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, 2025

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 29th 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 49,236,365 shares of the registrant's common stock, $0.0001 par value, outstanding as of April 28, 2025.

AXSOME THERAPEUTICS, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED MARCH 31, 2025

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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 U.S. 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 and regulatory approval of our product candidates, and commercialization of our pharmaceutical products 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 geopolitical conflicts or pandemics;
- our future revenue projections, sales forecasts, and potential peak market data;
- our expectations for generating revenue or 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 acquisitions and in-licensing transactions;
- our expectations or ability to build 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 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 share and per share amounts)

	March 31, 2025 (Unaudited)	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 300,910	$ 315,353
Accounts receivable, net	161,398	142,001
Inventories, net	16,319	15,732
Prepaid and other current assets	16,007	11,978
Total current assets	494,634	485,064
Equipment, net	773	584
Right-of-use asset - operating lease	23,294	5,383
Goodwill	12,042	12,042
Intangible asset, net	45,322	46,894
Non-current inventory and other assets	20,606	18,531
Total assets	$ 596,671	$ 568,498
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 85,659	$ 71,997
Accrued expenses and other current liabilities	149,199	147,987
Operating lease liability, current portion	454	1,835
Contingent consideration, current	8,602	8,285
Total current liabilities	243,914	230,104
Contingent consideration, non-current	90,590	91,680
Loan payable, long-term	181,377	180,710
Operating lease liability, long-term	23,905	6,046
Finance lease liability, long-term	3,680	2,943
Total liabilities	543,466	511,483
Stockholders' equity:		
Preferred stock, $0.0001 par value per share (10,000,000 shares authorized, none issued and outstanding)	—	—
Common stock, $0.0001 par value per share (150,000,000 shares authorized, 49,216,759 and 48,667,587 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively)	5	5
Additional paid-in capital	1,235,400	1,179,797
Accumulated deficit	(1,182,200)	(1,122,787)
Total stockholders' equity	53,205	57,015
Total liabilities and stockholders' equity	$ 596,671	$ 568,498

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

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

	Three months ended March 31,	
	2025	2024
Revenues:		
Product sales, net	$ 120,358	$ 74,096
Royalty revenue	1,105	903
Total revenues	121,463	74,999
Operating expenses:		
Cost of revenue (excluding amortization and depreciation)	9,789	6,297
Research and development	44,785	36,830
Selling, general and administrative	120,787	98,970
Loss (Gain) in fair value of contingent consideration	1,512	(1,412)
Intangible asset amortization	1,572	1,589
Total operating expenses	178,445	142,274
Loss from operations	(56,982)	(67,275)
Interest expense, net	(2,431)	(1,082)
Loss before income taxes	(59,413)	(68,357)
Income tax expense	—	—
Net loss	$ (59,413)	$ (68,357)
Net loss per common share, basic and diluted	$ (1.22)	$ (1.44)
Weighted average common shares outstanding, basic and diluted	48,871,163	47,393,563

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

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

	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount			
Balance at December 31, 2023	47,351,363	5	1,026,543	(835,571)	190,977
Stock-based compensation	—	—	20,533	—	20,533
Issuance of common stock upon exercise of options	80,294	—	2,501	—	2,501
Issuance of common stock upon vesting of RSUs	32,918	—	—	—	—
Shares tendered for withholding taxes	—	—	(1,618)	—	(1,618)
Net loss	—	—	—	(68,357)	(68,357)
Balance at March 31, 2024	47,464,575	5	1,047,959	(903,928)	144,036
Balance at December 31, 2024	48,667,587	5	1,179,797	(1,122,787)	57,015
Stock-based compensation	—	—	23,647	—	23,647
Issuance of common stock upon exercise of options	331,853	—	17,035	—	17,035
Issuance of common stock upon vesting of RSUs	60,835	—	—	—	—
Issuance of common stock upon financing	156,484	—	19,257	—	19,257
Shares tendered for withholding taxes	—	—	(4,336)	—	(4,336)
Net loss	—	—	—	(59,413)	(59,413)
Balance at March 31, 2025	49,216,759	$ 5	$ 1,235,400	$ (1,182,200)	$ 53,205

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,	
	2025	2024
Cash flows from operating activities		
Net loss	$ (59,413)	$ (68,357)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	23,308	20,190
Amortization of intangible asset	1,572	1,589
Amortization of debt discount	667	619
Depreciation	149	132
Loss (Gain) in fair value of contingent consideration	1,512	(1,412)
Gain from lease modification	(2,250)	—
Non-cash lease expense	609	360
Right-of-use asset amortization for finance lease	412	110
Change in operating lease liability	208	109
Changes in operating assets and liabilities:		
Accounts receivable, net	(19,396)	(6,615)
Inventories, net	(249)	(105)
Prepaid expenses and other current assets	(4,029)	(3,917)
Non-current inventory and other assets	(955)	(867)
Accounts payable	13,662	13,112
Accrued expenses and other current liabilities	818	(8,415)
Net cash used in operating activities	(43,375)	(53,467)
Cash flows from investing activities		
Purchases of equipment	(338)	(98)
Net cash used in investing activities	(338)	(98)
Cash flows from financing activities		
Payments on principal portion of finance lease obligation	(401)	(163)
Proceeds from issuance of common stock upon financing	19,650	—
Cash paid for common stock issuance costs	(393)	—
Proceeds from issuance of common stock upon exercise of options	17,035	2,501
Payment of contingent consideration	(2,285)	(1,907)
Payments of tax withholdings on stock awards	(4,336)	(1,618)
Net cash (used in) provided by financing activities	29,270	(1,187)
Net decrease in cash	(14,443)	(54,752)
Cash at beginning of period	315,353	386,193
Cash at end of period	$ 300,910	$ 331,441
Supplemental disclosures of cash flow information:		
Interest paid	$ 4,590	$ 4,903
Operating lease right-of-use asset obtained in exchange for operating lease liability	23,869	—
Finance lease right-of-use asset obtained in exchange for finance lease liability	1,532	2,492
Decrease in operating lease right-of-use asset due to lease modification	5,349	—
Decrease in operating lease liability due to lease modification	7,599	—

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

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

Note 1. Nature of Business and Basis of Presentation

Axsome Therapeutics, Inc. ("Axsome" or the "Company"), based in New York, New York, is a biopharmaceutical company dedicated to the development and commercialization of innovative medicines for people living with central nervous system ("CNS") conditions. Axsome has a diverse portfolio of U.S. Food and Drug Administration (FDA) approved treatments for major depressive disorder, excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea, and migraine, and an expansive pipeline comprising of multiple late-stage development programs addressing a broad range of serious neurological and psychiatric conditions that impact over 150 million people in the United States.

In August 2022, the Company acquired the U.S. rights to Sunosi® (solriamfetol) from Jazz Pharmaceuticals plc ("Jazz"), and in November 2022, the Company acquired worldwide ex-U.S. rights (excluding certain Asian markets) from Jazz (collectively, the "Acquisition"). Sunosi was approved for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy or obstructive sleep apnea by the FDA in March 2019 and by the European Commission in January 2020. 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, Auvelity® (dextromethorphan-bupropion) was approved by the FDA for the treatment of major depressive disorder in adults. The Company announced the commercial availability of Auvelity in the U.S. in October 2022.

In January 2025, Symbravo® (MoSEIC™ meloxicam-rizatriptan) was approved by the FDA for the acute treatment of migraine with or without aura in adults. The Company refers herein to Auvelity, Sunosi, Symbravo, 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 ("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 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, 2024 filed with the SEC on February 18, 2025.

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, 2025 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 and may never become profitable. As of March 31, 2025, the Company had an accumulated deficit of $1,182.2 million.

The Company's primary sources of cash have been proceeds from the sales of Auvelity and Sunosi, 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 continues to generate revenues from its products.

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 Auvelity, Sunosi, and Symbravo 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 capital. 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 three commercial products, Auvelity and Sunosi, and its recently FDA-approved product, Symbravo. There can be no assurance that the Company's research and development efforts will result in additional successfully commercialized products. 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 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; determination of fair value of warrants; accounting for research and development costs; accounting for acquisitions; impairments of goodwill and the intangible asset; determination of fair value of 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 Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers ("ASC 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 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 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 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 and Note 13. Revenues.

License Agreements

The Company generates revenue from license or similar agreements with pharmaceutical companies for the development and commercialization of certain products. Such agreements may include the transfer of intellectual property rights in the form of licenses. Payments made by the customer 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 the Company 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 to the extent that it is probable that a significant revenue reversal would not occur and are 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 a significant revenue reversal would not occur and, if necessary, adjusts 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 (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalties have been allocated has been satisfied (or partially satisfied).

Product Sales, net

Revenues from product sales are recorded net of reserves for variable consideration. These reserves reflect the Company's best estimate of the amount of consideration to which the Company is entitled based on the terms of the contracts. The Company sells Auvelity and Sunosi in the United States to wholesale distributors with whom the Company has entered into formal agreements (collectively, the "Distributors"). These Distributors subsequently resell the Company's products to retail pharmacies. The Company also sells Sunosi to Distributors in Canada and on a product supply basis to Pharmanovia. Sunosi is subsequently sold by Pharmanovia in certain ex-U.S. markets. The Company does not sell products under consignment arrangements, and the collection of proceeds from product sales is not contingent upon customers' sale of the goods to third parties. The Company received FDA approval for Symbravo in January 2025 and did not record any product sales with respect to Symbravo for the periods covered by this report. See Note 13. Revenues for a further breakout of product sales, net.

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 the Company's best estimate of the amount of consideration to which the Company is entitled based on the terms of the contracts and are classified as reductions to accounts receivable, net if payable to a customer or accrued expenses and other current liabilities if payable to a third-party. 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 receivable, net on the consolidated balance sheets.

Product Returns - 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 sale 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, historical product sales information, and actual returns experience.

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 receivable, 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 are 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. Allowances for rebates also include amounts due for Medicare Inflation Based Rebates resulting from the Inflation Reduction Act of 2022 which includes measures requiring manufacturers to pay rebates where price increases exceed the rate of inflation. The Company estimates these rebates and records such estimates in the same period the related product sales are recognized, resulting in a reduction to product sales as well as a component of accrued expenses 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 to patients in the 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 expenses and other current liabilities.

Medicare Part D Program Redesign - Effective January 1, 2025, the Medicare Part D coverage gap program was replaced with a redesigned program under the Inflation Reduction Act of 2022. The standard Part D benefit now comprises three phases: the deductible phase, the initial coverage phase and the catastrophic coverage phase. Applicable dispensed drugs will be subject to manufacturer discounts of 10% during the initial coverage phase and 20% during the catastrophic coverage phase. The Company estimates the percentage of goods sold to patients in the initial coverage and catastrophic coverage phases 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 expenses 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 reserves 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 expenses 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.

Cost of Revenue

The Company's cost of revenue consists of cost of product sales. 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.

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 $165.0 million based on revenue milestones and $1.0 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 of Directors (the "Board"), Herriot Tabuteau, M.D., equal to 3.0% of Auvelity net sales.

Foreign Currency Translation

Revenues and expenses denominated in foreign currency are translated into U.S. dollars at the exchange rate on the date they are 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 consolidated financial statements.

Segment 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 and reporting segment, which is the business of developing and delivering novel therapies for the management of CNS disorders. See Note 18. Segment Information below for further information.

Cash and 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, 2025, the balance of cash and cash equivalents was $300.9 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 on the fair value hierarchy.

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 deposits at financial institutions, which cash deposits exceed insured limits. At March 31, 2025, 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 Receivable, net below for further information.

Concentration of Risk, Other - The Company has a limited number of contract manufacturers for its products. At times, the Company may have only one manufacturer or supplier for its products.

Business Combination

The Company accounted for the 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 the intangible asset 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, 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. When reviewing goodwill for impairment, the Company first evaluates the qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If the qualitative factors determine it is necessary to complete a goodwill impairment test, 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 completes its annual goodwill assessment as of December 31. As of March 31, 2025, 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, 2025. The balance of goodwill was $12.0 million at both March 31, 2025 and December 31, 2024.

Intangible Asset

The Company's intangible asset is amortized using the straight-line method over its estimated period of benefit of ten years. The Company evaluates recoverability of the intangible asset 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 the intangible asset during the three months ended March 31, 2025.

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 probability weighted income approach and makes significant assumptions, including estimated future sales of Sunosi in current and future indications, timing of regulatory and commercial milestone achievements, probability of technical and regulatory success rates, and discount rates. 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 expenses and other liabilities, contingent warrant liability, current and long-term debt, and current and non-current contingent consideration. The Company's Level 1 financial instruments include cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses and other liabilities. They are considered Level 1 as the carrying values reported in the accompanying consolidated financial statements approximate their respective fair values due to their short-term maturities. The carrying value of debt on the Company's balance sheet is estimated to approximate its fair value. The Company's Level 3 financial instruments include contingent warrant liability and current and non-current contingent consideration due to the significant unobservable inputs required in determining their respective fair values.

The Company categorized the fair value of contingent consideration liabilities as Level 3 within the fair value hierarchy as the estimate is based on significant unobservable inputs requiring management judgment. The fair value of contingent consideration liabilities is estimated by using the probability weighted income approach using significant assumptions, including estimated future sales of Sunosi in current and future indications, timing of regulatory and commercial milestone achievements, probability of technical and regulatory success and discount rates. Contingent consideration liabilities are subject to remeasurement at each prospective balance sheet date, with any changes in the fair value recorded in the consolidated statements of operations. See Note 6. Fair Value of Financial Instruments for further detail.

The Company estimated the fair value of the warrant liabilities using the Black-Scholes model based on key assumption and inputs. The Company utilizes a probability assessment to estimate the likelihood of vesting for the remaining Loan Agreement (as defined below) warrants and allocated the probability of occurrence percentage to the fair values calculated, and, therefore, is considered Level 3 within the fair value hierarchy. The Company accounts for warrants anticipated to be issued in the future under the Loan Agreement as liabilities and measures them at fair value using the Black-Scholes valuation model. The warrants are subject to remeasurement at each prospective balance sheet date, with any changes in the fair value recorded in the consolidated statements of operations. See Note 6. Fair Value of Financial Instruments for further detail.

Accounts Receivable, net

The Company's accounts receivable, net arise from product sales and represent amounts due from its customers. They are generally stated at the gross sales amount, less reserves resulting from trade discounts and allowances and chargebacks. Accounts receivable typically has a standard payment term of 60 days or less and does not bear interest.

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, 2025, the Company has not recorded any allowances for doubtful accounts receivable. For further information about accounts receivable, see Note 3. Accounts Receivable, net.

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 and subsequently amortized as interest expense in the consolidated statement of operations using the effective interest rate method.

The Company evaluates amendments to its debt instruments in accordance with ASC 470-50, *Debt – Modifications and Extinguishments* ("ASC 470") to determine whether the amendment should be accounted for as a modification or an extinguishment. An amendment may be considered modified when the terms of the new debt and original instrument are not "substantially different" (as defined in the debt modification guidance in ASC 470). Amendments that are considered modifications are accounted for prospectively as yield adjustments, based on the revised terms, and lender fees and costs directly incurred with third parties, to the extent material, are recorded as debt discount and amortized to interest expense using the effective interest rate method.

Inventory

The Company values its inventories at the lower of cost or estimated net realizable value. The remaining inventory associated with the 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 the 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 after 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 conducting research, preclinical and clinical studies, laboratory supplies, product license fees, consulting and other related expenses. Research, preclinical and clinical study expenses are estimated based on services performed, pursuant to contracts with third-party research and development organizations that conduct and manage research, preclinical and clinical activities on the Company's behalf, including 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, accruals are adjusted 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.

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, 2025 and 2024, advertising costs were $27.7 million and $24.0 million, respectively.

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 estimates an annual effective tax rate of 0% for the year ending December 31, 2025 and has not recorded an income tax benefit for the three months ended March 31, 2025 since it is projecting losses and has incurred year to date losses in all jurisdictions from which the Company does not benefit due to the full valuation allowance position against the Company's deferred tax assets.

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, 2025, 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.

