written notice to Subtenant of such election, specifying the date of termination of this Sublease, which date shall in no event be prior to the date that is six (6) months from the date of such notice. If Subtenant does not vacate the Premises within such six (6) month period, Subtenant shall be considered a month-to-month tenant and shall be liable for the payment of holdover rent and damages as specified in this Section 12.

(c) *Waiver*. Notwithstanding anything herein to the contrary, the parties absolutely and unconditionally waive any and all rights to dispute or otherwise adjudicate whether the remedies set forth in this Section 12 constitute a penalty or are otherwise unenforceable, such waiver being a material inducement to Sublandlord to enter into this Sublease and to accept the terms of this Sublease.

(d) *Sublandlord Indemnity.* Sublandlord shall indemnify Subtenant against, and hold Subtenant harmless from, all liabilities, losses, obligations, damages, penalties, claims, costs and expenses (including, without limitation, attorneys' fees and other costs) which are paid, suffered or incurred by Subtenant as a result of (i) the failure of any representation or warranty of Sublandlord set forth in this Sublease to be true, correct or complete in any material respect when made, or (ii) the nonperformance or nonobservance of any such terms, provisions, covenants, stipulations, conditions, obligations or agreements by Sublandlord, except to the extent arising

from the negligence or willful misconduct of Subtenant. The provisions of this Section 12(e) shall survive the expiration or earlier termination of this Sublease.

13. Insurance. Subtenant, at Subtenant's sole cost and expense, shall throughout the Term, maintain all property, liability and other insurance required by the provisions of the Lease incorporated herein by reference (including, without limitation, Article 16 of the Original Lease) in accordance therewith. Without limiting the provisions of Article 16.01(A) of the Original Lease incorporated herein by reference, Subtenant shall indemnify the Landlord Parties (as such term is defined in the Lease without incorporation herein by reference) to the same extent that Sublandlord is required to indemnify the Landlord Parties pursuant to Article 16.01(A) of the Original Lease. On or prior to the Commencement Date, Subtenant shall deliver to Sublandlord certificates of insurance naming Sublandlord, Prime Landlord and such other parties as are required to be named pursuant to the Lease as additional insureds. If the certificates of insurance provided by Subtenant do not evidence the provisions required by Article 16.04 of the Original Lease, Subtenant shall permit Sublandlord and Prime Landlord to review a copy of its insurance policies at reasonable times on reasonable prior notice (and subject to the parties signing a reasonable confidentiality agreement with respect to such review), which copies may contain reasonable redactions, to confirm that the policies contain such required provisions.

14. Premises Condition. Subtenant shall accept the Premises "as is," on the Commencement Date without any warranty or recourse to Sublandlord, subject to the following:

(a) *Delivery of Possession*. Sublandlord, at its cost, shall deliver the Premises to Subtenant broom clean, vacant and, to Sublandlord's actual knowledge, in compliance with Legal Requirements, and with all of Sublandlord's personal property and all other personal property other than the FF&E (as hereinafter defined) removed, and Sublandlord's Work (as defined on Exhibit D) substantially completed (all of the items in this Section 14(a) are collectively called the "**Premises Condition**").

(b) *No Sublandlord Obligation to Perform Alterations*. Other than as specifically set forth on Exhibit D, annexed hereto and made a part hereof, and the Premises Condition, Sublandlord shall have no obligation to perform any alterations, work or repairs on behalf of Subtenant or contribute any sums toward same (other than the Work Allowance as hereinafter defined).

(c) *No Reps or Warranties as to Physical Condition*. Except as otherwise expressly provided herein, Subtenant acknowledges that, no representations or warranties at to the condition of the Premises, the use to which the Premises may be put, or with respect to the condition or usefulness of any fixtures, equipment or furnishings therein contained, have been made to Subtenant.

15. Merger. All prior understandings and agreements between the parties are merged within this Sublease, which alone fully and completely sets forth the understanding of the parties. This Sublease may not be changed or terminated orally or in any manner other than by an

agreement in writing and signed by the party against whom enforcement of the change or termination is sought.

16. Notices. All notices, demands, consents, approvals, waivers or other communications which may or are required to be given by either party to the other under this Sublease (each, "**Notice**") shall be in writing and shall be delivered by (a) personal delivery; (b) the United States mail, certified or registered, postage prepaid, return receipt requested; or (c) a nationally recognized overnight courier, in each case addressed to the party to be notified at the address for such party specified below or to such other place as the party to be notified may from time to time designate by at least 5 days' notice to the notifying party. Notices from either party may be given by such party's attorney. Each Notice shall be deemed to have been given on the date such Notice is actually received as evidenced by a written receipt therefor, and in the event of failure to deliver by reason of changed address of which no Notice was given or refusal to accept delivery, as of the date of such failure.

If to Sublandlord:

Advance Magazine Publishers Inc.
One World Trade Center
New York, New York 10007
Attn: Chief Executive Officer

with a copy to:

Advance Magazine Publishers Inc.
One World Trade Center
New York, New York 10007
Attn: Managing Director-Real Estate

and

Advance Finance Group
One World Trade Center
New York, New York 10007
Attn: Chief Financial Officer

and

Advance Legal
One World Trade Center
New York, New York 10007
Attn: Real Estate Dept.

If to Subtenant:

Prior to the Commencement Date:

Axsome Therapeutics, Inc.
22 Cortlandt St, 16th floor
New York, NY 10007
Attn: Nick Pizzie, Chief Financial Officer

With a copy to:

Axsome Therapeutics, Inc.
22 Cortlandt St, 16th floor
New York, NY 10007
Attn: Hunter Murdock, General Counsel

and in each case with a copy of any default notice to:

Morgan Lewis Bockius LLP
101 Park Avenue
New York, New York 10178
Attn: J. Goodwin Bland, Esq.

From and after Subtenant's occupancy of the Premises for the conduct of its business:

Axsome Therapeutics, Inc.
One World Trade Center
New York, New York 10007
Attn: Nick Pizzie, Chief Financial Officer

with a copy to:

Axsome Therapeutics, Inc.
One World Trade Center
New York, New York 10007
Attn: Hunter Murdock, General Counsel

and in each case with a copy of any default notice to:

Morgan Lewis Bockius LLP
101 Park Avenue
New York, New York 10178
Attn: J. Goodwin Bland, Esq.

Either party may, by like notice, direct that future notices or demands be sent to a different address. Any such notice, statement, certificate, request or demand which is sent by (a) hand or by such registered or certified mail shall be deemed to have been given when the addressee either actually receives such notice or refuses to accept delivery thereof and (b) such courier service shall be deemed to have been given one (1) Business Day after the date it shall have been sent by such courier service.