For restricted stock units ("RSUs") and performance stock units ("PSUs"), 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 and for certain awards that are subject to a post-vesting holding period, an illiquidity discount is also applied.

The Company recognizes the grant date fair value of the stock options and RSUs over the requisite service period, which is generally the vesting term. For awards only subject to service-based vesting conditions, the Company elected to recognize stock-based compensation expense on a straight-line basis. For PSUs, the Company recognizes stock-based compensation expense when the achievement of the performance condition becomes probable. Stock-based compensation expense for PSUs with cliff-vesting terms is recognized on a straight-line basis. At the end of each reporting period, the Company reassesses the probability of achieving the performance condition and adjusts the stock-based compensation expense accordingly.

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, vesting of RSUs and PSUs 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. In addition, the Company accounts for equity award forfeitures as they occur.

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, RSUs and/or common stock pursuant to the 2023 Employee Stock Purchase Plan (the "ESPP"), 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, 2025 and 2024.

Leases

The Company determines if an arrangement is a lease at contract inception. Right-of-use assets represent the Company's right to use an underlying asset for the lease term and 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.

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 interest rate implicit in the contract when such rate is readily determinable and uses the Company's incremental borrowing rate when the rate implicit in the contract is not readily determinable based upon the information available at the commencement date in determining the present value of the lease payments.

Leases are accounted for under *ASC 842, Leases* ("ASC 842"). The Company made an accounting policy election not to apply the recognition requirements to short-term leases. The Company recognizes the lease payments for short-term leases in the consolidated statements of operations on a straight-line basis over the lease term, and variable lease payments in the period in which the obligation for those payments is incurred. Therefore, the Company is not recognizing a lease liability or right-of-use asset for any lease that, at the commencement date, has a lease term of 12 months or less and does not include an option to extend the term or purchase the underlying asset that the Company is reasonably certain to exercise. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. The Company evaluates amendments to its lease arrangements in accordance with ASC 842.

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. Operating lease expense is recognized on a straight-line basis over the lease term and included in selling, general and administrative expenses. Finance leases are included in the non-current inventory and other assets; accrued expenses and other current liabilities; and finance lease liability, long-term in the Company's consolidated balance sheets. Assets under the finance leases are amortized on a straight-line basis over the lease term and included in selling, general and administrative expenses. 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

In December 2023, the FASB issued ASU 2023-09, Improvements to Income Tax Disclosures, which requires disclosure of disaggregated income taxes paid by jurisdiction, enhances disclosures in the effective tax rate reconciliation, and modifies other income tax-related disclosures. The amendments are effective for annual periods beginning after December 15, 2024. The Company is currently evaluating the effect of adopting this guidance on its consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses. This ASU requires additional disaggregated disclosures in the notes to financial statements for certain categories of expenses that are included on the face of the income statement. The guidance is effective for fiscal years beginning after December 15, 2026 and for interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the effect of adopting this guidance on its consolidated financial statements.

Note 3. Accounts Receivable, net

Accounts receivable, net consisted of the following:

	March 31, 2025	December 31, 2024
Trade receivables	$ 176,178	$ 155,505
Less: Reserves for variable consideration	(14,780)	(13,504)
Accounts receivable, net	$ 161,398	$ 142,001

Note 4. Inventory

Inventory consisted of the following:

	March 31, 2025	December 31, 2024
Raw materials	$ 11,533	$ 9,541
Work in process	6,797	7,723
Finished goods	8,962	8,986
Total	$ 27,292	$ 26,250

There were no material inventory reserves or write downs of any excess and obsolete inventory as of March 31, 2025. Non-current inventory, which consists of raw materials and work in progress inventory, is included in non-current inventory and other assets on the accompanying consolidated balance sheets. Non-current inventory is estimated to be consumed beyond the next 12 months.

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

	March 31, 2025	December 31, 2024
Balance sheet classification		
Inventories, net	$ 16,319	$ 15,732
Non-current inventory and other assets	10,973	10,518
Total	$ 27,292	$ 26,250

Note 5. Intangible Asset

The following table provides the Company's carrying amount of the intangible asset for each of the periods indicated.

	Gross carrying amount	Accumulated amortization	Net carrying amount	Remaining weighted-average useful life
Balance at December 31, 2024				
Finite-lived intangible asset	$ 63,800	$ 16,906	$ 46,894	8-years
Balance at March 31, 2025				
Finite-lived intangible asset	$ 63,800	$ 18,478	$ 45,322	7-years

Based on the finite-lived intangible asset recorded as of March 31, 2025, and assuming the underlying asset will not be impaired and that the Company will not change the expected life of the asset, future amortization expense over the next five years and periods thereafter are estimated to be as follows:

	Estimated amortization expense
2025	$ 4,803
2026	6,375
2027	6,375
2028	6,392
2029	6,375
Thereafter	15,002
Total	$ 45,322

Note 6. Fair Value of Financial Instruments

In connection with the Acquisition, the Company pays royalty on U.S. 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 $8.6 million and non-current contingent consideration liability of $90.6 million in the consolidated balance sheet as of March 31, 2025.

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

	March 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents - money market funds	$ 231,582	$ —	$ —	$ 231,582
Liabilities:				
Contingent consideration	$ —	$ —	$ 99,192	$ 99,192

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents - money market funds	$ 244,097	$ —	$ —	$ 244,097
Liabilities:				
Contingent consideration	$ —	$ —	$ 99,965	$ 99,965

Contingent Consideration Liabilities

The fair value of the contingent consideration liabilities is marked-to-market at each reporting period and was remeasured at March 31, 2025. Changes in fair value of the contingent consideration liabilities as of March 31, 2025 are as follows:

	Contingent consideration
Balance at December 31, 2024	$ 99,965
Adjustment to fair value	1,512
Payments	(2,285)
Balance at March 31, 2025 (Level 3)	$ 99,192

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, 2025	As of December 31, 2024
	Valuation methodology	Significant unobservable input	Weighted average (range, if applicable)	Weighted average (range, if applicable)
Contingent consideration	Probability weighted income approach	Discount rate	12.7%	12.0%
		Revenue discount rate	17.3% - 20.3%	17.6% - 20.6%

The Company's fair value measurement of contingent consideration liabilities has been classified as Level 3 as its valuation requires substantial judgment and estimation of factors which requires use of unobservable inputs. The fair value of contingent consideration liabilities are estimated by using the probability weighted income approach using significant assumptions including estimated future sales of Sunosi in current and future indications, timing of regulatory and commercial milestone achievements, probability of technical and regulatory success rates, and discount rates. If significant changes are made to one or more of these assumptions, the estimated fair value of contingent consideration liabilities may result in a significantly higher or lower fair value measurement.

Note 7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	March 31, 2025	December 31, 2024
Accrued research and development	$ 11,246	$ 14,431
Accrued compensation	19,598	28,225
Accrued selling, general, and administrative	10,361	17,498
Accrued sales discounts, rebates, and allowances	95,768	73,952
Accrued royalties	7,908	9,958
Accrued interest	1,542	1,542
Accrued taxes	960	960
Finance lease liability, current	1,816	1,421
Total	$ 149,199	$ 147,987

Note 8. Loan and Security Agreement

Hercules Capital, Inc.

For the purposes of this Note 8, capitalized terms used but not otherwise defined herein shall have the meanings assigned to them in the Loan Agreement (as defined below).

Fifth Amendment to the Loan Agreement

On September 30, 2024, the Company entered into a Fifth Amendment (the "Fifth 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, as further amended by the Second Amendment to Loan and Security Agreement, dated as of March 27, 2022, as further amended by the Third Amendment to Loan and Security Agreement, dated as of January 9, 2023, and as further amended by the Waiver and Fourth Amendment to Loan and Security Agreement, dated as of May 8, 2023) (the "Loan Agreement") 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 (collectively, the "Lenders"), with respect to the term loan thereunder (the "2020 Term Loan").

The Fifth Amendment amended the terms of the Loan Agreement to, among other things: (i) increase the Tranche 3 Commitment from $75.0 to $80.0 million; (ii) extend the availability periods of Tranche 1D to June 15, 2025 and that of Tranche 1E to December 15, 2025, as set forth in greater detail in the Fifth Amendment; (iii) alter the terms of Performance Covenant A, Performance Covenant B, and Performance Covenant C and also add a Performance Covenant D, as set forth in greater detail in the Fifth Amendment; (iv) conditionally waive the requirement that the Company maintain Qualified Cash in an amount greater than or equal to the sum of $30.0 million plus the Qualified Cash A/P Amount at all times during such periods of time that the Company's Market Capitalization exceeds $1.5 billion; and (v) permit Axsome Malta Ltd. ("Axsome Malta") to request an Advance from the Lenders up to a certain amount to the extent that the Company may request an Advance in such amount and to increase the amount of Cash that Axsome Malta may hold outside of the United States, as set forth in greater detail in the Fifth Amendment.

The Waiver and Fourth Amendment (the "Fourth Amendment") to the Loan Agreement with Hercules and the Third Amendment (the "Third Amendment") to the Loan Agreement with Hercules incorporate the following amendments:

- The increase of cash held by Axsome Malta outside of the United States from $3.0 million to $15.0 million for a 45-day period after the closing of the Fourth Amendment and to $10.0 million thereafter;
- The waiver of any purported default with respect to the amount of cash held by Axsome Malta prior to the date of the Fourth Amendment;
- In August 2023, Hercules granted the Company a waiver to the Fourth Amendment, permitting Axsome Malta to hold up to $12.5 million in Cash outside of the United States until December 31, 2023;
- 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 availability dates under the Tranche 1 Advance through Tranche 5 Advance, 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 from three sub-tranches of $35.0 million, $35.0 million, and $30.0 million, respectively, to one tranche of $25.0 million, changing the Tranche 3 Advance from two sub-tranches of $15.0 million and $5.0 million, respectively, to one tranche of $75.0 million, and removing the Tranche 4 Advance 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 the sum of $30.0 million plus the Qualified Cash A/P Amount; 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, Tranche 1C Advance, Tranche 1D Advance, Tranche 1E Advance, Tranche 2 Advance, and Tranche 3 Advance.

As of March 31, 2025, the Company had allowed Tranche 2, which totaled $25.0 million, to expire undrawn.

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, Antecip 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. Effective upon closing of the Fifth Amendment in September 2024, the following limited financial covenants apply:

- The Company at all times must maintain Qualified Cash in an aggregate amount greater than or equal to $30.0 million plus the Qualified Cash A/P Amount; provided that compliance with such covenant shall be conditionally waived during such periods of time that the Company's Market Capitalization exceeds $1.5 billion.
- The Company must meet, beginning June 30, 2023, any of the following conditions: (A) ensure that at all times its market capitalization exceeds $1.0 billion and that it maintains Qualified Cash in an amount not less than 30% of the sum of the outstanding principal amount of the Term Loan Advances plus the Qualified Cash A/P Amount, (B) ensure that at all times that it maintains Qualified Cash in an amount not less than 50% of the sum of the outstanding principal amount of the Term Loan Advances plus the Qualified Cash A/P Amount, or (C) ensure that at all times its market capitalization exceeds $1.5 billion. Alternatively, the Company must, beginning with fiscal quarter ending September 30, 2024, and for each quarter thereafter, achieve T6M Net Product Revenue in an amount equal to at least the amount set forth on Schedule 7.20(b) of the Loan Agreement opposite the last day of each fiscal quarter identified in the table therein, tested on a quarterly basis.

- Axsome Malta, a company organized under the laws of the Republic of Malta, may request an Advance from the Lenders up to a certain amount to the extent that the Company may request an Advance in such amount, and Axsome Malta may not hold Cash outside of the United States in excess of the sum of $10.0 million and the aggregate outstanding principal amount of Advances drawn by Axsome Malta.
- 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 minus (iii) any charges paid by the Borrower to the Lenders related to partial prepayments of the outstanding Secured Obligations. The end of term charges are being accreted into interest expense using the effective interest rate method over the term of the loan.

If certain maturity extension conditions 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 Advance amount prepaid if the prepayment occurs prior to February 1, 2024, (ii) 1.5% of the Advance amount prepaid if the prepayment occurs on or after February 1, 2024 but prior to February 1, 2025, and (iii) 1.0% of the Advance 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.

The Company also evaluated whether the Fifth Amendment entered into September 2024 represented a debt modification or extinguishment in accordance with ASC 470. As the terms of the Fifth Amendment are not substantially different as compared to that of the Fourth Amendment, the Company treated the amendment as a debt modification.

Loan Interest Expense and Amortization

Long-term debt and unamortized debt discount balances are as follows:

	March 31, 2025	December 31, 2024
Total outstanding debt	$ 180,000	$ 180,000
Add: accreted final payment fee	4,478	4,085
Less: unamortized debt discount, long-term	(3,101)	(3,375)
Less: current portion of long-term debt	—	—
Loan payable, long-term	$ 181,377	$ 180,710

The book value of debt approximates its fair value given its variable interest rate.

Interest expense, amortization of the final payment fee, and amortization of the debt discount related to the issuance costs and warrants for the Company's debt are as follows:

	Three months ended March 31,	
	2025	2024
Interest expense	$ 4,478	$ 4,869
Amortization of final payment fee	393	349
Amortization of debt discount related issuance costs and warrants	274	270

Scheduled principal payments on outstanding debt, as of March 31, 2025, are as follows:

2025	$ —
2026	—
2027	—
2028	180,000
2029	—
Thereafter	—
Total principal payments outstanding	$ 180,000

Note 9. Commitments and Contingencies

Leases

In February 2023, the Company entered into a sublease agreement ("Initial Sublease") for the previous office space located at One World Trade Center.

In January 2025, the Company entered into an amended sublease agreement (the "First Amendment") to terminate the existing space in its corporate office and commence occupancy of different space within the same building. The First Amendment was treated as a lease modification to the Initial Sublease which resulted in the recognition of a gain on modification of $2.3 million which is included in selling, general and administrative expenses. The Company also recorded a right-of-use asset and corresponding lease liability of $23.9 million during the three months ended March 31, 2025. Based on the Company's past experience and current expectations for administrative office needs, the Company determined the lease term to be approximately six years. As of March 31, 2025, the remaining lease term for the Company's operating lease was 6.0 years with the discount rate of 7.12%. 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.

The Company entered into a fleet lease program beginning the first quarter of 2024. The lease agreement includes an initial 12-month noncancelable period with monthly renewal options thereafter. Lease terms range from approximately 40 to 50 months and are classified as finance leases. During the three months ended March 31, 2025, the Company recognized a right-of-use asset and lease liability, both, of $1.5 million in connection to this lease. As of March 31, 2025, right-of-use asset and lease liability related to the finance lease were $5.4 million and $5.5 million, respectively, and the weighted average remaining lease term was 3.1 years, with a weighted average discount rate of 9.5%.

Lease expenses recognized were as follows:

	Three months ended March 31,	
	2025	2024
Operating lease expense	$ 971	$ 583
Finance lease expense:		
Amortization of right-of-use assets	412	110
Interest on lease liabilities	113	35

Future minimum lease payments of the Company's leases as of March 31, 2025 were as follows:

	Operating lease	Finance lease
2025	$ 1,639	$ 1,689
2026	2,478	2,139
2027	4,791	1,639
2028	4,807	812
2029	11,284	1
Thereafter	6,317	—
Total lease payments	31,316	6,280
Less: imputed interest	(6,957)	(784)
Present value of lease liabilities	$ 24,359	$ 5,496

Note 10. Stockholders' Equity

Public Offerings

At-the-Market Offerings

In December 2019, the Company entered into a sales agreement (the "December 2019 Sales Agreement") with SVB Securities LLC (now known as Leerink Partners LLC) ("Leerink"), pursuant to which the Company may sell up to $80 million in shares of the Company's common stock from time to time through Leerink, 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 U.S. Securities and Exchange Commission (the "SEC") on December 5, 2019 for the issuance of common stock, preferred stock, warrants, rights, debt securities and units. Leerink 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 (as defined below).