17. Landlord's Consents. This Sublease is subject to, and shall become effective upon, the written consent of Prime Landlord in accordance with all applicable terms of the Lease ("**Landlord's Consent")** Subtenant shall furnish to Sublandlord such information as may be reasonably necessary to obtain Landlord's Consent, and to enter into such agreements among Prime Landlord, Sublandlord and Subtenant as Prime Landlord may reasonably require pursuant to the Lease in connection with Landlord's Consent, including, without limitation, an agreement to attorn to Prime Landlord in the event of a termination of this Sublease pursuant to the then executory provisions of this Sublease. Any delay in Prime Landlord's furnishing the Consent shall not postpone or extend the Expiration Date. If Landlord's Consent is denied, this Sublease shall thereupon terminate and be of no further force or effect and Sublandlord shall promptly return the Letter of Credit (as hereinafter defined) to Subtenant. Sublandlord shall request Landlord's Consent with reasonable promptness, and Sublandlord shall use commercially reasonable efforts to obtain same. Upon receiving Landlord's Consent from Prime Landlord, Sublandlord shall promptly deliver a copy thereof to Subtenant.

(a) If the Landlord's Consent has not been obtained on or before April 15, 2023, then (at any time thereafter until the Landlord's Consent has been obtained) either party shall have the right to give a termination notice to the other party. If (and only if) the Landlord's Consent still has not yet been obtained on or before the date that is ten (10) days after the receiving party's receipt of such termination notice, then Sublandlord shall promptly return to Subtenant the Letter of Credit and upon such return this Sublease shall terminate. Upon the making of such return and the occurrence of such termination (and provided Sublandlord used commercially reasonable efforts to obtain such Landlord's Consent in accordance herewith), neither party hereto shall have any further obligation to the other under this Sublease, except to the extent that the provisions of this Sublease expressly survive the termination of this Sublease. If the Landlord's Consent shall be obtained after the giving of any termination notice under this Section 17(b) but prior to the termination of this Sublease under this Section 17(b), then such termination notice shall automatically be deemed withdrawn (and of no effect whatsoever).

18. Delivery of Possession. *Sublandlord Failure to Deliver Premises Due to Casualty*. Notwithstanding anything herein contained to the contrary or any contrary provision of the Lease incorporated herein by reference (except as provided in Sections 17(b) and 18(b) hereof, if Sublandlord is unable to deliver to Subtenant possession of the Premises, or any part thereof, because of a fire or casualty therein or for any other reason whatsoever; (1) Sublandlord shall not be subject to any liability for failure to deliver possession, (2) the validity of this Sublease shall not be impaired, (3) the same shall not be construed to extend the Term and (4) the Term shall

commence on, and the Commencement Date shall be, the date on which Sublandlord delivers possession of the Premises to Subtenant in the Premises Condition.

(a) Notwithstanding anything to the contrary contained herein, if any time after the Landlord's Consent has been obtained, (a) the Commencement Date has not occurred by May 1, 2023 (the "**Outside Date**"), then the Rent Commencement Date shall be delayed by one (1) day for each day occurring during the period commencing on the Outside Date and ending on the day immediately preceding the Commencement Date. If Sublandlord has not caused the Commencement Date to occur on or before sixty (60) days after the Outside Date, then Subtenant shall have the right at any time thereafter (but prior to the Commencement Date) to terminate this Sublease by giving written notice of termination to Sublandlord, and upon such termination, this Sublease shall be of no further force or effect except that Sublandlord shall promptly return to Subtenant the Letter of Credit.

(b) The provisions of this Section 18 are intended to constitute "an express provision to the contrary" within the meaning of Section 223 of the New York Real Property Law and any other law of like import now or hereafter in effect.

19. Damage by Fire or Other Cause. Notwithstanding any contrary provision of the Lease incorporated herein b reference, Subtenant shall have no right; (1) to terminate this Sublease as to all or any part of the Premises by reason of a casualty or condemnation or (2) to receive an abatement of Fixed Rent or Additional Rent by reason of a casualty or condemnation or another event entitling Sublandlord to an abatement of Fixed Rent or Additional Rent under the Lease with respect to the Premises, unless Sublandlord is entitled to a corresponding termination right or abatement with respect to its corresponding obligations under the Lease. In furtherance of the foregoing, if the Premises shall be damaged by fire or casualty and the damaged portion of the Premises consists of all or a material portion of the Premises and the estimated repair period extends beyond the date that is 12 months following the date of such fire or casualty, then Subtenant as its sole remedy may elect to terminate this Sublease in accordance therewith. Further, the provisions of Section 17.02(C) of the Original Lease are incorporated herein by reference such that if the repair is not completed by the date that is 12 months following the date of such fire or casualty, Subtenant may elect to terminate the Sublease in accordance therewith. Subtenant shall promptly notify Sublandlord of any fire or other casualty affecting the Premises.

(a) Subtenant acknowledges that Sublandlord shall not carry any insurance on, or be obligated to repair or replace, any fixtures, equipment, furnishings or other personal property, whether located in, attached to or built into the Premises, and Subtenant shall look solely to Subtenant's insurance for recovery of any damage to or loss of the same.

(b) The provisions of this Section 19 shall be deemed an express agreement governing any case of damage or destruction of the Premises by fire or other casualty, and Section 227 of the New York Real Property Law, providing for such a contingency in the absence of an express agreement, and any other law of like import, now or hereafter in force, shall have no application in such case.

20. Security. Subtenant has concurrently with the execution of this Sublease deposited with Sublandlord as security for the full and faithful performance and observance by Subtenant of