In March 2022, the Company entered into a sales agreement (the "March 2022 Sales Agreement") with Leerink and filed a prospectus supplement, pursuant to which the Company could sell up to $200 million in shares of the Company's common stock from time to time through Leerink, acting as the Company's sales agent, in one or more at-the-market offerings utilizing the 2019 Shelf Registration Statement. Leerink 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 Leerink. The Company exhausted sales of 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 Leerink a commission of up to 3.0% of the gross sales proceeds of any shares sold through Leerink, 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 the Company's common stock that may be issued and sold from time to time through Leerink, as the Company's sales agent, under the March 2022 Sales Agreement.

Under the March 2022 Sales Agreement, for the three months ended March 31, 2025, the Company received approximately $19.7 million in gross proceeds through the sale of 156,484 shares, of which net proceeds were approximately $19.3 million. The Company did not utilize the March 2022 Sales Agreement with Leerink during the three months ended March 31, 2024.

Upon the closing of the Second Amendment, which occurred in March 2022, Hercules also purchased 152,487 of the Company's unregistered common stock for a total consideration of $5.0 million at a share price equal to $32.79 per share, pursuant to a share transfer agreement.

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.

June 2023 Public Offering

In June 2023, the Company completed an underwritten public offering of its common stock (the "June 2023 Public Offering"). The Company sold 3.0 million shares of its common stock at a public offering price of $75.00 per share. The net proceeds were $211.3 million, net of underwriting discounts and commissions of $13.5 million and other offering costs of $0.2 million. Additionally, in connection with this public offering, in July 2023, the underwriters fully exercised their option to purchase 450,000 additional shares of the Company's common stock at a public offering price of $75.00 per share. The net proceeds from the exercise of the option were $31.7 million, net of underwriting discounts and commissions of $2.0 million and other minimal offering costs.

Shelf Registration Statement

On December 2, 2022, the Company filed an automatic shelf registration statement (the "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.

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 Plan

In November 2015, the 2015 Omnibus Incentive Compensation Plan (the "2015 Plan") was adopted by the Company's stockholders. As of March 31, 2025, there were 2,419,922 shares available for future grant under the 2015 Plan.

Stock Options

The following table sets forth stock option activity as of March 31, 2025:

	Number of shares	Weighted average exercise price	Weighted average contractual term (years)	Aggregate intrinsic value
Outstanding at December 31, 2024	8,439,121	$ 46.72		
Granted	274,595	128.92		
Exercised	(331,853)	51.33		
Forfeited/Canceled	(92,006)	72.79		
Outstanding at March 31, 2025	8,289,857	$ 48.97	6.3	$ 565,499
Vested and expected to vest at March 31, 2025	8,289,857	$ 48.97	6.3	$ 565,499
Exercisable at March 31, 2025	5,431,100	$ 36.45	5.2	$ 435,560

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 was based on historical volatilities of similar entities within the Company's industry which were commensurate with the Company's expected term assumption. Currently, expected volatility is based on historical volatility information of the Company's common stock since the Company's initial public offering in 2015.

The weighted average grant date fair value of options granted was $92.48 per option for the three months ended March 31, 2025. As of March 31, 2025, there was $148.8 million of total unrecognized compensation cost related to unvested stock options which is expected to be recognized over a weighted average period of 2.3 years.

Restricted Stock Units

The fair value of the RSUs is recognized as an expense ratably over the vesting period of four years. As of March 31, 2025, total compensation cost not yet recognized related to unvested RSUs was $79.1 million, which is expected to be recognized over a weighted-average period of 2.9 years. The intrinsic value of RSUs lapsed during the three months ended March 31, 2025 was $12.1 million.

The following table sets forth the RSU activity for the three months ended March 31, 2025:

	Number of shares	Weighted average grant date fair value
Outstanding at December 31, 2024	906,944	$ 59.48
Granted	347,482	125.48
Vested	(244,299)	49.24
Forfeited	(16,925)	83.17
Outstanding at March 31, 2025	993,202	$ 84.69

Performance Stock Units

In February 2025, the Company granted PSUs to the executive officers. Vesting of the PSUs is subject to achievement of specified performance goals, which include achieving revenue, clinical, and regulatory targets. The actual number of common shares that would ultimately be issued is calculated by multiplying the number of PSUs granted by a payout multiplier ranging from 0 to 2. Achievement of the performance goals will ultimately be determined by the Compensation Committee or the Board at the end of the vesting term, which is approximately 3 years from the grant date. As of March 31, 2025, total compensation cost not yet recognized related to unvested PSUs was $5.9 million, which is expected to be recognized over a weighted-average period of 3.0 years.

The following table sets forth the PSU activity for the three months ended March 31, 2025:

	Number of shares	Weighted average grant date fair value
Outstanding at December 31, 2024	—	$ —
Granted	64,281	94.39
Vested	—	—
Forfeited	—	—
Outstanding at March 31, 2025	64,281	$ 94.39

Employee Stock Purchase Plan

The ESPP allows eligible employees to purchase shares of the Company's common stock. The purchase price is equal to 85% of the lower of the closing price of the Company's common stock on (1) the first day of the offering period or (2) the last day of the offering period. The ESPP has consecutive offering periods that begin on or about June 1st of each year with a duration of 12 months. The Company commenced the first offering period pursuant to the ESPP on June 1, 2023, and such offering ended on May 31, 2024.

During the three months ended March 31, 2025, no shares of common stock have been purchased or issued pursuant to the ESPP, and $0.3 million of expense was recorded for the same period.

Stock-based Compensation Expense

Stock-based compensation expense recognized was as follows:

	Three months ended March 31,	
	2025	2024
Research and development	$ 6,459	$ 4,568
Selling, general and administrative	16,849	15,622
Total	$ 23,308	$ 20,190

Stock-based compensation expense capitalized into inventory totaled $0.3 million for both the three months ended March 31, 2025 and 2024. Capitalized stock-based compensation is recognized as an expense in cost of product sales when the related product is sold or in selling, general and administrative expense when the related product is dispensed as a physician sample.

Note 11. Warrants

The following table summarizes warrant activity for the three months ended March 31, 2025:

	Warrants	Weighted average exercise price
Outstanding at December 31, 2024	79,220	$ 56.80
Issued	—	—
Exercised	—	—
Outstanding at March 31, 2025	79,220	$ 56.80

Outstanding Warrants

In connection with the entry into the Third Amendment, Hercules received warrants to purchase an aggregate of 18,724 shares of the Company's common stock at an exercise price of $55.01 per share, and in connection with the draw down of the Tranche 1C Advance, Hercules received warrants to purchase 9,700 shares of the Company's common stock at an exercise price of $77.31 per share (collectively, the "2023 warrants"). In connection with the entry into the Second Amendment, Hercules received warrants to purchase an aggregate of 35,255 shares of the Company's common stock at an exercise price of $31.91 per share (the "2022 warrants"), and in connection with the first advance of the 2020 Term Loan, Hercules received warrants to purchase an aggregate of 15,541 shares of the Company's common stock at an exercise price of $80.43 per share (the "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 $1.6 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 12. Net Loss per Common Share

The following table sets forth the computation of basic and diluted net loss per common share:

	Three months ended March 31,	
	2025	2024
Basic and diluted net loss per common share:		
Net loss	$ (59,413)	$ (68,357)
Weighted average common shares outstanding—basic and diluted	48,871,163	47,393,563
Net loss per common share—basic and diluted	$ (1.22)	$ (1.44)

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

	March 31,	
	2025	2024
Stock options	8,289,857	9,156,130
Restricted stock units	993,202	922,651
Performance stock units	64,281	—
Warrants	79,220	79,220
ESPP	61,717	53,500
Total	9,488,277	10,211,501

Note 13. Revenues

The Company sells Auvelity and Sunosi in the United States through the Distributors. The Company also sells Sunosi to Distributors in Canada and on a product supply basis to Pharmanovia. Sunosi is subsequently sold by Pharmanovia in certain ex-U.S. markets. For the three months ended March 31, 2025, the Company's three largest customers represented approximately 32%, 30%, and 27% of the Company's gross product sales.

Royalty revenue is related to sales of Sunosi by Pharmanovia in certain ex-U.S. markets.

The following table presents a summary of total revenues by product:

	Three months ended March 31,	
	2025	2024
Product sales, net		
Auvelity	$ 96,231	$ 53,395
Sunosi	24,127	20,701
Total product sales, net	120,358	74,096
Sunosi royalty revenue	1,105	903
Total revenues	$ 121,463	$ 74,999

The following table presents a summary of total revenues by geographic location:

	Three months ended March 31,	
	2025	2024
Product sales, net		
United States	$ 119,413	$ 73,271
Outside of the United States	945	825
Total product sales, net	120,358	74,096
Royalty revenue		
Outside of the United States	1,105	903
Total revenues	$ 121,463	$ 74,999

For the three months ended March 31, 2025, product sales, net includes adjustments for provisions for product sales made in 2024 resulting from changes in estimates of $1.1 million for Auvelity and $0.9 million for Sunosi. For the three months ended March 31, 2024, product sales, net includes adjustments for provisions for product sales made in 2023 resulting from changes in estimates of $1.2 million for Auvelity and $0.6 million for Sunosi.

Note 14. License Agreements

License Agreement with Pharmanovia

In February 2023, Axsome Malta, a Malta limited company 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 Sunosi intellectual property and licenses those rights in the Territory to Pharmanovia. Pharmanovia is solely responsible for the clinical development and commercialization of Sunosi 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 product is supplied to Pharmanovia.

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 upon transfer of the license to Pharmanovia, as the requirement 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 development or regulatory 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. The Company recognized royalty revenue of $1.1 million and $0.9 million for the three months ended March 31, 2025 and 2024, respectively, related to Pharmanovia's sales of Sunosi. No other development or sales-based milestones were recognized during the three months ended March 31, 2025 and 2024.

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 December 31, 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, 2025 and 2024, 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 owned by the Company's Chief Executive Officer and Chairman of the Board, Herriot Tabuteau, M.D., in which the Company was granted exclusive licenses to develop, manufacture and commercialize Antecip's patents and applications related to the development of AXS-05 (now marketed as Auvelity) and two product candidates no longer under active development, 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 these product candidates. Under the terms of the agreements, the Company is required to pay to Antecip a royalty equal to 3.0% for AXS-05 (and 1.5% or 4.5% for the other two product candidates no longer under active development), 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 (the components of which are referred to as "AXS-05") in the fourth quarter of 2022. For the three months ended March 31, 2025 and 2024, the Company recorded royalty expense of $2.9 million and $1.6 million, respectively, for royalty due 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 Loan Agreement, the Company entered into the Direct Agreement with Antecip and Hercules, pursuant to which Antecip consented to the collateral assignment of the License Agreement under the Loan Agreement, among other things.

Note 15. Royalty Agreements

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 in certain U.S. and ex-U.S. markets. The Acquisition occurred in two separate closings. The sale and purchase of specified initial assets contemplated by the Purchase Agreement occurred on May 9, 2022 (the "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 (the "Final 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.

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, or (B) mid-single-digit royalty for any future indication of net sales in the U.S. Territory made during the applicable royalty term. 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 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 additionally, the Company is committed to pay up to $165.0 million based on revenue milestones and $1.0 million based on development milestones.

Note 16. Income Taxes

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

	Three months ended March 31,	
	2025	2024
Loss before income taxes	$ (59,413)	$ (68,357)
Income tax expense	—	—
Effective tax rate	—%	—%

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 (the "IRS") and other tax authorities to determine the adequacy of its income tax reserves and expense. Should actual events or results differ from the Company's current expectations, charges or credits to its income tax expense may become necessary.

The Company did not record a tax expense for the three months ended March 31, 2025 and 2024.

The Company did not have any unrecognized tax benefits as of March 31, 2025 related to uncertain tax positions that would impact the effective income tax rate if recognized.

The Company is currently under examination by the IRS for the Company's 2021 U.S. income tax return. The Company is not currently under examination at the state level. The Company's U.S. federal and state net operating losses have occurred since its inception in 2012 and as such, tax years subject to potential tax examination could apply from that date because the utilization of net operating losses from prior years opens the relevant year to audit by the IRS and/or state taxing authorities.

Note 17. Related Party Transactions

From the Company's inception, Herriot Tabuteau, M.D. has been the Company's founder, Chief Executive Officer, Chairman of the Company's Board, and the beneficial owner of more than 5% of the outstanding shares of the Company's common stock. In connection with the formation of the Company, in January 2012, the Company issued to Antecip Bioventures II LLC, an entity controlled by Dr. Tabuteau, an aggregate of 7,344,500 shares of the Company's common stock for nominal consideration. Additionally, since the launch of Auvelity in the fourth quarter of 2022, the Company recorded royalty expense of $2.9 million and $1.6 million for the three months ended March 31, 2025 and 2024, respectively, which equal 3.0% of net sales for those respective periods.

The Company is a party to three exclusive license agreements with Antecip Bioventures II LLC, an entity owned by Dr. Tabuteau. See Note 14. License Agreements for further information regarding the license agreements.

Note 18. Segment Information

The Company views its operations and manages its business as one operating and reportable segment, which is the business of developing and delivering novel therapies for the management of CNS disorders. The Company's focus centers around the CNS disorders market as its primary operating environment. Consistent with the operational structure, the Chief Executive Officer, as the chief operating decision maker ("CODM"), manages and allocates resources on a consolidated basis. This decision making process reflects the way in which the financial information is regularly reviewed and used by the CODM to evaluate performance, set operational targets, forecast future financial results, and allocate resources.

The Company's CODM assesses financial performance and allocates resources based on consolidated net loss that also is reported on the consolidated statements of operations. The measure of segment assets is reported on the balance sheet as total consolidated assets. The CODM utilizes consolidated net loss by comparing actual results against budgeted amounts on a quarterly basis. As part of this process, consolidated net loss is a critical performance measure used to evaluate the Company's operating performance and guide strategic decisions and resource allocations, including additional investments in research and development and commercialization activities.

The following table provides information about the Company's one reportable segment and includes the reconciliation to consolidated net loss.

	Three months ended March 31,	
	2025	2024
Total revenues	$ 121,463	$ 74,999
Less:		
Cost of revenue (excluding amortization and depreciation)	9,789	6,297
Research and development expense (excluding share-based compensation expense):		
Solriamfetol	11,806	8,564
AXS-05	14,477	13,525
AXS-07	4,479	2,972
AXS-12	2,409	2,046
AXS-14	1,186	2,609
Other research and development[(a)]	3,969	2,546
General and administrative expense (excluding share-based compensation expense)	11,650	12,152
Selling and marketing expense (excluding share-based compensation expense)	92,288	71,196
Share based compensation expense	23,308	20,190
Loss (Gain) in fair value of contingent consideration	1,512	(1,412)
Interest expense, net[(b)]	2,431	1,082
Other segment items[(c)]	1,572	1,589
Segment net loss	(59,413)	(68,357)
Reconciliation of net loss		
Adjustments and reconciling items	—	—
Consolidated net loss	(59,413)	(68,357)

(a) Other research and development expenses primarily consist of facilities charges, third party consultant costs, costs related to other product candidates, and other unallocated costs.
(b) Interest expense, net of $2,431 for the three months ended March 31, 2025 comprises (i) consolidated interest expense of $5,258 and (ii) consolidated interest income of $2,827. Interest expense, net of $1,082 for the three months ended March 31, 2024 comprises (i) consolidated interest expense of $5,406 and (ii) consolidated interest income of $4,324.
(c) Other segment items included in Segment net loss include intangible asset amortization and other miscellaneous items.

See Note 2. Summary of Significant Accounting Policies for further details on the products from which the Company derives its revenues.

See Note 13. Revenues for details of revenue from external customers by geography.

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, 2024 which was filed with the U.S. Securities and Exchange Commission, or SEC, on February 18, 2025.

Overview

We are a biopharmaceutical company dedicated to the development and commercialization of innovative medicines for people living central nervous system ("CNS") conditions.