Subtenant's covenants and obligations under this Sublease, an unconditional, irrevocable letter of credit in the amount of $[*****] (the "**LC Amount**") substantially in the form annexed hereto as Exhibit C and issued by a bank reasonably satisfactory to Sublandlord (the "**Letter of Credit**"), and as of the date hereof, Sublandlord agrees that Silicon Valley Bank is a bank reasonably satisfactory to Sublandlord. The Letter of Credit shall provide that it is assignable by Sublandlord without charge and shall either (1) expire on the date that is 60 days after the expiration or earlier termination of this Sublease (the "**LC Date**") or (2) be automatically self-renewing until the LC Date. If any Letter of Credit is not renewed at least 30 days prior to the expiration thereof or if Subtenant holds over in the Premises without the consent of Sublandlord and Prime Landlord after the expiration or termination of this Sublease, Sublandlord may draw upon the Letter of Credit and hold the proceeds thereof as security for the performance of Subtenant's obligations under this Sublease. If Subtenant defaults beyond any notice and cure period in the full and prompt payment and performance of any of Subtenant's covenants and obligations under this Sublease, including, without limitation, the payment of Fixed Rent and Additional Rent, Sublandlord may, but shall not be required to draw upon the Letter of Credit (or the proceeds thereof), to the extent required for the payment of any Fixed Rent and Additional Rent or any other sums as to which Subtenant is in default or for any sum which Sublandlord may expend or may be required to expend by reason of Subtenant's default in respect of any of the terms, covenants and conditions of this Sublease, including, without limitation, any damages or deficiency in the reletting of the Premises, whether such damages or deficiency accrue before or after summary proceedings or other re-entry by Sublandlord. If Sublandlord shall have so drawn upon the Letter of Credit (or the proceeds thereof), Subtenant shall within three (3) Business Days of written demand deposit with Sublandlord a sum equal to the amount so drawn by Sublandlord, as security as aforesaid failing which Sublandlord shall have the same rights and remedies as for the non-payment of Fixed Rent beyond the applicable notice and grace period. If Subtenant shall fully and faithfully comply with all of Subtenant's covenants and obligations under this Sublease, the Letter of Credit (or the proceeds thereof) or any balance thereof, to which Subtenant is entitled, shall be returned or paid over to Subtenant within sixty (60) days after the date fixed as the end of this Sublease and after delivery to Sublandlord of possession of the Premises in the manner required under this Sublease. Subtenant shall not assign or encumber or attempt to assign or encumber the Letter of Credit or any interest thereon to which Subtenant is entitled, and Sublandlord shall not be bound by any such assignment, encumbrance, attempted assignment or attempted encumbrance. Subtenant shall cooperate, at Subtenant's reasonable expense, with Sublandlord to promptly execute and deliver to Sublandlord any and all reasonable modifications, amendments and replacements of the Letter of Credit, as Sublandlord may reasonably request to carry out the intent, terms and conditions of this Section 20. Sublandlord will promptly notify Subtenant of any assignment of the Letter of Credit by Sublandlord.

(a) *Reduction (Burn Down) of the Letter of Credit.* If the Subtenant has not been in monetary or material non-monetary default of this Sublease after the expiration of any notice and cure period more than one (1) time in any year of the Term and more than a total of two (2) times during the first five (5) years of the Term and Subtenant has not exercised its Termination Option, then upon the fifth (5^{th}) anniversary of the Rent Commencement Date, the LC Amount shall be allowed to be reduced to [*****] of the then Fixed Rent totaling [*****]. If at any time thereafter during the Term and after the reduction of the LC Amount, Subtenant is then in monetary or material non-monetary default of this Sublease after the expiration of any notice and cure period, then Sublandlord may demand that Subtenant increase the LC Amount to $[*****].

21. Alterations and Work Allowance. *Alterations and Sublandlord and Prime Landlord's Consent*. Notwithstanding anything to the contrary contained herein or in the Lease, Subtenant shall not make (1) any Material Alterations (including, without limitation, Subtenant Work (as hereinafter defined)) without Prime Landlord's consent (to the extent required under the Lease) and Sublandlord's consent, (2) any Alterations which do not constitute Material Alterations but (A) have a cost greater than [*****] in the aggregate during any six (6) month period and/or (B) require the approval of any Governmental Authorities (including QAD) without Prime Landlord's consent (to the extent required under the Lease) and Sublandlord's consent, or (3) any Specialty Alterations without Prime Landlord's and Sublandlord's consent (which consent shall be granted in Prime Landlord's and Sublandlord's sole discretion). Sublandlord's approval of any Alterations, including Material Alterations, shall be governed by Article 13 of the Original Lease as, and to the extent, incorporated herein by reference pursuant to Section 5 hereof; provided that (i) the time periods for Sublandlord's responses under Article 13 of the Original Lease shall be increased by 3 days; and (ii) Sublandlord shall not unreasonably withhold its approval to Subtenant Alterations or Subtenant Work if Prime Landlord has approved the same. Notwithstanding the foregoing, to the extent permitted in the Lease, Subtenant may perform (1) Decorative Alterations and (2) non-Material Alterations that cost less than [*****] in the aggregate during any six (6) month period without Prime Landlord's consent (unless such consent is required under the Lease) and without Sublandlord's consent; provided that, such Alterations do not require the approval of Governmental Authorities (including QAD) upon installation. Anything contained in this Sublease to the contrary notwithstanding, all such work and alterations shall be performed in full compliance with the applicable provisions of the Lease, including the submission of plans, drawings, and specifications for such work, including Subtenant Work, and Alterations. In the event that there is a dispute arising out of this Section 21, either party may submit such dispute to arbitration pursuant to Article 25 of the Original Lease. All Alterations, including Material Alterations and Specialty Alterations, but excluding Decorative Alterations, shall be removed by Subtenant prior to the expiration of the Term, unless Sublandlord grants Subtenant, in writing consent not to remove same as set forth in the following sentence. Subtenant shall have the right, when seeking Sublandlord's consent to any Alteration, permission from Sublandlord to leave such Alteration at the end of the Term; provided however, Prime Landlord's obligation regarding the removal of any Specialty Alteration shall be governed by the Lease.

(a) *Work Allowance*. Sublandlord shall reimburse Subtenant for the cost of Subtenant Work at [*****] per rentable square foot of the Premises in an amount equal to [*****] (the "**Work Allowance**") upon the following terms and conditions:

(1) The Work Allowance shall be payable to Subtenant in installments as Subtenant Work progresses, but in no event more frequently than monthly. Installments of the Work Allowance shall be payable by Sublandlord within thirty (30) days following Subtenant's satisfaction of each of the conditions required for disbursement set forth in this Section 21(b);

(2) Prior to the payment of any installment, Subtenant shall deliver to Sublandlord a request for disbursement which shall be accompanied by (A) paid invoices for the Subtenant Work performed or incurred since the last disbursement of the Work Allowance, (B) a representation signed by Subtenant's architect or project manager (if any) or an officer or partner of Subtenant stating that to their actual knowledge, the Subtenant Work and services represented by the aforesaid invoices have been satisfactorily completed in accordance with the plans and

specifications therefor approved by Sublandlord and/or Prime Landlord, as applicable, and have not been the subject of a prior disbursement of the Work Allowance, and (C) partial lien waivers by, contractors, subcontractors and all materialmen for all such work and services, if applicable. In addition, Sublandlord shall be permitted to retain from each disbursement an amount equal to ten percent (10%) of the amount requested to be disbursed by Subtenant. The aggregate amount of the retainages shall be paid by Sublandlord to Subtenant upon the completion of all Subtenant Work and upon receipt from Subtenant of: (i) a representation from Subtenant's architect or project manager (if any) or an officer or partner of Subtenant stating that all of the Subtenant Work has been satisfactorily completed in accordance with the plans and specifications therefor approved by Sublandlord and/or Prime Landlord, as applicable, and (ii) evidence of applicable Building Department sign-offs and/or applicable inspection certificates and any permits, if any, required to be issued by the Building Department, QAD and all Governmental Authority having jurisdiction in connection with Subtenant Work, and (iii) full lien waivers from all contractors and subcontractors performing the Subtenant Work.