Commercial Products

1. ***Auvelity®.*** Auvelity (dextromethorphan-bupropion) is a novel, oral, N-methyl-D-aspartate (NMDA) receptor antagonist, sigma-1 receptor agonist, aminoketone, and CYP2D6 inhibitor. Auvelity was developed by the Company and approved by the FDA for the treatment of major depressive disorder (MDD) in adults in August 2022. We initiated the commercial launch of Auvelity in the United States in October 2022. We refer to the proprietary dextromethorphan-bupropion formulation contained in Auvelity as AXS-05. As used in this report, "Auvelity" refers to AXS-05 approved by the FDA for the treatment of MDD in adults, and "AXS-05" refers to, where applicable, Auvelity as well as AXS-05 for the treatment of indications beyond MDD in adults.

2. ***Sunosi®.*** Sunosi (solriamfetol) is a novel, oral, dopamine and norepinephrine reuptake inhibitor (DNRI), trace amine-associated receptor 1 (TAAR1) agonist, and 5-HT_{1A} agonist. Sunosi was approved for the treatment of EDS in adult patients with narcolepsy or obstructive sleep apnea (OSA) by the FDA 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 the 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., or SK, is the originator of Sunosi and retains rights in 12 Asian markets, including China, Korea, and Japan. We refer to the acquisition of Sunosi herein as the Acquisition. In February 2023, we entered into a licensing agreement, or the Pharmanovia License Agreement, with Atnahs Pharma UK Limited, or Pharmanovia, that granted to Pharmanovia the exclusive right to market Sunosi in Europe and certain countries in the Middle East and North Africa, referred to as the Licensed Territory. As used in this report, "Sunosi" refers to solriamfetol approved for the treatment of EDS in patients with narcolepsy or OSA, and "solriamfetol" refers to, where applicable, Sunosi as well as solriamfetol for the treatment of indications beyond EDS in patients with narcolepsy or OSA.

3. ***Symbravo®.*** Symbravo (MoSEIC™ meloxicam-rizatriptan) is a novel, oral, rapidly absorbed, multi-mechanistic, selective COX-2 inhibitor and 5-$HT_{1B/1D}$ agonist. Symbravo was developed by the Company and approved by the FDA for the acute treatment of migraine with or without aura in adults in January 2025.

Pipeline

We are advancing a diversified, late-stage pipeline of novel product candidates for serious neurological and psychiatric conditions.

AXS-05 (dextromethorphan-bupropion) is a novel, oral, investigational NMDA receptor antagonist, sigma-1 receptor agonist, aminoketone, and CYP2D6 inhibitor being developed for the treatment of Alzheimer's disease agitation, or AD agitation, and smoking cessation. AXS-05 utilizes a proprietary formulation and dose of dextromethorphan and bupropion, and Axsome's metabolic inhibition technology, to modulate the delivery of the components. We have successfully completed the Phase 3 clinical program of AXS-05 in AD agitation consisting of four Phase 3, placebo-controlled efficacy trials and a long-term safety trial. AXS-05 has been granted FDA Breakthrough Therapy designation for AD agitation.

Solriamfetol is an oral, DNRI, TAAR1 agonist, and 5-HT_{1A} agonist being developed for the treatment of attention deficit hyperactivity disorder ("ADHD"), major depressive disorder (MDD) with EDS, binge eating disorder ("BED") and excessive sleepiness associated with shift work disorder ("SWD"). We recently announced topline results from the FOCUS Phase 3 trial of solriamfetol in ADHD in adults and the PARADIGM Phase 3 trial of solriamfetol in MDD. Enrollment for the ENGAGE and SUSTAIN Phase 3 trials of solriamfetol in BED and SWD, respectively, are ongoing.

AXS-12 (reboxetine) is a novel, oral, investigational, highly selective and potent norepinephrine reuptake inhibitor and cortical dopamine modulator being developed for the treatment of narcolepsy. We have successfully completed three Phase 2 and Phase 3, placebo-controlled efficacy trials and a long-term safety trial. AXS-12 has been granted FDA Orphan Drug Designation for narcolepsy.

AXS-14 (esreboxetine) is a novel, oral, investigational, highly selective and potent norepinephrine reuptake inhibitor being developed for the management of fibromyalgia. Esreboxetine, the SS-enantiomer of reboxetine, is more potent and selective than racemic reboxetine. We have submitted an NDA to the FDA for AXS-14 for the management of fibromyalgia.

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, the commercial launches of Auvelity and Sunosi, and preparatory activities for the launch of Symbravo. Subsequent to our IPO, we financed our operations primarily through proceeds from sales of our common stock to equity investors and debt borrowings. 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 begun commercial sales of Auvelity and Sunosi, and plan to commercially launch Symbravo, but we have limited experience with commercializing these, or any, products.

We have incurred significant operating and net losses since inception. We incurred net losses of $59.4 million and $68.4 million for the three months ended March 31, 2025 and 2024, respectively. Our accumulated deficit as of March 31, 2025 was $1,182.2 million, and we expect to incur significant expenses and continuing operating losses. We expect our expenses to increase in connection with our ongoing activities, as we continue the commercialization of our on-market products and the development and clinical trials of, and seek regulatory approval for, our current product candidates and any other product candidates that we develop or in-license and advance to clinical development. Further, we have incurred and will continue to incur additional costs associated with operating as a public company. Accordingly, we may need additional financing to support our continuing operations. We may seek to fund our operations through public 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.

Financial Overview

Revenue

We generated total revenues of $121.5 million and $75.0 million in the three months ended March 31, 2025 and 2024, respectively.

We expect that Auvelity, Sunosi, and Symbravo 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 or may not generate revenue in the future.

License Agreement with Pharmanovia

In February 2023, we entered into the Pharmanovia License Agreement with Pharmanovia to commercialize and further develop Sunosi® in the Territory. Pharmanovia is a UK-based global life cycle management healthcare company that focuses on four core therapeutic areas – Oncology, Endocrinology, Neurology and Cardiovascular.

We are eligible to receive sales-based and other milestone payments 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. We recognized royalty revenue of $1.1 million and $0.9 million for the three months ended March 31, 2025 and 2024, respectively, related to Pharmanovia's sales of Sunosi.

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 an 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 Auvelity, Sunosi, Symbravo 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.

Selling, general and administrative expenses

Selling, general and administrative expenses 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 marketing costs, other 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 and cash equivalents.

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 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.

Reserves for Variable Consideration

Medicare Part D Program Redesign - Effective January 1, 2025, the Medicare Part D coverage gap program was replaced with a redesigned program under the Inflation Reduction Act of 2022. The standard Part D benefit now comprises three phases: the deductible phase, the initial coverage phase and the catastrophic coverage phase. Applicable dispensed drugs will be subject to manufacturer discounts of 10% during the initial coverage phase and 20% during the catastrophic coverage phase. We estimate the percentage of goods sold to patients in the initial coverage and catastrophic coverage phases 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 expenses and other current liabilities.

Except for the Medicare Part D Program Redesign, as discussed above, there have been no material changes to the critical accounting policies disclosed in our 2024 Annual Report on Form 10-K. 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, except share and per share amounts):

	Three months ended March 31,	
	2025	2024
Revenues:		
Product sales, net	$ 120,358	$ 74,096
Royalty revenue	1,105	903
Total revenues	121,463	74,999
Operating expenses:		
Cost of revenue (excluding amortization and depreciation)	9,789	6,297
Research and development	44,785	36,830
Selling, general and administrative	120,787	98,970
Loss (Gain) in fair value of contingent consideration	1,512	(1,412)
Intangible asset amortization	1,572	1,589
Total operating expenses	178,445	142,274
Loss from operations	(56,982)	(67,275)
Interest expense, net	(2,431)	(1,082)
Loss before income taxes	(59,413)	(68,357)
Income tax expense	—	—
Net loss	$ (59,413)	$ (68,357)
Net loss per common share, basic and diluted	$ (1.22)	$ (1.44)
Weighted average common shares outstanding, basic and diluted	48,871,163	47,393,563

Product sales, net. Auvelity U.S. net sales were $96.2 million and $53.4 million for the three months ended March 31, 2025 and 2024, respectively. Sunosi net sales were $24.1 million and $20.7 million for the three months ended March 31, 2025 and 2024, respectively. The increases in product sales were primarily due to the increase in unit sales volume for both Auvelity and Sunosi.

The following table summarizes the activity of our sales allowance and reserves as of and for the three months ended March 31, 2025 (in thousands):

	Commercial discounts and rebates, returns and other	Cash discounts and chargebacks	Medicaid and Medicare rebates	Total
Balance at December 31, 2024	$ 55,412	$ 13,504	$ 18,538	$ 87,454
Provisions	84,614	30,992	18,022	133,628
Payments/credits	(72,916)	(29,715)	(7,904)	(110,535)
Balance at March 31, 2025	$ 67,110	$ 14,781	$ 28,656	$ 110,547

Royalty revenue. In connection with the February 2023 Pharmanovia License Agreement to commercialize Sunosi in certain ex-U.S. markets, we recognized royalty revenue of $1.1 million and $0.9 million for the three months ended March 31, 2025 and 2024, respectively, attributable to Pharmanovia sales of Sunosi in the out-licensed markets. The increase was in line with the increase in unit sales volume of Sunosi in certain ex-U.S. markets.

Cost of revenue. Cost of revenue was $9.8 million for the three months ended March 31, 2025, as compared to $6.3 million for the same period in 2024. The increase was in line with the increase in sales of Auvelity and Sunosi.

Research and development. The following table summarizes our research and development expenses for our primary products for the three months ended March 31, 2025 and 2024 (in thousands):

	Three months ended March 31,	
	2025	2024
Solriamfetol	$ 11,806	$ 8,564
AXS-05	14,477	13,525
AXS-07	4,479	2,972
AXS-12	2,409	2,046
AXS-14	1,186	2,609
Other research and development (*)	3,969	2,546
Stock-based compensation	6,459	4,568
Total research and development expenses	$ 44,785	$ 36,830

(*) Other research and development expenses primarily consist of facilities charges, third party consultant costs, costs related to other product candidates, and other unallocated costs.

Research and development expenses increased by $8.0 million for the three months ended March 31, 2025, as compared to the same period in 2024. The increase was primarily related to the ongoing Phase 3 trials for solriamfetol and AXS-12, higher pre-FDA approval activity costs for AXS-07, and higher personnel costs due to organizational growth. We expect research and development costs to increase moderately from current levels as we continue to further develop our current and future product candidates.

Selling, general and administrative. Selling, general and administrative expenses were $120.8 million for the three months ended March 31, 2025, as compared to $99.0 million for the same period in 2024. The increase was primarily related to higher commercial activities for Auvelity, launch readiness activities for Symbravo, and higher personnel costs related to organizational growth, including non-cash stock-based compensation. We expect selling, general and administrative expenses to increase as we expand marketing, promotional, and advertising costs for Auvelity, and prepare for the launch of Symbravo and other potential product launches.

Loss (Gain) in Fair Value of Contingent Consideration. The $1.5 million change for the three months ended March 31, 2025, as compared to a $1.4 million change for the same period in 2024, was primarily related to changes in significant unobservable inputs, including discount rates.

Intangible asset amortization. We amortize the intangible asset, which we recognized as part of the Acquisition, over its useful life of 10 years. Intangible asset amortization was $1.6 million for both the three months ended March 31, 2025 and 2024.

Interest expense, net. Interest expense, net was $2.4 million for the three months ended March 31, 2025, as compared to $1.1 million for the same period in 2024. The increase was mainly due to less interest income on lower cash balances.

Income tax expense. We did not record an income tax expense for both the three months ended March 31, 2025 and 2024 due to losses incurred in all jurisdictions during the quarter from which we do not benefit due to the full valuation allowance position against our deferred tax assets.

Net loss. Net loss was $59.4 million for the three months ended March 31, 2025, as compared to $68.4 million for the same period in 2024. The decrease was primarily due to higher sales which was partially offset by higher research and development spend from ongoing clinical trial expenses, higher selling, general and administrative expenses from commercial activities related to Auvelity, Sunosi, and Symbravo, including sales force and marketing spend, and higher personnel costs due to organizational growth, including non-cash stock compensation expense.

Liquidity and Capital Resources

Since our inception through March 31, 2025, 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 (now known as Leerink Partners LLC), or Leerink, pursuant to which we may sell up to $80 million in shares of our common stock from time to time through Leerink, 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. Leerink 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 Leerink, and filed a prospectus supplement, pursuant to which we may sell up to $200 million in shares of our common stock from time to time through Leerink, acting as our sales agent, in one or more at-the-market offerings utilizing the 2019 Shelf Registration Statement. Leerink 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 us and Leerink. We exhausted sales of shares of our common stock under our 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. Leerink 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 Leerink, as the sales agent, under the March 2022 Sales Agreement.

Under the March 2022 Sales Agreement, for the three months ended March 31, 2025, we received approximately $19.7 million in gross proceeds through the sale of 156,484 shares, of which net proceeds were approximately $19.3 million. We did not utilize the March 2022 Sales Agreement with Leerink during the three months ended March 31, 2024.

In January 2023, we entered into a Third Amendment to the Loan Agreement, or the Third Amendment, with Hercules. The Third Amendment increased 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. In September 2024, we entered into a Fifth Amendment to the Loan Agreement, or the Fifth Amendment, with Hercules. The Fifth Amendment amended the terms of the Loan Agreement to, among other things: (i) increase the size of the aggregate principal amount under tranche 3 of the 2020 Term Loan (as defined below) from $75.0 to $80.0 million; (ii) extend the availability periods of certain tranches of the 2020 Term Loan; (iii) alter the terms of the performance covenants contained in the Loan Agreement and also add a new performance covenant; (iv) conditionally waive the minimum cash requirement during such periods of time that Axsome's market capitalization exceeds $1.5 billion; and (v) permit Axsome Malta Ltd., or the Malta Subsidiary, to request an advance from the Lenders (as defined in the Loan Agreement) up to a certain amount to the extent that Axsome may request an advance in such amount and to increase the amount of cash that the Malta Subsidiary may hold outside of the United States, as set forth in greater detail in the Fifth Amendment. We drew down upon tranche 1C of the 2020 Term Loan, and as of March 31, 2025, we had approximately $180 million outstanding and $150 million remaining under the 2020 Term Loan. See the "Contractual Obligations and Commitments – January 2023 Third Amendment to the Loan and Security Agreement – Hercules" and "Contractual Obligations and Commitments – September 2024 Fifth Amendment to the Loan and Security Agreement – Hercules" sections below, and Note 8. Loan and Security Agreement for more information.

In June 2023, we completed an underwritten public offering of our common stock and sold 3.0 million shares of our common stock at a public offering price of $75.00 per share. Net proceeds were $211.3 million, net of underwriting discounts and commissions of $13.5 million and other offering costs of $0.2 million. Additionally, in connection with this public offering, in July 2023, the underwriters fully exercised their option to purchase 450,000 additional shares of our common stock, at a public offering price of $75.00 per share. The net proceeds were $31.7 million, net of underwriting discounts and commissions of $2.0 million and other minimal offering costs.

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.

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 Initial Sublease.

On January 17, 2025, we entered into an Amendment to our Sublease, or First Amendment, pursuant to which we will relinquish our existing space in One World Trade Center and commence occupancy of different space within the building. This space is utilized as our corporate and executive offices. The First Amendment extends the Initial Sublease expiration date to January 31, 2036. We now have a one-time option to terminate the Sublease effective March 30, 2031 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 Initial Sublease and First Amendment, we received certain rent and work concessions from the sublandlord.

The Company entered into a fleet lease program beginning the first quarter of 2024. The lease agreement includes an initial 12-month noncancelable period with monthly renewal options thereafter. Lease terms range from approximately 40 to 50 months and are classified as finance leases. See Note 9. Commitments and Contingencies for further information on future contractual obligations.

We believe that our current cash 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,	
	2025	2024
Net cash (used in) provided by:		
Operating activities	$ (43,375)	$ (53,467)
Investing activities	(338)	(98)
Financing activities	29,270	(1,187)
Net decrease in cash	$ (14,443)	$ (54,752)

Operating Activities. Cash used in operating activities for the three months ended March 31, 2025 was $43.4 million, as compared to $53.5 million for the three months ended March 31, 2024. The decrease of $10.1 million was primarily due to higher net product revenues from Auvelity and Sunosi in 2025, which was partially offset by an increase in cash used in commercial and clinical activities.