(3) If Subtenant is not then in monetary or material non-monetary default under this Sublease beyond any applicable notice and cure period (and if such a default exists, then as soon as such default is cured), Sublandlord shall promptly make such Work Allowance payment to Subtenant within such aforesaid thirty (30) day period provided Subtenant satisfies the requirements of this Section 21.

(4) All requests for disbursement under clause (2) above must be submitted by Subtenant to Sublandlord no later than the second (2nd) anniversary of the Commencement Date.

(b) *No Third-Party Beneficiary and Subtenant Work Allowance Indemnity Obligations*. The right to receive reimbursement for the cost of Subtenant Work as set forth in this Section 21 shall be for the exclusive benefit of Subtenant, it being the express intent of the parties hereto that in no event shall such right be conferred upon or for the benefit of any third party, including, without limitation, any contractor, subcontractor, materialman, laborer, architect, engineer, attorney or any other person, firm or entity except in the case of Subtenant's permitted assignee or sublessee pursuant to Section 9(a)(2) and (3) of this Sublease, if any. Without in any way limiting the provisions of any indemnity in this Sublease, Subtenant shall indemnify and hold harmless Sublandlord from and against any and all liability, damages, claims, costs or expenses arising out of or relating to Sublandlord's payment of any installment of the Work Allowance, directly to Subtenant's general contractor or construction manager, provided that such direct payment is made (1) at Subtenant's express written direction or (2) due to Subtenant's failure (beyond any applicable notice and cure period) to timely remove or discharge any lien caused by or on behalf of Subtenant in accordance with the Lease, together with all reasonable and actual out-of-pocket costs, expenses and liabilities incurred in or in connection with each such claim or action or proceeding brought thereon, including, without limitation, all reasonable attorneys' fees and expenses.

(c) "**Subtenant Work**" means the installation of alterations, fixtures, improvements and appurtenances attached to or built into the Premises by Subtenant, or otherwise located by Subtenant in the Premises, for Subtenant's use and/or occupancy or otherwise and the "soft costs" of construction incurred by Subtenant to perform such work (including, without

limitation, filing and permit fees and expenses, architecture, engineering and other consulting fees and expenses and moving expenses, and expenses in connection with signage, graphics, furniture, audio visual, data and telecommunications wiring, and other office equipment); provided, that in no event shall more than [*****] of the Work Allowance be made available to Subtenant in respect of such soft costs.

(d) *Prime Landlord Reimbursement Pursuant to Article 13 of the Lease*. Subtenant shall pay to Prime Landlord or its designee (which may include Sublandlord) the reasonable actual third party out of pocket costs for which Prime Landlord is entitled to reimbursement under Article 13 of the Original Lease in connection with any Alterations by Subtenant to the Premises. Sublandlord shall not charge Subtenant any supervisory fee, surcharges or other like charges in connection with Subtenant's alterations other than reasonable actual third party out of pocket charges incurred by Sublandlord or other charges Sublandlord is required to pay under the Lease under Original Lease Article 13. In the event Subtenant is granted early access to the Premises prior to the Commencement Date to perform Subtenant Work (including without limitation, pursuant to Section 1 hereof), Subtenant shall not be required to pay Sublandlord for the cost of any services including but not limited to utilities used by Subtenant or its vendors during the performance of Subtenant Work prior to Subtenant's occupancy of the Premises.

(e) *Sublandlord's Cooperation*. Upon Subtenant's request, Sublandlord, at no cost to Sublandlord, shall cooperate with Subtenant in obtaining any Port Authority, QAD, Governmental Authority or Prime Landlord approvals required in connection with Subtenant Work.

(f) *Unused Amount*. If Subtenant has not requested and/or received all of the Work Allowance by the Rent Commencement Date, the amount of the Work Allowance not received by Subtenant (the "**Unused Amount**"), provided that Subtenant is not then in monetary default or material non-monetary default beyond any applicable notice and cure period under this Sublease (and if such a default exists, then as soon as such default is cured), will be provided by Sublandlord to Subtenant as a rent credit in an amount equal to the Unused Amount, to be applied as a rent credit against the monthly Fixed Rent due beginning on the first (1st) anniversary of the Rent Commencement Date and continuing on a monthly basis until the Unused Amount is zero; provided, however, if the Subtenant has been in monetary or material non-monetary default of this Sublease after the expiration of any notice and cure period more than one (1) time in any year of the Term and more than a total of two (2) times during the period when the rent credit for the Unused Amount is being provided, then any rent credit for the Unused Amount shall be null and void.

(g) *Removal of Alterations*. On or prior to the Expiration Date or sooner termination of the Term, Subtenant shall, at Subtenant's sole cost and expense, remove all Alterations, including Specialty Alterations but excluding Decorative Alterations, installed by Subtenant (unless Sublandlord has agreed in writing (pursuant to Section 21(a) hereof) to waive any requirement that any Alterations be removed and Prime Landlord has agreed in writing to waive any requirement that any Specialty Alterations be removed). At Subtenant's request, Sublandlord shall request confirmation from Prime Landlord (and Sublandlord shall also confirm if Sublandlord has received Prime Landlord's response), what part of Subtenant Work constitutes a Specialty Alteration which needs to be removed at the end of the Term. Subtenant shall repair

and restore, in a good and workmanlike manner, any damage to the Premises or the Building caused by Subtenant's removal of any Alteration, Material Alteration or Specialty Alterations, as the case may be, and if Subtenant fails to do so, Subtenant shall reimburse Sublandlord, within fifteen (15) days of receipt of written demand from Sublandlord, for Sublandlord's reasonable out-of-pocket cost of repairing and restoring such damage. Any such Specialty Alterations by Subtenant not removed on or before the Expiration Date or sooner termination of the Term shall be deemed abandoned and Sublandlord may either retain the same as Sublandlord's property or remove and dispose of same, and repair and restore any damage caused thereby, all at Subtenant's cost. Notwithstanding anything to the contrary contained herein, Subtenant shall have no obligation to remove any Alterations or other improvements existing in the Premises on the Commencement Date.

(h) *Subtenant Work is Property of Sublandlord*. Subtenant Work for which Subtenant has received payments from the Work Allowance, shall, solely for federal, state and local income tax purposes, be deemed to be the property of and owned by, Sublandlord. The foregoing shall in no event modify or amend any of the clauses of this Sublease setting forth the obligations of Sublandlord and Subtenant with respect to the maintaining of insurance with respect to such items and the repair or replacement of such items following a fire or other casualty, all of which shall be Subtenant's responsibility.