Investing Activities. Cash used in investing activities for the three months ended March 31, 2025 was $338 thousand, as compared to $98 thousand for the three months ended March 31, 2024. The increase was impacted by the move into our new corporate office space during the first quarter of 2025.

Financing Activities. Cash provided by financing activities was $29.3 million for the three months ended March 31, 2025, which included net proceeds of $19.3 million from issuance of common stock for financing purposes as well as proceeds of $17.0 million from the issuance of common stock upon the exercise of employee stock options, which was partially offset by payments of contingent consideration and tax withholdings on stock awards, for a total of $6.6 million. Cash used in financing activities was $1.2 million for the three months ended March 31, 2024, which included payments of contingent consideration and tax withholdings on stock awards for a total of $3.5 million, which was partially offset by proceeds of $2.5 million from the issuance of common stock upon the exercise of employee stock options.

Funding Requirements

We have not achieved profitability since our inception, and we expect to continue to have losses as we continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercially launch Symbravo while further investing in Auvelity and Sunosi. 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 our commercialization activities, including product manufacturing, marketing, sales, and distribution, for any of our products and 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 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, 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.

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.

Loan and Security Agreement with Hercules Capital, Inc.

Capitalized terms used but not otherwise defined herein shall have the meanings assigned to them in the Loan Agreement.

September 2024 Fifth Amendment to the Loan and Security Agreement

On September 30, 2024, we entered into the Fifth Amendment. The Fifth Amendment amended the terms of the Loan Agreement to, among other things: (i) increase the Tranche 3 Commitment from $75.0 to $80.0 million; (ii) extend the availability periods of Tranche 1D to June 15, 2025 and that of Tranche 1E to December 15, 2025, as set forth in greater detail in the Fifth Amendment; (iii) alter the terms of Performance Covenant A, Performance Covenant B, and Performance Covenant C and also add a Performance Covenant D, as set forth in greater detail in the Fifth Amendment; (iv) conditionally waive the requirement that the Company maintain Qualified Cash in an amount greater than or equal to the sum of $30.0 million plus the Qualified Cash A/P Amount at all times during such periods of time that the Company's Market Capitalization exceeds $1.5 billion; and (v) permit the Malta Subsidiary, to request an Advance from the Lenders up to a certain amount to the extent that the Company may request an Advance in such amount and to increase the amount of Cash that the Malta Subsidiary may hold outside of the United States, as set forth in greater detail in the Fifth Amendment.

May 2023 Fourth Amendment to the Loan and Security Agreement

On May 8, 2023, we entered into the Waiver and Fourth Amendment to the Loan Agreement, or the Fourth Amendment, with Hercules, in its capacity as administrative agent and collateral agent, and the Lenders. The Fourth Amendment increased the amount of Cash that could be held by the Malta Subsidiary outside of the United States from $3.0 million to $15.0 million for a 45-day period after the closing of the Fourth Amendment and to $10.0 million thereafter. The Fourth Amendment also waived any purported default with respect to the amount of cash held by the Malta Subsidiary prior to the date of the Fourth Amendment. In August 2023, Hercules granted Axsome a waiver to the Fourth Amendment, permitting the Malta Subsidiary to hold up to $12.5 million in Cash outside of the United States until December 31, 2023.

January 2023 Third Amendment to the Loan and Security Agreement

On January 9, 2023, we entered into the Third Amendment.

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 availability dates under the Tranche 1 Advance through Tranche 5 Advance, 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 from three sub-tranches of $35.0 million, $35.0 million, and $30.0 million, respectively, to one tranche of $25.0 million, changing the Tranche 3 Advance from two sub-tranches of $15.0 million and $5.0 million, respectively, to one tranche of $75.0 million, and removing the Tranche 4 Advance 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 the sum of $30.0 million plus the Qualified Cash A/P Amount; 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, Tranche 1C Advance, Tranche 1D Advance, Tranche 1E Advance, Tranche 2 Advance, and Tranche 3 Advance.

We allowed Tranche 2, which totaled $25.0 million, to expire undrawn.

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 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 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.

Employees and Human Capital Management

As of April 28, 2025, we had 712 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 commercialization or 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 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. These market risks are principally limited to interest rate fluctuations. We had cash of $300.9 million and $315.4 million as of March 31, 2025 and December 31, 2024, 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, which use short term interest rates and the prime rate, respectively, 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 manufacturers located in Europe and certain invoices are denominated in foreign currencies. Royalty revenues from Pharmanovia are derived from their sales of Sunosi in ex-U.S markets and those sales are denominated in Euros. We are therefore subject to fluctuations in foreign currency rates for the Euro, Swiss Franc, and British Pound, 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 transactions.

We do not believe a 10% change in these currencies on March 31, 2025 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, 2025.

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, 2025, 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, or the SDNY District Court, against the Company and certain of its current and former officers and one director, which we refer to as the Securities Class Action. The complaint asserts claims under Sections 10(b) and 20(a) of the Exchange Act 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 NDA with the FDA, with respect to one of its then product candidates, AXS-07, now Symbravo®. The named plaintiff sought unspecified damages, fees, interest, and costs. On August 11, 2022, the SDNY District Court appointed co-lead plaintiffs in the Securities Class Action, one of whom later withdrew. On October 7, 2022, the Securities Class Action plaintiffs filed an amended complaint, which contained substantially similar allegations as in the initial complaint. On September 25, 2023, the SDNY District Court granted defendants' motion to dismiss the amended complaint.

On October 13, 2023, plaintiffs' counsel filed a letter seeking leave to file an amended complaint and to substitute new plaintiffs. On January 22, 2024, the SDNY District Court granted that motion and ordered that the case name be changed to In re Axsome Therapeutics, Inc. Securities Litigation. On January 26, 2024, the replacement plaintiffs renewed their request for leave to file a proposed second amended complaint, and, on February 6, 2024, the SDNY District Court granted that request. Plaintiffs filed the second amended complaint on February 7, 2024. On March 11, 2024, the defendants moved to dismiss the second amended complaint. On March 31, 2025, the SDNY District Court entered an order granting in part and denying in part defendants' motions to dismiss, dismissing plaintiffs' claims against three of Axsome's current and former officers and allowing the claims against the Company and two current officers to proceed.

Shareholder Derivative Action

On July 21, 2022, Daniel Engel filed a stockholder derivative complaint captioned Engel v. Herriot Tabuteau, et al. in the SDNY District Court 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 SDNY District Court 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 Securities Class Action.

Auvelity Paragraph IV Litigation

On March 24, 2023, we commenced a patent infringement action against Teva Pharmaceuticals, Inc., or Teva, relating to Teva's ANDA 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, or the NJ District Court. On December 15, 2023, we commenced a second patent infringement action against Teva relating to Teva's ANDA. This action is captioned *Axsome Therapeutics, Inc., and Antecip Bioventures II LLC v. Teva Pharmaceuticals, Inc.* No. 2:23-cv-23142 in the NJ District Court. On February 26, 2024, the NJ District Court consolidated the first and second actions. Fact discovery is currently scheduled to close on March 24, 2025 in the consolidated action. On May 28, 2024, we commenced a third patent infringement action against Teva relating to Teva's ANDA. This action is captioned *Axsome Therapeutics, Inc., and Antecip Bioventures II LLC v. Teva Pharmaceuticals, Inc.* No. 2:24-cv-06489 in the NJ District Court. On September 30, 2024, we commenced a fourth patent infringement action against Teva relating to Teva's ANDA. This action is captioned *Axsome Therapeutics, Inc., and Antecip Bioventures II LLC v. Teva Pharmaceuticals, Inc.* No. 2-24-cv-09535 in the NJ District Court. On December 5, 2024, we commenced a fifth patent infringement action against Teva relating to Teva's ANDA. The fifth action is captioned *Axsome Therapeutics, Inc., and Antecip Bioventures II LLC v. Teva Pharmaceuticals, Inc.* No. 2-24-cv-10938 in the NJ District Court. On January 7, 2025, the NJ District Court consolidated that third, fourth, and fifth actions.

On February 10, 2025, the Company announced that it had entered into a settlement agreement with Teva to resolve all outstanding litigation between the parties relating to Auvelity. Under the terms of the settlement agreement, Axsome will grant Teva a license to sell its generic version of Auvelity beginning on or after March 31, 2039, if pediatric exclusivity is granted for Auvelity, or on or after September 30, 2038, if no pediatric exclusivity is granted, subject to FDA approval and conditions and exceptions customary for agreements of this type. The matters are now concluded.

Sunosi Paragraph IV Litigation

On September 13, 2023, we commenced a patent infringement action against Hikma and five other drug companies relating to each defendant's ANDA for Sunosi®. This action is captioned *Axsome Malta Ltd. & Axsome Therapeutics, Inc. v. Alkem Laboratories Ltd., et al*. No. 2:23-CV-20354 in the NJ District Court. We commenced related patent infringement actions against the defendants relating to their ANDAs on December 20, 2023, January 11, 2024, January 18, 2024, February 14, 2024, March 19, 2024 (2 actions filed), April 5, 2024, July 2, 2024, August 8, 2024, August 21, 2024, September 16, 2024, November 20, 2024 (4 actions filed), January 21, 2025, and January 29, 2025. Those actions are captioned *Axsome Malta Ltd. & Axsome Therapeutics, Inc. v. Unichem Laboratories Ltd*. No. 2:23-cv-23255; *Axsome Malta Ltd. & Axsome Therapeutics, Inc. v. Hetero USA, Inc. et al*. No 2:24-cv-00196; *Axsome Malta Ltd. & Axsome Therapeutics, Inc. v. Aurobindo Pharma USA, Inc. et al*. No. 2:24-cv-00309; *Axsome Malta Ltd. & Axsome Therapeutics, Inc. v. Sandoz, Inc*. No. 2:24-cv-00860; *Axsome Malta Ltd. & Axsome Therapeutics, Inc. v. Hetero USA, Inc. et al*. No 2:24-cv-03999; *Axsome Malta Ltd. & Axsome Therapeutics, Inc. v. Aurobindo Pharma USA, Inc. et al*. No. 2:24-cv-04002; *Axsome Malta Ltd. & Axsome Therapeutics, Inc. v. Alkem Laboratories Ltd., et al*. No. 2:24-CV-04608; *Axsome Malta Ltd. & Axsome Therapeutics, Inc. v. Aurobindo Pharma USA, Inc. et al*. No. 2-24-cv-07511; *Axsome Malta Ltd. & Axsome Therapeutics, Inc. v. Alkem Laboratories Ltd.*No. 2-24-cv-08365; *Axsome Malta Ltd. & Axsome Therapeutics, Inc. v. Aurobindo Pharma USA, Inc. et al.* No. 2-24-cv-08624; *Axsome Malta Ltd. & Axsome Therapeutics, Inc. v. Alkem Laboratories Ltd. et al.* No. 2-24-cv-09209; *Axsome Malta Ltd. & Axsome Therapeutics, Inc. v. Alkem Laboratories Ltd.* No. 2-24-cv-10617; *Axsome Malta Ltd. & Axsome Therapeutics, Inc. v. Hetero USA, Inc. et al*. No 2:24-cv-10618; *Axsome Malta Ltd. & Axsome Therapeutics, Inc. v. Aurobindo Pharma USA, Inc. et al*. No 2:24-cv-10619; *Axsome Malta Ltd. & Axsome Therapeutics, Inc. v. Hikma Pharmaceuticals USA Inc*. No 2:24-cv-10620; *Axsome Malta Ltd. & Axsome Therapeutics, Inc. v. Aurobindo Pharma USA, Inc. et al*. No 2:25-cv-00643; and *Axsome Malta Ltd. et al v. Hetero USA Inc. et al*. 2-25-cv-00801, respectively, all of which are in the NJ District Court. On June 4, 2024, Axsome and the Malta Subsidiary entered into a settlement agreement with Unichem under which agreement Unichem agreed not to launch its generic solriamfetol product until June 30, 2042, or earlier under certain circumstances. On August 21, 2024, Axsome and the Malta Subsidiary reached an agreement to dismiss the actions pending against Sandoz. All other actions are currently pending. On September 25, 2024, Hikma Pharmaceuticals USA, Inc. filed a petition for Inter Partes Review of U.S. Patent No. 11,560,354 before the United States Patent and Trademark Office's Patent Trial and Appeal Board. That petition is captioned *Hikma Pharmaceuticals USA Inc. f/k/a West-Ward Pharmaceuticals Corp. v. Axsome Malta Ltd*. IPR2024-01418. On March 2, 2025, Axsome and the Malta Subsidiary entered into a settlement agreement with Hikma under which agreement Hikma agreed not to launch its generic solriamfetol product until September 1, 2040, if pediatric exclusivity is granted for Sunosi, or on or after March 1, 2040, if no pediatric exclusivity is granted, or earlier under certain circumstances. On March 6, 2025 the Malta Subsidiary and Hikma jointly requested that the PTAB dismiss IPR2024-01418. That request was granted on March 12, 2025.

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. We have restated and revised our risk factors for material updates for this quarter, where appropriate, from those included in our Annual Report on Form 10-K dated and filed with the SEC on February 18, 2025. 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 continue to have losses, 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 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, we may be unable to generate substantial product revenues.***

- ***We rely, and expect to continue to rely, on third parties to perform many essential services for our products and product candidates, including services related to our preclinical studies and clinical trials, warehousing and inventory control, distribution, government price reporting, customer service, and adverse event reporting. If these third parties fail to perform satisfactorily, including by failing to meet deadlines for the completion of our preclinical studies and clinical trials, or fail to comply with legal and regulatory requirements, our ability to commercialize any of our products will be significantly impacted and we may be subject to regulatory sanctions.***

- ***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 or fail to generate potential revenues.***

- ***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 laws governing fraud and abuse, transparency, health and data protection, information privacy and security, we could face substantial penalties and liabilities, 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 products, or if such payors and health care providers including health maintenance organizations (HMOs) and long-term care facilities choose to use therapies that are less expensive, our revenue and prospects for profitability may 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 continue to have losses, and may never achieve or maintain profitability.

We are a biopharmaceutical company with a limited operating history. Since inception, we have incurred significant operating losses. Our net loss was $59.4 million and $68.4 million for the three months ended March 31, 2025 and 2024, respectively. As of March 31, 2025, we had an accumulated deficit of $1,182.2 million. In 2022, we commenced the commercial sale of Auvelity in the United States and Sunosi in the United States and select global markets. In January 2025, Symbravo was approved by the FDA for the acute treatment of migraine with or without aura in adults. Apart from Auvelity, Sunosi, and Symbravo, we have no other products which have received regulatory approval.

We expect to continue to incur substantial expenses and operating losses, 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 Auvelity, Sunosi, Symbravo, and any other product candidate which the FDA may approve or which we may in-license. We anticipate that our expenses will increase substantially as we:

- seek regulatory approval for additional product candidates;
- 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;
- 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 additional indications;
- continue to evaluate, plan for, and potentially submit NDAs for other pipeline products;
- continue to expand commercial sales of Auvelity and Sunosi;
- commercially launch Symbravo;
- 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 cGMP;
- develop additional product candidates; and
- in-license other product candidates.

We believe that our current cash 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 the Third Amendment, which 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. In May 2023, we entered into the Fourth Amendment, which increased the amount of cash that could be held by the Malta Subsidiary outside of the United States and waived any purported default with respect to the amount of cash held by the Malta Subsidiary prior to the date of the Fourth Amendment. In August 2023, Hercules granted Axsome a waiver to the Fourth Amendment, increasing the amount of cash that could be held by the Malta Subsidiary outside of the United States until December 31, 2023. In September 30, 2024, we entered into the Fifth Amendment, which amended the terms of the Loan Agreement to, among other things: (i) increase the size of the aggregate principal amount under tranche 3 of the 2020 Term Loan from $75.0 to $80.0 million; (ii) extend the availability periods of certain tranches of the 2020 Term Loan; (iii) alter the terms of the performance covenants contained in the Loan Agreement and also add a new performance covenant; (iv) conditionally waive the minimum cash requirement during such periods of time that Axsome's market capitalization exceeds $1.5 billion; and (v) permit the Malta Subsidiary to request an advance from the Lenders up to a certain amount to the extent that Axsome may request an advance in such amount and to increase the amount of cash that the Malta Subsidiary may hold outside of the United States, as set forth in greater detail in the Fifth Amendment.

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 a commercial-stage company. Prior to our commercialization of Auvelity and Sunosi in 2022, and the recent approval of Symbravo, 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 continue to encounter unforeseen expenses, difficulties, complications and delays, and this may not be a successful transition.

We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability, ongoing military conflicts between Russia and Ukraine and between Israel and Hamas, Hezbollah, and the Houthis, and record inflation. 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 the conflicts in Ukraine and the Middle East, geopolitical tensions, or record inflation.

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.

In addition, on October 7, 2023, Hamas militants and members of other terrorist organizations infiltrated Israel's southern border from the Gaza Strip and conducted a series of terror attacks on civilian and military targets. Shortly following the attack, Israel's security cabinet declared war against Hamas, and Israel launched an aerial bombardment of various targets within the Gaza Strip and then also began ground operations in the Gaza Strip, which remain ongoing. Other terrorist and/or regional organizations have joined the hostilities as well, including Hezbollah in Lebanon, and the Houthis in Yemen, and it is possible that other countries in the Middle East, including Iran, will become further involved in hostilities with Israel, resulting in a further widening of the conflict. In March 2025, the United States launched a campaign of air and naval strikes against Houthi targets in Yemen, which remain ongoing. The intensity and duration of the current wars in the Middle East are difficult to predict as are such wars' implications for the global economy.

Although our business has not been materially impacted by these geopolitical issues, or the U.S. domestic political climate, 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 conflicts may impact our business. The extent and duration of 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.

Political uncertainty may have an adverse impact on our operating performance and results of operations.

General political uncertainty may have an adverse impact on our operating performance and results of operations. In particular, the U.S. continues to experience significant political events that cast uncertainty on global financial and economic markets, especially following the recent presidential election. For example, in April 2025, the U.S. administration imposed increased tariffs on all countries and individualized "reciprocal" higher tariffs on certain countries with which the U.S. has the largest trade deficits. Certain countries responded by announcing retaliatory tariffs on U.S. imports. A few days later, the U.S. administration reduced the tariffs imposed on most countries to 10 percent for a period of 90 days to allow trade negotiations with those countries. It is presently unclear exactly what actions the U.S. administration will implement, and if implemented, how these actions may impact the biopharmaceutical industry in the U.S. Any actions taken by the U.S. administration, including the many recent executive orders and tariff increases, may have a negative impact on the U.S. economy, global markets and on our business, financial condition, and results of operations.

The new U.S. administration may also enact other new regulations or policies that affect trade with China or otherwise impact the pharmaceutical industry by enacting laws to restrict U.S. pharmaceutical companies from contracting with Chinese companies on the development, research or manufacturing of pharmaceutical products. In April 2025, the U.S. Department of Commerce initiated national security investigations into the importation of pharmaceuticals and pharmaceutical ingredients pursuant to Section 232 of the Trade Expansion Act of 1962, which could result in the imposition of new tariffs on imports within the pharmaceutical industry. Further, in April 2025, the U.S. administration has signed an executive order to lower prescription drug prices. The details of such proposed regulations and policies are unclear and the final terms and impact remain uncertain, and may pose long-term risks to our business and our future commercialization plans of our drug candidates.

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 three 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 Auvelity, Sunosi, and Symbravo, 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. Multiple clinical trials 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 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 Symbravo for the acute treatment of migraines (which received a CRL and has now been approved) and for AXS-14 (which is pending), 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, 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 additional indications, AXS-05 for the treatment of agitation associated with AD and smoking cessation, 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 CNS therapies. 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 Symbravo product in 2022 (we have since obtained approval for Symbravo). 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 revenues from such product candidates 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. In the EU, we are not permitted to commercialize, market, promote, or sell any product candidate without obtaining marketing approval from the EC or national competent authorities at the EU member state level.

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 additional indications for AXS-05. The FDA interprets Section 505(b)(2) of the 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 have and/or 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. 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 submitted NDAs for Auvelity and Symbravo pursuant to the 505(b)(2) process, we have not conducted certain additional clinical trials for these products and, as such, we will have less experience with actual testing of these products.

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 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.

The regulatory approval timelines and 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 timeline for review and 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. The timeline for regulatory approval can be affected by a variety of factors, including budget and funding levels, agency staffing, and statutory, regulatory, and policy changes. 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, vary among jurisdictions, and/or require us to amend our clinical trial protocols or conduct additional studies that require regulatory 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 both of our product candidates, Auvelity and Symbravo. 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 or uncertainty in the timing of regulatory action could materially adversely impact our development efforts and 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 and/or national competent authorities 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 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;

- 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 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;

- 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, 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 that which 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.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our product development plans may be impacted. For example, in December 2022, with the passage of the Food and Drug Omnibus Reform Act (FDORA), Congress required sponsors to develop and submit a diversity action plan for each phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Specifically, diversity action plans must include the sponsor's goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them. In terms of the compliance deadline, the requirement to submit a diversity action plan applies to clinical studies for which enrollment begins 180 days after the final guidance is published, which was originally anticipated to occur in June 2025. In January 2025, the previously-published draft guidance was removed from the FDA website, which may impact the eventual publication date of the final guidance, and as a result, may delay the compliance deadline.

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 Symbravo, the FDA noted the need for additional CMC data. Symbravo was subsequently approved by the FDA. Furthermore, there is the possibility that the FDA or comparable foreign regulatory authorities have not previously reviewed product candidates for the indications we are pursuing, such as AD agitation or smoking cessation. As a result, we may experience delays in regulatory approval due to uncertainties in the approval process.

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. Furthermore, there is the possibility that the FDA or comparable foreign regulatory authorities have not previously reviewed product candidates for the indications we are pursuing, such as AD agitation or smoking cessation. As a result, we may experience delays in regulatory approval due to uncertainties in the approval process.

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 the EMA required product label for marketed drugs that contain the same active molecule as our product candidates, 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, Sunosi, and Symbravo 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;

- 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, 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 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, HHS's OIG, 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 or comparable foreign regulatory authorities' 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 FCA exposure. The FCA 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 FCA, 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 FCA lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements, 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 other actions 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. PDMA. 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 product, 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.

In addition, there is a great degree of uncertainty regarding how recent U.S. Supreme Court decisions, including *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024) and *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, 603 U.S. 799 (2024), will impact the FDA's enforcement and decision-making authority. *Loper Bright* explicitly overturned *Chevron* deference, which previously gave judicial deference to administrative action by agencies in the executive branch. Furthermore, the Supreme Court's decision in *Corner Post* may result in challenges to FDA decisions by new litigants long into the future. These decisions could result in additional legal challenges to regulations and guidance issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and could impact various aspects of the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, either in the United States or abroad. 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, our business could be materially harmed.

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.

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 personal data, including 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 FCPA 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 are exposed to market risk from fluctuations in currency exchange rates and interest rates.

We operate in multiple jurisdictions, and virtually all sales are denominated in currencies of the local jurisdiction. Additionally, we have entered and may enter into business development transactions, borrowings, or other financial transactions that may give rise to currency and interest rate exposure.

Since we cannot, with certainty, foresee and mitigate against such adverse changes, fluctuations in currency exchange rates, interest rates, and inflation could negatively affect our business, cash flow, results of operations, financial condition, and prospects.

In order to mitigate against the adverse impact of these market fluctuations, we may from time to time enter into hedging agreements. While hedging agreements, such as currency options and forwards and interest rate swaps, may limit some of the exposure to exchange rate and interest rate fluctuations, such attempts to mitigate these risks may be costly and not always successful.

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 products and 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 LLC; Intra-Cellular Therapies, Inc.; Janssen; Jazz; Otsuka Pharmaceutical Co. Ltd.; Pfizer; and Takeda Pharmaceutical Company Limited.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, more convenient, or 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 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. Additionally, beginning in August 2023, we received paragraph IV certification notice letters from six other pharmaceutical companies providing notification to the Company that each such filer has submitted an ANDA to the FDA seeking approval to manufacture, use, or sell a generic version of Sunosi.

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 significant product awareness and that lack of awareness may limit the product revenues that we generate.

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 effort 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 appropriately 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 or any coverage and reimbursement by government and private health plans or other payers;
- 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, or 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. Physicians and their patients may likewise make decisions about therapies based on cost and insurance coverage and reimbursement. Further, patients often acclimate to the therapy that they are currently taking. While they may switch if their physicians recommend switching products, there is no guarantee. Additionally, they may also switch therapies due to lack of reimbursement for existing therapies or for other reasons. Even if physicians prescribe our products, third-party payors may not provide coverage or 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 other 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 REMS 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 and third-party payors provide coverage and reimbursement for the same, 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 or may not accept it at all. 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.

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 cause injury or are 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, 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. 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, have 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 product 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 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 perform many essential services for our products and product candidates, including services related to our preclinical studies and clinical trials, warehousing and inventory control, distribution, government price reporting, customer service, and adverse event reporting. If these third parties fail to perform satisfactorily, including by failing to meet deadlines for the completion of our preclinical studies and clinical trials, or fail to comply with legal and regulatory requirements, our ability to commercialize any of our products will be significantly impacted and we may be subject to regulatory sanctions.

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 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 comply 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 terminate, 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 or disrupt 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 on 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 FCA; 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 commercial "virtual manufacturer," we may rely in many cases on third parties to perform many essential services for our products, 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 products 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. Moreover, these agreements might terminate for a variety of reasons. If we fail to enter into alternative arrangements, this could further delay the commercialization of our products and adversely affect our business.

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 FCA 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 products under our collaborators' labeler codes. Alternatively, we may enter into agreements with collaborators to market and sell our products 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.

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 expired 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 filer 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, 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, or that we would commence such proceedings. 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 and/or may choose not to file, prosecute, and maintain 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, or that we may choose not to pursue patent protection for all patentable aspects identified. 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, maintained, 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 reliably or accurately 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. Further, the degree of future protection for our proprietary rights is uncertain, for example, 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, and we may not have a continuing application (e.g., divisional, continuation, continuation-in-part) pending that covers the relevant subject matter;
- 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 products and 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 utility patent is typically 20 years from the date that the application for the patent is filed or 20 years from the earliest non-provisional filing date to which priority is claimed if the patent is granted from a continuing application (e.g., continuation, divisional, or continuation-in-part). 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 and regulatory review. However, the applicable authorities, including the 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. Future patent reform legislation in the U.S. and/or in jurisdictions outside the U.S. could potentially further increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

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 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/or 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 take time to publish and can take many years to issue, and because there is no way to guarantee we are aware of all third party patents and applications, 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 and/or to challenge the validity of the asserted patent(s) before a court or the USPTO (e.g., in post-grant proceedings such as Inter Partes Review before the Patent Trial and Appeal Board (PTAB) of the USPTO). In addition, in a patent infringement or validity proceeding, a decision maker (e.g., a court or the PTAB) 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. Any litigation proceeding or related proceeding at the USPTO could have adverse results, putting 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 product candidates 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 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 products in the United States and to seek and maintain regulatory approvals for the 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 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, 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 proprietary information and may not provide an adequate remedy in the event of unauthorized disclosure of proprietary 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, enforcing, 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, enforcing, 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 and/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 laws governing fraud and abuse, transparency, health and data protection, information privacy and security, we could face substantial penalties and liabilities, 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 this Annual Report on Form 10-K, such as the federal Anti-Kickback Statute, the federal civil and criminal FCA, the civil monetary penalties statute, the Medicaid Drug Rebate Statute and other price reporting requirements, the Veterans Health Care Act of 1992, the Sunshine Act, HIPAA, the FCPA, the ACA, and other 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, disclosures, and patients' rights are and will be applicable to our business. We are subject to healthcare laws by both the federal government and the states in which we conduct our business as well as by other third parties, such as patients.

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 in broader circumstances than HIPAA and its implementing regulations. For example, California enacted legislation – the CCPA, which went into effect in January 2020, as subsequently amended by the CPRA, passed on November 3, 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). Since the passage of the CCPA, certain other states have passed similar laws that may also have similar impacts on our data processing practices and incurred costs. Some of these state laws have not taken effect, and we cannot predict if states will subsequently amend those laws, if other states will pass similar laws, or the costs and expenses that we will incur to comply with such 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 data, including health data, relating to individuals located in the EU, which was formerly governed by the provisions of the EU Data Protection Directive 95/46, was replaced with the EU GDPR in May 2018. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the legal basis of the processing of personal data, 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 EEA to the U.S. and other non-EEA countries that do not provide a level of protection to personal data in line with the GDPR standard, provides an enforcement authority in each EU member state and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global turnover 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 coming into force 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.

There are also federal and state laws on marketing and solicitation, such as CAN-SPAM. The CAN-SPAM Act, among other things, obligates the sender of commercial emails to provide recipients with the ability to opt out of receiving future commercial emails from the sender. Any failure by us to comply fully with the CAN-SPAM Act may leave us subject to substantial fines and penalties.

In addition, foreign jurisdictions, such as Canada, have enacted laws that regulate our ability to send commercial messages via email. For example, Canada's Anti-Spam Legislation ("CASL") prohibits email marketing without the recipient's consent, with limited exceptions. The penalties for non-compliance with CASL are considerable, including administrative monetary penalties of up to $10 million and a private right of action.

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 products, or if such payors and health care providers including health maintenance organizations (HMOs) and long-term care facilities choose to use therapies that are less expensive, our revenue and prospects for profitability may 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 organizations, private health insurers, and other similar programs and 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 or other third party is responsible to pay the full price, which can significantly limit utilization. If reimbursement is not available, or is available only up 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 varies widely from country to country. Current and future legislation and/or administrative action may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. For example, on September 20, 2024, the Centers for Medicare & Medicaid Services issued a final rule titled "Medicaid Program; Misclassification of Drugs, Program Integrity Updates Under the Medicaid Drug Rebate Program," which may impact our reimbursement and rebate strategy. 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 healthcare programs, private health insurers, and other organizations. Regulatory authorities and third-party payors, such as private health insurers and HMOs, 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 of 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 of our product candidates for which we obtain marketing approval could have a material adverse effect on our operating results, ability to raise capital needed to commercialize products, and 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.

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.

We expect that 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. 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 IRA was signed into law by President Biden in August 2022. The IRA 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. The IRA's changes include, by way of example, capping Medicare beneficiary out-of-pocket spending at $2,000 for 2025 and providing for no beneficiary cost sharing above the annual out-of-pocket threshold. Additionally, as of January 1, 2025, the existing Medicare Coverage Gap Discount Program ended and was replaced by the Manufacturer Discount Program, through which a manufacturer provides discounts for brand-name drugs and biologics in the initial and catastrophic coverage phases under the Medicare Part D benefit. These changes eliminated the Medicare Part D coverage gap benefit phase (commonly referred to as the "donut hole"), in which a Medicare beneficiary was originally responsible for 100% of the costs of covered prescription drugs following an initial coverage phase until the costs initiated a catastrophic coverage phase, but which was gradually phased out through the end of 2024. 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 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 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. 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.

In the EU, recently adopted and pending legislation will impact regulatory procedures for medicinal products. Key developments include Regulation (EU) 2021/2282 on health technology assessment (HTA Regulation), which became applicable in the EU on 12 January 2025. Additionally, in April 2023, the EC adopted a proposal to revise the EU pharmaceutical legislation consisting of a new directive and a new regulation that would replace Directive 2001/83/EC and Regulation (EC) 726/2004, among others. In April 2024, the European Parliament introduced amendments to the EC's proposal. The EU legislative process remains ongoing, with several stages still required before the reform can receive final approval. If approved, the reform would mark the most significant overhaul of EU pharmaceutical law since 2004, with a wide range of impacts including on approval procedures, regulatory data protection, or RDP, and the so-called "Bolar exemption," among others.