22. Furniture, Fixtures and Equipment. Subtenant, at no charge to Subtenant, shall have the right during the Term to use all of the existing furniture, furnishings and equipment located at the Premises described on Exhibit D-1 annexed hereto (collectively, "**FF&E**"). All of the FF&E shall be Sublandlord's property until the end of the Term, in accordance with the terms set forth herein. Subject to Sublandlord's Work on Exhibit D annexed hereto, the FF&E shall be delivered to Subtenant on the Commencement Date in their "as-is" condition as of the Commencement Date without warranty or recourse to Sublandlord, and Sublandlord makes no representation to Subtenant concerning the condition or usefulness of, or otherwise, with respect to the FF&E (other than that Sublandlord owns title to the FF&E free and clear of any and all liens and encumbrances). Notwithstanding the foregoing, Subtenant shall have the one-time right to give a written notice to Sublandlord between the Effective Date of this Sublease and ninety (90) days thereafter directing that Sublandlord remove items of FF&E specifically identified in such notice, and if Subtenant shall give Sublandlord such notice then (i) Sublandlord shall, at Sublandlord's cost and expense, remove such identified items from the Premises on or before the later of (x) the date that is thirty (30) days after the date of such notice and (y) the Commencement Date and (ii) upon such removal, such identified FF&E shall be deemed deleted from the definition of "FF&E" hereunder. Subtenant shall leave the FF&E in the Premises on the expiration or earlier termination of the Sublease Term in their then "as-is" condition.

23. Condenser Water and Sprinklers. From and after the date that Subtenant first occupies the Premises for the conduct of Subtenant's business, 23 tons of condenser water shall be furnished to Subtenant twenty four (24) hours a day, seven (7) days a week for the Subtenant's Supplemental HVAC System (as herein defined), which shall be payable by Subtenant at the actual rate then paid by Sublandlord as tenant under the Lease, which as of the date of this Sublease is $885.00 per ton per annum. At all times during the Term, Sublandlord shall permit Subtenant to use Subtenant's Supplemental HVAC System and sprinkler system. Throughout the Term and in accordance with the Lease and Legal Requirements, Subtenant shall be obligated to (a) repair,

maintain and replace, the existing Subtenant's Supplemental HVAC System and sprinkler system, (b) enter into and maintain a service contract for the repair, maintenance and replacement of the Subtenant's Supplemental HVAC System and sprinkler system, and (c) obtain and maintain all permits necessary for the operation of the Subtenant's Supplemental HVAC System and sprinkler system.

24. Signage. Subject to the provisions of the Lease and the consent of Prime Landlord (to the extent such consent is required under the Lease, which Sublandlord shall reasonably cooperate in obtaining) and Sublandlord, which, in the case of Sublandlord, will not be unreasonably withheld, delayed, or conditioned, Subtenant (x) may, at Subtenant's sole cost and expense, install identification signage within the elevator lobby on the floor comprising the Premises and/or its entry door and (y) in accordance with Article 41.05 of the Original Lease, will be entitled to Building directory listings in the Main Lobby for Subtenant, its executives and senior employees. Notwithstanding the foregoing provisions of this Section 24, Sublandlord agrees that to the extent that Subtenant's elevator lobby and/or entry door signage consists of Subtenant's logo (as shown on Exhibit H annexed hereto, subject to changes in color and/or other minor changes), Sublandlord consents to such signage, subject to any required consent of Prime Landlord.

25. Building Amenities. As of the Effective Date, Prime Landlord (or an Affiliate of Prime Landlord) operates "Well&" amenity space on the 64th floor of the Building (the "**Amenity Space**") for tenants and occupants of the Building and their guests. For so long as Prime Landlord (or its Affiliate, as applicable) continues to operate the Amenity Space and to the extent expressly consented to by Prime Landlord in Landlord's Consent, Subtenant shall have the non-exclusive right, in common with Sublandlord and the other tenants and occupants of the Building, to use the Amenity Space. Any and all requests by Subtenant to use or reserve any portion of the Amenity Space shall be coordinated directly with Prime Landlord (or its Affiliate, as applicable). Sublandlord makes no representations or warranties whatsoever as to the Amenity Space or the permissibility of Subtenant to use the Amenity Space. To the extent Sublandlord is permitted to use and have access through the Subgrade Lobby and as expressly consented to by Prime Landlord, Subtenant shall also have access to the Subgrade Lobby.

26. Termination Option. Provided that on the date that Subtenant gives a Termination Notice (as hereinafter defined) to Sublandlord and on the Termination Date (as hereinafter defined), (i) Subtenant shall not then be in monetary or material non-monetary default under this Sublease beyond any applicable notice and cure period (and if such a default exists, then as soon as such default is cured) and (ii) the original named subtenant (i.e., Axsome Therapeutics, Inc.) (the "**Named Subtenant**") and its successors, assigns or Affiliates are occupying 65% of the Premises Subtenant shall have the one-time right (the "**Termination Option**") to terminate this Sublease effective on the day immediately preceding the 5th anniversary of the Rent Commencement Date (the "**Termination Date**"). Subtenant may exercise the Termination Option only by (a) giving to Sublandlord irrevocable notice of such exercise (the "**Termination Notice**") on or before the date that is 12 months prior to the Termination Date (the "**Termination Exercise Date**"), and (b) paying to Sublandlord, on or before the Termination Exercise Date, time being of the essence, a termination fee (the "**Termination Payment**") equal to all Transaction Costs (as hereinafter defined). The Termination Payment shall be in addition to, and not in lieu of, the payments of Fixed Rent, Additional Rent and other charges accruing under this Sublease through the Termination Date. If Subtenant shall fail to timely give the Termination Notice on or before

the Termination Exercise Date (time being of the essence) or pay the Termination Payment on or before the Termination Exercise Date (time being of the essence), then Subtenant shall conclusively be deemed to have waived Subtenant's right to exercise the Termination Option and Subtenant shall have no further rights under this Section.

(a) "**Transaction Costs**" means [*****].

27. Renewal Option. Provided that on the Renewal Exercise Date (as hereinafter defined) and on the commencement of the Renewal Term (as hereinafter defined), (i) Subtenant shall not then be in monetary or material non-monetary default under this Sublease beyond any applicable notice and cure period (and if such a default exists, then as soon as such default is cured), and (ii) intentionally omitted ((i)–(ii), collectively, the "**Renewal Conditions**"), Subtenant shall have the one-time right (the "**Renewal Option**") to extend the term of this Sublease for the entire Premises through October 30, 2039 (the "**Renewal Term**"), to commence at the expiration of the initial Term. Subtenant may exercise the Renewal Option on or before the date that is 12 months prior to the Expiration Date of the Term (the "**Renewal Exercise Date**"), only by giving to Sublandlord irrevocable notice of such exercise (the "**Renewal Notice**").