We are subject to a variety of U.S. and international laws and regulations.

We are currently subject to a number of government laws and regulations, and, in the future, could become subject to new government laws and regulations. The costs of compliance with such laws and regulations, or the negative results of non-compliance, could adversely affect our business, cash flow, results of operations, financial condition, and prospects; these laws and regulations include (i) additional health care reform initiatives in the U.S. or in other countries, including additional mandatory discounts or fees; (ii) the FCPA or other anti-bribery and corruption laws; (iii) new laws, regulations, and judicial or other governmental decisions affecting pricing, drug reimbursement, and access or marketing within or across jurisdictions; (iv) changes in intellectual property laws; (v) changes in accounting standards; (vi) new and increasing data privacy regulations and enforcement, particularly in the EU, the U.S., and China; (vii) legislative mandates or preferences for local manufacturing of pharmaceutical products; (viii) emerging and new global regulatory requirements for reporting payments and other value transfers to healthcare professionals; (ix) environmental regulations, such as the EU's Corporate Sustainability Reporting Directive; and (x) the potential impact of importation restrictions, embargoes, trade sanctions, and legislative and/or other regulatory changes.

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 April 28, 2025, we had 712 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 our commercial organization, and maintain 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 Stock Market LLC, or Nasdaq, 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 Nasdaq, 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 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 our ESG performance, we risk negative stockholder reaction, including from proxy advisory services, as well as damage to our 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 our investors, customers and other stakeholders, we could experience reduced demand for our products, loss of customers, and other negative impacts on our business and results of operations.

In addition, this emphasis on environmental, social, and other sustainability matters has resulted and may result in the adoption of new laws and regulations, including new reporting requirements. If we fail to comply with new laws, regulations, or reporting requirements, our reputation and business could be adversely impacted.

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. Since then, we have seen 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 April 28, 2025, our executive officers, directors, and 5% stockholders and their affiliates beneficially owned an aggregate of approximately 43% 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 April 28, 2025, we have outstanding 49,236,365 shares of common stock and 9,517,980 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, 41,197,215 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, or will soon file, one or more registration statements on Form S-8 registering the issuance of an aggregate of 17,546,713 shares of common stock subject to options or other equity awards issued or reserved for issuance under our 2015 Omnibus Incentive Compensation Plan and 1,100,000 shares of common stock reserved for issuance under our 2023 Employee Stock Purchase Plan. 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 the March 2022 Sales Agreement with Leerink, 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, 2024, we had U.S. federal net operating loss, or NOL, carryforwards of approximately $572.1 million and foreign NOL carryforwards of $4.8 million. U.S. federal net operating loss carry forwards amounting to $59.8 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 $512.3 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. In the event a change of ownership occurs, 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 will have the authority to issue up to 10,000,000 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 forum, 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 5. OTHER INFORMATION.

During the first quarter of 2025, the Company did not adopt or terminate a Rule 10b5-1 trading arrangement (as defined in Item 408(a)(1)(i) of Regulation S-K) for the purchase or sale of securities of the Company, whether or not intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Exchange Act.

During the first quarter of 2025, the following Rule 10b5-1 trading arrangements (as defined in Item 408(a)(1)(i) of Regulation S-K) and non-Rule 10b5-1 trading arrangements (as defined in Item 408(c) of Regulation S-K) intended to satisfy the affirmative defense of Rule 10b5-1(c) of the Exchange Act were adopted or terminated by our directors and/or executive officers:

Name	Title	Date of Adoption of Rule 10b5-1 Trading Arrangement[1]	Scheduled Expiration Date of Rule 10b5-1 Trading Arrangement	Aggregate Number of Securities to Be Sold
Mark Jacobson	Chief Operating Officer	February 24, 2025[2]	November 23, 2025	65,673
Hunter Murdock	General Counsel	March 4, 2025[2]	December 15, 2025	36,014
Mark Coleman	Director	February 25, 2025[2]	November 28, 2025	7,500
Roger Jeffs	Director	February 26, 2025[2]	November 28, 2025	110,158

(1) Date of adoption of Rule 10b5-1 trading arrangements is in accordance with both the Company's insider trading policy and applicable SEC rules and regulations.
(2) The first trade pursuant to the Rule 10b5-1 trading arrangement will be, in accordance with both the Company's insider trading policy and applicable SEC rules and regulations, on a date after the date of adoption of the Rule 10b5-1 trading arrangement.

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**##	Amendment to Sublease, dated January 17, 2025, between Advance Magazine Publishers Inc. d/b/a Condé Nast and Axsome Therapeutics, Inc.
10.2**	Axsome Therapeutics, Inc. Form of Stock Option Agreement pursuant to the Amended and Restated 2015 Omnibus Incentive Compensation Plan.
10.3**	Axsome Therapeutics, Inc. Form of Restricted Stock Unit Agreement (Non-Executives) pursuant to the Amended and Restated 2015 Omnibus Incentive Compensation Plan.
10.4**	Axsome Therapeutics, Inc. Form of Restricted Stock Unit Agreement (Executives and Non-Employee Directors) pursuant to the Amended and Restated 2015 Omnibus Incentive Compensation Plan.
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 With Embedded Linkbase Documents
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.)

**Filed herewith.

The exhibits and schedules to and certain provisions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K as they contain information that is both not material and of the type that the registrant treats as private or confidential. The registrant agrees to supplementally furnish an unredacted copy of this exhibit, including any exhibit or schedule hereto, to the SEC upon its request; however, the registrant may request confidential treatment of such unredacted copy.

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 5, 2025

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

Date: May 5, 2025

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

Exhibit 10.1

AMENDMENT TO SUBLEASE

This AMENDMENT TO SUBLEASE (this "**Amendment**") is made and entered into effective as of January 17, 2025 (the "**Effective Date**"), by and 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, Attn: Real Estate Department ("**Sublandlord**") and AXSOME THERAPEUTICS, INC., having offices at One World Trade Center, New York, New York 10007, Attn: General Counsel ("**Subtenant**").

RECITALS:

WHEREAS, Sublandlord and Subtenant entered into a certain sublease (hereinafter called the "**Original Sublease**"), dated February 21, 2023, with respect to the entire 22nd floor (the "**Original Premises**") of the building located at One World Trade Center, New York, New York (the "**Building**"), which Sublease was amended by that certain Consent to Sublet dated February 1, 2023 among WTC TOWER 1 LLC, as Prime Landlord, Sublandlord and Subtenant (the "**Consent**"), and (2) that certain Confirmation Agreement dated June 7, 2024 between Sublandlord and Subtenant (the "**Confirmation Agreement**"; together with the Original Sublease and Consent, the "**Sublease**";

WHEREAS, Subtenant desires to sublet the entire 29th floor (the "**Replacement Floor**") and 30th floor (the "**Incremental Floor"**) in the Building, as more particularly shown on **Exhibit A** annexed hereto and made a part hereof (the Replacement Floor and the Incremental Floor are hereinafter referred to as the "**New Premises**") and to return the Original Premises to Sublandlord; and

WHEREAS, Sublandlord and Subtenant desire, in connection with the foregoing, to otherwise amend and modify the terms of the Sublease, as set forth herein below, all on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing recitals, the covenants in this Amendment, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and for the mutual promises hereinafter set forth, Sublandlord and Subtenant agree to amend the Sublease as of the above Effective Date as follows:

AGREEMENT

1. Incorporation. The statements set forth above are incorporated herein as if restated. All capitalized terms used herein shall have the same meanings given such terms in the Sublease unless expressly superseded by the terms of this Amendment. In the event of an inconsistency between the Sublease and this Amendment, the provisions of this Amendment shall control.

2. The New Premises.

(a) Sublandlord hereby subleases to Subtenant, and Subtenant hereby hires from Sublandlord, the New Premises for a term to commence (subject to the provisions of Section

16 entitled "Landlord's Consents" and Section 17 entitled "Delivery of Possession of New Premises" hereof) on the later to occur of (a) the full execution and delivery of this Amendment by both Sublandlord and Subtenant, (b) the date Sublandlord receives Prime Landlord's written consent to this Amendment and (c) the date on which the New Premises Sublandlord's Work (as hereinafter defined) is deemed to have been substantially completed and Sublandlord has delivered the New Premises to Subtenant in the Premises Condition, as hereinafter defined (the later of such dates is called the "**New Premises Commencement Date**"). Sublandlord shall provide Subtenant with five (5) business days' advance notice of the New Premises Commencement Date. Sublandlord estimates that the New Premises Commencement Date will occur on or about three (3) weeks from the date Prime Landlord executes the Landlord's Consent (as defined in Section 16 hereof) to this Amendment. Except as otherwise expressly provided in this Amendment, from and after the New Premises Commencement Date, (i) all references in the Original Sublease to the "Premises" shall be deemed to mean the New Premises for all purposes of the Sublease, (ii) all references in the Original Sublease to the "Commencement Date" shall be deemed to mean the New Premises Commencement Date for all purposes of the Sublease; (iii) all references in the Original Sublease to the "Rent Commencement Date" shall be deemed to mean the RP Rent Commencement Date (as hereinafter defined) for all purposes of the Sublease; and (iv) all references in the Original Sublease to the "Effective Date" shall be deemed to mean the Effective Date of this Amendment for all purposes of the Sublease. From and after the New Premises Commencement Date, Subtenant shall sublease the New Premises upon all of the terms and conditions of the Sublease, as modified by this Amendment.

(b) Promptly after the occurrence of the New Premises Commencement Date, Sublandlord and Subtenant shall confirm the occurrence thereof, as well as the RP Rent Commencement Date, IP Rent Commencement Date (as hereinafter defined) 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 New Premises Commencement Date in accordance with Section 2(a) hereof.

(c) For the avoidance of doubt, Section 1(c) and 1(d) of the Original Sublease shall apply to the New Premises, and Subtenant will have the Early Access right with respect to the New Premises during the thirty (30) day period prior to the New Premises Commencement Date.

3. The Original Premises.

(a) Subtenant shall move out of the Original Premises no later than four (4) months after the New Premises Commencement Date, subject to Force Majeure (the "**Original Premises Termination Date**"). On the Original Premises Termination Date, Subtenant shall surrender to Sublandlord in the condition required herein, and Sublandlord shall accept the surrender of, the Original Premises if same are in the condition required herein, to the intent and purpose that the estate of Subtenant in and to the Original Premises shall be wholly extinguished and that the term of the Sublease with respect to the Original Premises shall expire on the Original Premises Termination Date in the same manner and with the same effect as if such date were the date set forth in the Sublease for the expiration of the term thereof in respect of the Original Premises (provided, that all Rent and other amounts payable under the Sublease with respect to the Original Premises shall be apportioned as of the Original Premises Termination Date, but

Subtenant's obligation to pay Rent, including CAM Payments and other Additional Rent items with respect to the Original Premises shall survive the Original Premises Termination Date and be due and owing in accordance with the terms and provisions of the Original Sublease). Prior to the later of (i) Original Premises Termination Date and (ii) the date Subtenant delivers vacant possession of the Original Premises in the condition required by the Original Sublease as hereby amended, Subtenant shall sublease the Original Premises upon all of the terms of the Sublease applicable to such Original Premises without giving effect to this Amendment (including, without limitation, the continued payment of all Rent with respect thereto) and such terms shall separately apply to the Original Premises, except that Subtenant shall not be required to pay Fixed Rent with respect to the Original Premises for [*****] after the New Premises Commencement Date (the "**Original Premises Free Rent Period**"). For the avoidance of doubt, until the Original Premises Termination Date, after the Original Premises Free Rent Period, Subtenant will continue to pay the Rent with respect to the Original Premises until the Original Premises Termination Date; provided, however, notwithstanding anything to the contrary contained herein or in the Original Sublease, at any time prior to [*****] (as such date may be extended by any Prime Landlord Delay [as hereinafter defined]) after the New Premises Commencement Date, Subtenant, at its election, may vacate the Original Premises and deliver possession thereof in the condition required herein, to Sublandlord on either (i) thirty (30) days' prior written notice by Subtenant to Sublandlord, provided that Sublandlord has provided Subtenant with notice of reasonable evidence substantiating that Sublandlord has a signed sublease with a third party for the Original Premises, which signed sublease has been consented to by Prime Landlord ("**Another Sublease**"), and such 30th day shall be the Original Premises Termination Date, or (ii) one (1) business day's prior written notice by Subtenant to Sublandlord, provided that Subtenant has not received such notice of Another Sublease, and such 1st business day shall be the Original Premises Termination Date.

(b) Subject to the provisions of Subsection (c) below, on or before the Original Premises Termination Date, Subtenant shall surrender and deliver vacant, broom clean possession of the Original Premises to Sublandlord in the condition required by the Original Sublease, as amended hereby. The Original Premises shall be delivered "as is" condition as of the date hereof, subject to reasonable wear and tear, casualty and condemnation, and damage for which Subtenant is not responsible. In furtherance thereof, and notwithstanding anything to the contrary contained in the Original Sublease, Sublandlord acknowledges, as of the Effective Date, that (1) none of the Alterations in the Original Premises constitute a Material Alteration or a Specialty Alteration, and Subtenant shall have no obligation to remove, demolish, repair, close or restore any Alterations in or about the Original Premises prior to the Original Premises Termination Date, other than Subtenant's signage.

(c) Subtenant shall remove the furniture and equipment from the Original Premises as more particularly set forth on **Exhibit D-2**, annexed hereto and made a part hereof (including without limitation, any furniture and equipment purchased by Subtenant with the Work Allowance or any other furniture and equipment owned by Subtenant), either moving same to the New Premises or otherwise disposing of same. Subtenant shall leave all other furniture and equipment in the Original Premises that are not listed on **Exhibit D-2**. Notwithstanding anything contained in the Original Sublease to the contrary, Sublandlord shall retain ownership of the FF&E not listed on **Exhibit D-2**, which shall remain in the Original Premises, If Subtenant does not surrender and deliver possession of the Original Premises to Sublandlord in the condition required herein on the Original Premises Termination Date, Subtenant shall be in default of the Sublease,

as amended by this Amendment. Furthermore, Subtenant shall be deemed to be a holdover, shall immediately pay Rent to Sublandlord for the Original Premises Free Rent Period and shall thereafter pay holdover Rent on the Original Premises to Sublandlord in accordance with Section 12 of the Original Sublease until Subtenant delivers possession of the Original Premises to Sublandlord.

(d) Provided Subtenant delivers possession of the Original Premises in the condition required herein, Sublandlord shall accept the surrender of the Original Premises as of the Original Premises Termination Date and in consideration of such surrender by Subtenant and of the acceptance of such surrender by Sublandlord, Subtenant and Sublandlord do hereby mutually release each other, their respective successors and assigns of and from any and all claims, damages, obligations, liabilities, actions and causes of action, of every kind and nature whatsoever arising under or in connection with the Sublease in respect of the Original Premises from and after the Original Premises Termination Date, except that nothing herein contained shall be deemed to constitute a release or discharge of Sublandlord or Subtenant with respect to any obligation or liability (i) accrued or incurred under the Sublease in respect of the Original Premises and outstanding and unsatisfied on the Original Premises Termination Date, and (ii) to a third party (under the insurance and indemnification provisions of the Sublease or otherwise) arising prior to, on or after the Original Premises Termination Date in respect of the Original Premises as a result of an event occurring or condition existing prior to or on the Original Premises Termination Date.

4. Sublease Provisions. Sublandlord and Subtenant acknowledge that Subtenant has performed only Decorative Alterations in the Original Premises. All terms and provisions of the Sublease with respect to Subtenant Work in the Original Premises are hereby deemed fulfilled, except with respect to the Work Allowance. All provisions regarding Initial Alterations, construction, and other similar provisions shall apply to Subtenant Work in the New Premises. The following Sections of the Original Sublease are deleted: Section 18. **Exhibit A** of the Original Sublease is replaced with **Exhibit A** (the New Premises) attached to this Amendment. **Exhibit D** of the Original Sublease is replaced with **Exhibit D (New Premises Sublandlord's Work)** attached to this Amendment. **Exhibit D-1** of the Original Sublease is replaced with **Exhibit D-3 (FF&E to be left on 29th and 30th floors)** attached to this Amendment. Number 14 on **Exhibit B** of the Original Sublease is modified by adding the following words "except for the fire stairs between the 29th and 30th floors, which Subtenant shall have the right to use in accordance with the Original Lease".