(a) The Renewal Term shall be upon all of the terms and conditions set forth in this Sublease, except that (i) the Fixed Rent shall be as determined pursuant to the further provisions of this Section; (ii) Sublandlord shall not be required to perform alterations, work or repairs on behalf of Subtenant or contribute any sums toward same, and Subtenant shall accept the Premises in its "as is" condition on the commencement of the Renewal Term; (iii) Subtenant shall have no option to renew this Sublease beyond the expiration of the Renewal Term; and (iv) all references in this Sublease to the Expiration Date shall be deemed to mean the last day of the Renewal Term.

(b) The Rent for the Premises for the Renewal Term shall be the Fair Market Rent (as hereinafter defined). "**Fair Market Rent**" means the rental rate that a willing sublessee would pay and a willing sublessor would accept for the subleased Premises during the Renewal Term during the balance of the Term (as applicable), each party acting prudently and under no compulsion to sublease, and taking into account all relevant factors. If Subtenant timely and validly exercises the Renewal Option, Sublandlord shall notify Subtenant at least 120 days before the last day of the initial Term of Sublandlord's determination of the Fair Market Rent ("**Sublandlord's Determination**"). Subtenant shall notify Sublandlord, within 20 days after Subtenant's receipt of Sublandlord's Determination, whether Subtenant accepts or disputes Sublandlord's Determination, and if Subtenant disputes Sublandlord's Determination, Subtenant's notice shall set forth Subtenant's determination of the Fair Market Rent ("**Subtenant's Determination**"). If Subtenant fails to accept or dispute Sublandlord's Determination within such 20-day period, or if Subtenant disputes Sublandlord's determination within such 20-day period but fails to set forth therein Subtenant's Determination, then Subtenant shall be deemed to have accepted Sublandlord's Determination.

(c) If Subtenant timely and validly disputes Sublandlord's Determination of the Fair Market Rent and Sublandlord and Subtenant fail to agree as to the Fair Market Rent within

20 days after the giving of Subtenant's Determination, then the Fair Market Rent shall be determined by arbitration in the City of New York, as set forth in this Section 27(d).

(1) Subtenant shall initiate the arbitration process by giving notice to that effect to Sublandlord within 20 days after the giving of Subtenant's Determination, which notice shall include the name and address of Subtenant's designated arbitrator. If Subtenant fails to give such notice within such 20-day period, then Subtenant shall be deemed to have accepted Sublandlord's Determination. Within 30 days after the designation of Subtenant's arbitrator, Sublandlord shall give notice to Subtenant of the name and address of Sublandlord's designated arbitrator. If Sublandlord shall fail timely to appoint an arbitrator, then Subtenant may request that the American Arbitration Association (or any organization which is the successor thereto) (the "**AAA**") appoint an arbitrator on Sublandlord's behalf. Such two (2) arbitrators shall have 30 days to appoint a 3rd arbitrator who shall be impartial. If such arbitrators fail to do so, then either Sublandlord or Subtenant may request the AAA to appoint an arbitrator who shall be impartial within 30 days after such request and both parties shall be bound by any appointment so made within such 30-day period. If no such 3rd arbitrator shall have been appointed within such 30-day period, either Sublandlord or Subtenant may apply to the Supreme Court, New York County to make such appointment. The 3rd arbitrator only shall subscribe and swear to an oath fairly and impartially to determine such dispute.

(2) Within 7 days after the appointment of the 3rd arbitrator, the three (3) arbitrators will meet (the "**Initial Meeting**") and set a hearing date for the arbitration. The hearing shall not exceed 2 days and shall be scheduled to be held within 60 days after the meeting of the three (3) arbitrators. At the Initial Meeting, Sublandlord and Subtenant may each submit a revised Fair Market Rent determination (each, a "**Final Determination**"); provided that Sublandlord's Final Determination may not be greater than Sublandlord's Determination and Subtenant's Final Determination may not be lower than Subtenant's Determination. If either party shall fail so to submit a Final Determination, then Sublandlord's Determination or Subtenant's Determination, as applicable, shall constitute such party's Final Determination.

(3) There shall be no discovery in the arbitration. Thirty (30) days prior to the scheduled hearing, the parties shall exchange opening written expert reports and opening written pre-hearing statements. Opening written pre-hearing statements shall not exceed 20 pages in length. Two weeks prior to the hearing, the parties may exchange rebuttal written expert reports and rebuttal written pre-hearing statements. Rebuttal written pre-hearing statements shall not exceed 10 pages in length. Ten days prior to the hearing, the parties shall exchange written witness lists, including a brief statement as to the subject matter to be covered in the witnesses' testimony. One week prior to the hearing, the parties shall exchange all documents that they intend to offer at the hearing. Other than rebuttal witnesses, only the witnesses listed on the witness lists shall be allowed to testify at the hearings. Closing arguments shall be heard immediately following conclusion of all testimony. The proceedings shall be recorded by stenographic means. Each party may present live witnesses and offer exhibits, and all witnesses shall be subject to cross-examination. The arbitrators shall conduct the two-day hearing so as to provide each party with sufficient time to present its case, both on direct and on rebuttal, and permit each party appropriate time for cross examination; provided that the arbitrators shall not extend the hearing beyond 2 days. Each party may, during its direct case, present evidence in support of its position and in opposition to the position of the opposing party.

(4) The 3rd arbitrator shall make a determination of the Fair Market Rent by selecting either the amount set forth in Sublandlord's Final Determination or the amount set forth in Subtenant's Final Determination, whichever the 3rd arbitrator determines is closest to Fair Market Rent for the Premises during the Renewal Term The 3rd arbitrator may not select any other amount as the Fair Market Rent. The fees and expenses of any arbitration pursuant to this Section 27(d) shall be borne by the parties equally, but each party shall bear the expense of its own arbitrator, attorneys and experts and the additional expenses of presenting its own proof. The arbitrators shall not have the power to add to, modify or change any of the provisions of this Sublease. Each arbitrator shall be a licensed real estate broker having at least 15 years of experience in leasing of first-class office buildings in downtown Manhattan. After a determination has been made of the Fair Market Rent, the parties shall execute and deliver an instrument setting forth the Fair Market Rent, but the failure to so execute and deliver any such instrument shall not affect the determination of Fair Market Rent.

(d) If Subtenant disputes Sublandlord's Determination and if the final determination of Fair Market Rent shall not be made on or before the commencement of the Renewal Term, then, pending such final determination, Subtenant shall pay, as Fixed Rent for the Renewal Term, an amount equal to Sublandlord's Determination. If, based upon the final determination of the Fair Market Rent, the Fixed Rent payments made by Subtenant for the Renewal Term were greater than the Fair Market Rent as finally determined in accordance with Section 27(d), Sublandlord shall credit the amount of such excess against future installments of Fixed Rent and/or Additional Rent payable by Subtenant.

28. OFAC Representations. Sublandlord represents and warrants to Subtenant that as of the date of execution and delivery of this Sublease: (i) Sublandlord is not acting, directly or indirectly, for or on behalf of any person, group, entity or nation listed by the United States Treasury Department as a Specially Designated National and Blocked Person ("**SDN List**"), or for or on behalf of any person, group, entity or nation designated in Presidential Executive Order 13224 as a person who commits, threatens to commit, or supports terrorism; (ii) Sublandlord is not engaged in this transaction directly or indirectly on behalf of, or facilitating this transaction directly or indirectly on behalf of, any such person, group, entity or nation; (iii) Sublandlord is not a person and/or entity with whom United States Persons are restricted from doing business under the International Emergency Economic Powers Act, 50 U.S.C. §1701 et seq.; the Trading with the Enemy Act, 50 U.S.C. App. §5; any executive orders promulgated thereunder; any implementing regulations promulgated thereunder by the U.S. Department of Treasury Office of Foreign Assets Control ("**OFAC**") (including those persons and/or entities named on the SDN List); or any other applicable law of the United States; (iv) intentionally omitted; (v) intentionally omitted; and (vi) Sublandlord is not in violation of the U.S. Federal Bank Secrecy Act, as amended by Title III (the "**International Money Laundering Abatement and Financial Anti-Terrorism Act**") of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (the "**Patriot Act**"), Public Law 107-56; its implementing regulations promulgated by the U.S. Department of Treasury Financial Crimes Enforcement Network ("**FinCEN**") (31 CFR Part 103); or any other anti-money laundering law of the United States.

(a) Subtenant represents and warrants to Sublandlord that as of the date of execution and delivery of this Sublease: (i) Subtenant is not acting, directly or indirectly, for or on

behalf of any person, group, entity or nation on SDN List, or for or on behalf of any person, group, entity or nation designated in Presidential Executive Order 13224 as a person who commits, threatens to commit, or supports terrorism; (ii) Subtenant is not engaged in this transaction directly or indirectly on behalf of, or facilitating this transaction directly or indirectly on behalf of, any such person, group, entity or nation; (iii) Subtenant is not a person and/or entity with whom United States Persons are restricted from doing business under the International Emergency Economic Powers Act, 50 U.S.C. §1701 et seq.; the Trading with the Enemy Act, 50 U.S.C. App. §5; any executive orders promulgated thereunder; any implementing regulations promulgated thereunder by OFAC (including those persons and/or entities named on the SDN List); or any other applicable law of the United States; (iv) intentionally omitted; (v) intentionally omitted; and (vi) Subtenant is not in violation of the International Money Laundering Abatement and Financial Anti-Terrorism Act of the Patriot Act, Public Law 107-56; its implementing regulations promulgated by FinCEN (31 CFR Part 103); or any other anti-money laundering law of the United States.

29. Sublandlord and Subtenant's Representations. Sublandlord represents to the best of Sublandlord's knowledge and belief, to Subtenant as follows as of the date of execution and delivery of this Sublease:

(a) the Lease is unmodified and in full force and effect in accordance with, and subject to, all of the terms, covenants, conditions and agreements contained therein, and a true, correct and complete copy of the Lease (excluding redacted terms not relevant to Subtenant) has been delivered to Subtenant;

(b) the Expiration Date of the Lease is November 30, 2039, as the same may be extended pursuant to the terms of Original Lease Article 38 (or the date upon which the term of the Lease shall sooner terminate pursuant to any of the terms of the Lease);

(c) Sublandlord has not received any notice of any default by Sublandlord or Prime Landlord under the Lease, which default remains uncured, and Sublandlord has no actual knowledge of any event which, with the giving of notice or the passage of time, would constitute a default by Sublandlord or Prime Landlord under the Lease;

(d) Sublandlord holds the entire tenant's interest in the Premises under the Lease, free and clear of any liens, claims, mortgages, charges or encumbrances, subleases and occupancies, other than this Sublease;

(e) Sublandlord has full right, power and authority to enter into this Sublease;

(f) Sublandlord has not granted any other person or party any right to use or occupy the Premises which remains in effect, and Sublandlord has not assigned or otherwise transferred its leasehold interest in the Premises or sublet the Premises;

(g) the persons signing this Sublease on behalf of Sublandlord are vested with authority to act on behalf of Sublandlord with respect to this Sublease, and the execution of this Sublease by Sublandlord has been duly authorized;

(h) to Sublandlord's actual knowledge, the Premises are in compliance with Legal Requirements, including the restrooms (including without limitation, the ADA) and do not contain any Hazardous Materials; and

(i) Sublandlord is the only current occupant of the Premises.

Subtenant represents to the best of Subtenant's knowledge and belief, to Sublandlord as follows as of the date of execution and delivery of this Sublease:

(a) Subtenant has full right, power and authority to enter into this Sublease, subject to obtaining Landlord's Consent; and

(b) the persons signing this Sublease on behalf of Subtenant are vested with authority to act on behalf of Subtenant with respect to this Sublease, and the execution of this Sublease by Subtenant has been duly authorized.

30. Services.

(a) *After Hours HVAC*. Upon request of Subtenant, After Hours HVAC Service shall be provided to the Premises at a rate of $51.12 per floor per hour, subject to escalations pursuant to Article 6 of the Original Lease. Sublandlord shall provide Subtenant with notice of any such escalations or other increases as it receives same from Prime Landlord.

(b) *HVAC Supplemental Units*. The Premises are exclusively serviced by the two (2) existing HVAC supplemental units ("**Subtenant's Supplemental HVAC System**") and such Subtenant's Supplemental HVAC System shall be delivered by Sublandlord in their "as-is" condition on the Commencement Date.

(c) *Cleaning Services*. Cleaning services shall be provided at the Premises pursuant to the specifications set forth in Exhibit H of the Original Lease; provided, however, that if at any time Sublandlord elects to provide its own cleaning services to the Prime Leased Premises, Sublandlord shall also provide (at no additional cost to Subtenant for Sublandlord's standard cleaning services provided free of charge pursuant to the Lease), such cleaning services to the Premises in a manner reasonably acceptable to Subtenant. Sublandlord shall promptly notify Subtenant of any such election and such notice shall be accompanied by Sublandlord's proposed cleaning specifications for review and approval by Subtenant. If Subtenant elects to have Prime Landlord provide cleaning or other services above the standard services provided pursuant to the Lease provided free of charge, Subtenant shall pay all such costs and expenses within ten (10) days of receipt of the bill therefore.

(d) *Physical Security*. Subtenant shall, during the Term of this Sublease, comply with the terms of the security provisions of the Lease (including Exhibit AA), and may, at its election, subject to Prime Landlord's consent, and to Sublandlord's consent, which as to Sublandlord's consent shall not be unreasonably conditioned, withheld or delayed, install its own security system within the Premises provided the same is compatible with Prime Landlord's Building-wide security system and Subtenant complies with the terms of the Lease, and (1) on or prior to the Commencement Date, Sublandlord shall provide 100 access cards to the Building and Premises to Subtenant's personnel at no additional cost to Subtenant, and (2) on or prior to April

30, 2023, Sublandlord shall provide an additional 100 access cards to the Building and Premises to Subtenant's personnel at no additional cost to Subtenant

(e) *Building Telecommunications.* Subtenant may use, at Subtenant's sole cost and expense, telecommunications and cable service providers who are then currently providers to the Building by tapping into the telecommunications closets on the 22nd floor of the Building. The telecommunications and cable service providers to the Building, as of the date of this Sublease, are Spectrum, Verizon, Crown Castle and Cogent.

(f) *Freight Elevator and Loading Dock Access*. Notwithstanding anything herein contained to the contrary, in connection with Subtenant's move into the Building and the delivery of furniture and equipment prior thereto, Sublandlord shall provide 40 hours of free overtime freight elevator service and use of the loading dock, including Sublandlord paying for security screening in connection with the freight elevator usage. Except for the above mentioned 40 hours of free overtime freight elevators, loading dock and security screening, Subtenant shall pay for its use of freight elevators, loading dock and security screening as set forth in the Lease.

31. Building Access. Subtenant shall have 24 hour, 7 days a week access to the lobbies, via the Main Lobby and Conde Nast Subgrade Lobby, elevators and the Premises in accordance with the provisions of the Lease.

32. Authority. To induce Sublandlord to enter into this Sublease, Subtenant hereby represents to Sublandlord that as of the date hereof and subject to obtaining the Landlord's Consent and a fully-executed counterpart of this Sublease, (1) Subtenant is a duly formed and validly existing corporation with full power and authority to enter into this Sublease and to perform Subtenant's obligations under this Sublease in accordance with its terms and (2) this Sublease has been duly authorized, executed and delivered by Subtenant and constitutes the legal, valid and binding obligation of Subtenant.

33. Definitions. All of the capitalized terms herein shall have the same meaning ascribed to them in the Lease except as specifically provided herein.

34. Consequential Damages. Except as specifically provided in Section 12, neither party shall be responsible for consequential or punitive damages under the Lease or this Sublease.

35. Sublandlord's Right to Early Termination of Prime Lease. Provided Subtenant is not then in monetary or material non-monetary default under this Sublease beyond applicable periods of notice and grace (and if such a default exists, then as soon as such default is cured), Sublandlord covenants and agrees not to (x) voluntarily cancel or surrender the Lease, except for a termination permitted under Original Lease Article 17 (Damage By Fire Or Other Cause), Article 18 (Condemnation), or if Prime Landlord agrees to recognize this Sublease as a direct lease between Prime Landlord and Subtenant upon the terms of this Sublease or (y) consent to any modification, amendment or supplement to the Lease which will deprive Subtenant of its rights or impose any further obligations on Subtenant under this Sublease (except to a de minimis extent), without the prior written consent of Subtenant in each instance. Sublandlord agrees that prior to exercising such termination right under Original Lease Articles 17 or 18, Sublandlord shall deliver notice thereof to Subtenant. A termination of the Lease due to the default of Sublandlord, other

than a default caused by Subtenant under this Sublease or the Lease, or both, shall be considered a voluntary cancellation or surrender of the Lease in breach of Sublandlord's obligations under this Section 35.

36. Counterparts; Original Agreement. This Sublease may be executed (including by facsimile, "pdf" or other electronic transmission) in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Sublandlord and Subtenant hereby acknowledge and agree that electronic signatures, including execution using Adobe Sign, DocuSign, or other signature generating software or signatures transmitted by electronic mail in so-called "pdf" format, shall be legal and binding without the need to deliver an original of this Sublease. Sublandlord and Subtenant (a) intend to be bound by the signatures (whether original or electronic) on any document sent by electronic mail, (b) are aware that the other party will rely on such signatures, (c) hereby waive any defenses to the enforcement of the terms of this Sublease based on the foregoing forms of electronic signatures, and (d) the parties further consent and agree that (1) to the extent a party signs this Sublease using electronic signature technology, by clicking "SIGN" or an equivalent, such party is signing this Sublease electronically, and (2) the electronic signatures appearing on this Sublease shall be treated, for purposes of validity, enforceability and admissibility, the same as handwritten signatures.

SIGNATURE PAGE FOLLOWS

IN WITNESS WHEREOF, Sublandlord and Subtenant have executed this Sublease as of the day and year first above written.

SUBLANDLORD:

ADVANCE MAGAZINE PUBLISHERS INC.,
a New York corporation, D/B/A CONDÉ NAST

/s/ Oren Klein
Signature

Oren Klein
Printed Name

CFO
Title

Feb 14, 2023
Date

SUBTENANT:

AXSOME THERAPEUTICS, INC.
a Delaware corporation

/s/ Nick Pizzie
Signature

Nick Pizzie
Printed Name

Chief Financial Officer
Title

2-Feb-2023

Exhibit 31.1

CERTIFICATION OF PERIODIC REPORT
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Herriot Tabuteau, M.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Axsome Therapeutics, 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.

Date: May 8, 2023

/s/ Herriot Tabuteau, M.D.
Herriot Tabuteau, M.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PERIODIC REPORT
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Nick Pizzie, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Axsome Therapeutics, 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.

Date: May 8, 2023

/s/ Nick Pizzie
Nick Pizzie
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

STATEMENT OF PRINCIPAL EXECUTIVE OFFICER OF
AXSOME THERAPEUTICS, INC.
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Axsome Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2023 as filed with the Securities and Exchange Commission (the "Report"), I, Herriot Tabuteau, M.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

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

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

Date: May 8, 2023

/s/ Herriot Tabuteau, M.D.

Herriot Tabuteau, M.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

STATEMENT OF PRINCIPAL FINANCIAL OFFICER OF
AXSOME THERAPEUTICS, INC.
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Axsome Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2023 as filed with the Securities and Exchange Commission (the "Report"), I, Nick Pizzie, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

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

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

Date: May 8, 2023

/s/ Nick Pizzie

Nick Pizzie
Chief Financial Officer
(Principal Financial and Accounting Officer)