5. Rent Commencement Date:

5.1. The Rent Commencement Date for the Replacement Floor shall be [*****] after the New Premises Commencement Date (the "**RP Rent Commencement Date**").

5.2. The Rent Commencement Date for the Incremental Floor shall be [*****] after the New Premis Commencement Date (the "**IP Rent Commencement Date**").

6. Term: Effective as of the New Premises Commencement Date, the Term of the Sublease is hereby extended so that the "**Expiration Date**" shall be (unless sooner terminated in

accordance with applicable Legal Requirements or pursuant to Section 26 of the Original Sublease (as modified hereby) or extended pursuant to Section 27 of the Original Sublease) on the day immediately preceding the 10th anniversary of the IP Rent Commencement Date if the IP Rent Commencement Date is the first day of the month or, if the IP Rent Commencement Date is not the first day of a month, then the Expiration Date will be the last day of the month in which the 10th anniversary of the IP Rent Commencement Date occurs.

7. Fixed Rent. The Fixed Rent payable by Subtenant to Sublandlord for the New Premises during the Term shall be as set forth in the following schedule:

Replacement Floor:		
Period commencing on RP Rent Commencement Date and ending on 12/6/2028	$2,505,464.00 Annual	$208,788.66 Monthly
Period commencing on 12/7/2028 and ending on the Expiration Date	$2,746,374.00 Annual	$228,864.50 Monthly
Incremental Floor:		
Period commencing on IP Rent Commencement Date and ending on the day immediately preceding the fifth (5th) anniversary of the IP Rent Commencement Date	$2,285,272.50 Annual	$190,439.37 per month
Period commencing on the fifth (5th) anniversary of the IP Rent Commencement Date and ending on the Expiration Date	$2,525,827.50 Annual	$210,485.62 per month

Sublandlord and Subtenant acknowledge that pursuant to Section 2(d) of the Original Sublease, Fixed Rent is reduced by $69,333.33 ("**Monthly Rent Reduction**") per month through February 6, 2025 (the "**Rent Reduction End Date**"). Provided Subtenant is not then in material monetary or material non-monetary default beyond any applicable notice and cure periods under the Sublease, as amended (and if such a default exists, then as soon as such default is cured), and otherwise complies with the requirements set forth in such Section 2(d) for obtaining the above reduction, Fixed Rent for the Replacement Floor shall be reduced each month by the amount of the Monthly Rent Reduction until the Rent Reduction End Date. The last full sentence of Section 2(d) of the Original Sublease is deleted and replaced with the following sentence: "If Subtenant does not exercise the Termination Option (as hereinafter defined), then, provided that (i) Subtenant is not then in material 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 with respect to the Replacement Floor for a two month period commencing on the first full month after the 6th anniversary of the RP Rent Commencement Date." Sublandlord and Subtenant

acknowledge that the term "material monetary default" as used in this Amendment shall mean a default by Subtenant in an amount equal to or greater than one (1) monthly installment of Fixed Rent for the Incremental Floor.

8. Additional Rent. Effective as of the New Premises Commencement Date, except as specifically set forth herein, Subtenant shall pay Additional Rent as set forth in Section 3 of the Original Sublease. The PILOT Base Year for the Replacement Floor shall be as set forth in the Sublease. The PILOT Base Year for the Incremental Floor shall be the average of 2024/2025 and 2025/2026 fiscal years, provided that no Additional Rent under Original Sublease Section 3(a)(1), as amended hereby, shall be due and payable by Subtenant with respect to the Incremental Floor until (and for the period prior to) the later of January 1, 2026 or the IP Rent Commencement Date. The Sublease Operating Expense Base Year for the Replacement Floor shall be as set forth in the Sublease. The Sublease Operating Expense Base Year for the Incremental Floor shall be the 2025 calendar year, provided that no Additional Rent under Original Sublease Section 3(a)(2), as modified hereby, shall be due and payable by Subtenant for the Incremental Floor until (and for the period prior to) the later of January 1, 2026 or the IP Rent Commencement Date. The Sublease CAM Base Year for the Replacement Floor shall be as set forth in the Sublease. The Sublease CAM Base Year for the Incremental Floor shall be the 2025 calendar year, provided that no Additional Rent under Original Sublease Section 3(a)(3), as modified hereby, shall be due and payable by Subtenant for the Incremental Floor until (and for the period prior to) the later of January 1, 2026 or the IP Rent Commencement Date.

(a) Original Sublease Section 3(b) is hereby modified to provide that as of the New Premises Commencement Date, Subtenant's Share with respect to the (i) Replacement Floor is 4.03% (based on the rentable square feet in the Replacement Floor being deemed to be 48,182) and (ii) Incremental Floor is 4.0241% (based on the rentable square feet in the Incremental Floor being deemed to be 48,111).

(b) Original Sublease Section 3(a)(4) is hereby modified to provide that prior to the New Premises Commencement Date, a submeter has or will be installed by Sublandlord (at no additional cost to Subtenant) to separately submeter each floor of the New Premises, which submeters shall exclusively measure the consumption of electricity on each floor of the New Premises.

9. Subtenant Work and Allowance for the New Premises. (a) Sublandlord and Subtenant acknowledge that the Wo Allowance set forth in Section 21(b) of the Original Sublease is with respect to the Original Premises and has been paid or a credit is being provided as set forth below. In addition, Sublandlord shall reimburse Subtenant the cost of Subtenant Work in the New Premises at [*****] per rentable square foot for the Incremental Floor in an amount equal to [*****] (the "**IP Work Allowance**") in accordance with the terms and conditions set forth in Section 21 of the Original Sublease, as modified hereby. Furthermore, Subtenant shall have the right to request from Sublandlord the balance of its unused amount of the Work Allowance (originally with respect to the Original Premises) as set forth in such Section 21 of the Original Sublease in the amount of [*****] as of the date hereof in connection with Subtenant Work in the New Premises (the "**Original Premises Work Allowance Balance**"; together with the IP Work Allowance, the "**Work Allowance**"). The Work Allowance shall be accessible in accordance the terms and conditions of Section 21 of the Original Sublease, as modified hereby, and for the

avoidance of doubt, the Work Allowance can be applied by Subtenant to either and/or both floors of the New Premises.

(a) Section 21 of the Original Sublease is modified as follows:

(i) "[*****]" is replaced with [*****]";

(ii) clause (b)(4) shall be deleted and replaced with the following: "All requests for disbursement under clause (2) above must be submitted by Subtenant to Sublandlord no later than the second (2nd) anniversary of the New Premises Commencement Date.";

(iii) clause (d) shall be deleted and replaced with the following: ""**Subtenant Work**" means the installation of alterations, fixtures, improvements and appurtenances attached to or built into the New Premises by Subtenant, or otherwise located by Subtenant in the New 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.";

(iv) clause (g) shall be deleted and replaced with the following: "*Unused Amount*. If (x) Subtenant has not requested and/or received all of the Work Allowance by the second (2nd) anniversary of the New Premises Commencement Date (the amount of the Work Allowance not received by Subtenant, the "**Unused Amount**"), or (y) prior to the second (2nd) anniversary of the New Premises Commencement Date, Subtenant elects by notice to Sublandlord to convert the Unused Amount to a Fixed Rent credit, the Unused Amount, provided that Subtenant is not then in material 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 RP Rent Commencement Date and continuing on a monthly basis until the Unused Amount is zero; provided, however, if the Subtenant has been in material 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."; and

(v) the last sentence of clause (h) shall be deleted and replaced with: "Notwithstanding anything to the contrary contained herein, Subtenant shall have no obligation to remove any Alterations or other improvements existing in the New Premises on the New Premises Commencement Date.".

(vi) a new Section 21(j) shall be added as follows: "Subject to compliance with the terms and provisions of the Sublease and this Amendment, Subtenant may perform

Subtenant Work described in **Exhibit E** annexed hereto (sometimes called the "**New Premises Subtenant Work**"). Sublandlord consents to the concept of the New Premises Subtenant Work described in **Exhibit E**, has approved Subtenant's "test fit" as shown on **Exhibit E**, and agrees that Sublandlord shall not require Subtenant to remove, demolish, repair, close or restore any New Premises Subtenant Work prior to the expiration of the Term, other than Subtenant's signage. Sublandlord's consent to the actual work to be done is subject to its review of plans and specifications of the work to be performed in accordance with the terms and provisions of the Lease and this Sublease. As part of Landlord's Consent, Sublandlord shall, in accordance with the terms and provisions of the Lease, at no cost to Sublandlord, use commercially reasonable efforts to seek Prime Landlord's consent to New Premises Subtenant Work, if required under the Lease. As part of seeking Prime Landlord's consent to the New Premises Subtenant Work, Sublandlord shall also ask Prime Landlord for an acknowledgement either that (i) that none of the New Premises Subtenant Work constitutes a Material Alteration or a Specialty Alteration or (ii) some of the New Premises Subtenant Work constitutes a Material Alteration or Specialty Alteration, and in such event, either that (a) Prime Landlord consents to the performance thereof and whether Subtenant shall be required to remove same in accordance with the terms and provisions of the Lease or (b) Prime Landlord does not consent to those portions of the New Premises Subtenant Work that are either Material Alterations or Specialty Alterations. If either Prime Landlord does not consent to Material Alterations or Specialty Alterations or requires the removal of Specialty Alterations, and Subtenant elects to revise its plans for the performance of New Premises Subtenant Work, provided Subtenant is diligent in its performance of the New Premises Subtenant Work and uses commercially reasonable efforts to perform same, if Subtenant is delayed in completing the New Premises Subtenant Work due to (x) Prime Landlord's delay in delivering its consent to the New Premises Subtenant Work, (y) Prime Landlord's determination that the New Premises Subtenant Work includes Material Alterations and/or Specialty Alterations, and/or (y) Prime Landlord's non-consent to the plans for the New Premises Subtenant Work, so that Subtenant does not complete the New Premises Subtenant Work and vacate the Original Premises within four (4) months of the New Premises Commencement Date, subject to Force Majeure (the Original Premises Termination Date), then, notwithstanding anything to the contrary contained herein, Subtenant shall not be required to pay holdover rent as set forth in Section 3 above for the amount of time that Prime Landlord's actions delayed Subtenant in completing the New Premises Subtenant Work (such amount of time, the "**Prime Landlord Delay**") and the Original Premises Termination Date shall be extended by such period of Prime Landlord Delay; provided however that maximum amount of time for the delay in Subtenant paying holdover rent pursuant to Section 3 hereof shall be an additional thirty (30) days so that if Subtenant has not vacated the Original Premises and delivered possession of the Original Premises to Sublandlord due to Prime Landlord Delay within five (5) months of the New Premises Commencement Date, for whatever reason whatsoever, Subtenant shall pay such holdover rent pursuant to Section 3 hereof. If there is an extra fee for Prime Landlord to review the plans and/or include the foregoing acknowledgement in its consent, such cost shall be at Subtenant's cost. In the event Subtenant is delayed in commencing or completing the New Premises Subtenant Work due to a Prime Landlord Delay, Subtenant shall comply with all provisions of the Lease, the Sublease and to the extent required by law, obtain the approval of Governmental

Authorities (including QAD) upon installation. Anything contained in this Sublease to the contrary notwithstanding, all such New Premises Subtenant Work 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(j), either party may submit such dispute to arbitration pursuant to Article 25 of the Original Lease. Notwithstanding anything contained in this Amendment to the contrary, Subtenant shall remove Subtenant's signage."

10.Furniture, Fixtures and Equipment. The provisions of Section 22 of the Original Sublease shall apply to the FF&E in the New Premises, except that **Exhibit D-1** of the Original Sublease is replaced with **Exhibit D-3** annexed hereto.

11.Termination Option.

(a) Paragraph 26(a) of the Original Sublease is modified by (i) changing the number "5th" in the first sentence to the number "6th", (ii) changing the number "12" in the second sentence to the number "15", and (iii) deleting subsection (ii) in the first sentence. The parties agree that the Termination Option shall be applicable only to the 29th and 30th floors, and not applicable with respect to any ROFO Space and/or ROFR Space that Subtenant is subleasing pursuant to its options in this Amendment.

(b) Paragraph 26(b) of the Sublease is deleted and replaced with the following: "**Original Premises Transaction Costs**" means [*****]. "**New Premises Transaction Costs**" means the sum of (A) the unamortized value as of the Termination Date of: (i) all brokerage commissions incurred by Sublandlord in connection with the leasing of the New Premises by Subtenant during the Term; (ii) the cost of any tenant improvements constructed by Sublandlord in connection with the New Premises (including, without limitation, Sublandlord's Work), (iii) the Work Allowance for the New Premises, and (iv) the aggregate value of any abatement of Fixed Rent granted to Subtenant in connection with the New Premises (including, without limitation, pursuant to Section 2(d) hereof, but not pursuant to Section 17(b) hereof), determined by amortizing such costs in constant monthly payments of principal and interest, at a rate of [*****] per annum, over the period commencing on the Rent Commencement Date and ending on the Expiration Date and (B) four (4) months of the then Rent payable with respect to the New Premises (Fixed Rent and Additional Rent). Together the "Original Premises Transaction Costs" and the "New Premises Transaction Costs" shall be referred to as the "**Transaction Costs**". Subtenant shall have the right to send written notice to Sublandlord six (6) months prior to the date Subtenant has the right to exercise the Termination Option requesting the amount of the Transaction Costs. Sublandlord shall respond within sixty (60) days of receipt of such notice. Based on the dates and assumptions set forth therein, an example of the Transaction Costs is included herein as **Exhibit F** annexed hereto.

12.Right of First Offer Option.

(a) Definitions. As used herein:

"**Available**" means, Offer Space (as hereinafter defined) that is vacant and free of any present or future possessory right now or hereafter existing in favor of any third party; provided, that any Offer Space shall not be deemed Available unless and until such space is first subleased to another subtenant and then again becomes Available or, if Sublandlord elects not to sublease such space, then when Sublandlord next offers such space for sublease. Anything to the contrary contained herein notwithstanding, Subtenant's right of first offer pursuant to this Paragraph is subject to and subordinate to (1) the rights of existing occupants of the Offer Space, including, without limitation future expansion rights granted, (2) any right of offer, right of first refusal, expansion right or similar right or option with respect to the Offer Space in favor of any third party existing as of the date of this Amendment which are set forth on **Exhibit G** annexed hereto, (3) intentionally omitted, (4) Sublandlord's right to renew or extend the term of any sublease of Offer Space to another existing subtenant, whether or not pursuant to an option or right set forth in such other subtenant's sublease, (5) Sublandlord's, including its related entities, right in its sole discretion to occupy or use any such Offer Space and (6) the Lease. Sublandlord agrees that it will not, after the Effective Date, give any person rights of first offer, rights of first refusal, expansion rights or similar rights or options superior to Subtenant's rights in the Offer Space or Available Space or Additional Space, but any subtenant now or in the future occupying Offer Space or Available Space will have the right to renew or extend the term of its sublease.

"**Offer Period**" means the period commencing on the New Premises Commencement Date to and including the date that is 4 years prior to the Expiration Date, as may have been extended by Subtenant's Renewal Option (or, if there are not at least four (4) years remaining to the initial Sublease term, Subtenant may simultaneously exercise the Renewal Option set forth in Section 27 of the Original Sublease).

"**Offer Space**" means space on the 27th, 28th, 31st, and/or 32nd floor of the Building.

"**Fair Market Value**", for purposes of this Paragraph, means the rent that a willing subtenant would pay and a willing sublandlord of comparable first-class office space in this Building would accept for the applicable Offer Space during the applicable Term, adjusted to take into account all of the then relevant factors. Sublandlord shall include with the Offer Notice Sublandlord's estimate of the Fair Market Value of the applicable Offer Space for the applicable Term. If Subtenant disagrees with Sublandlord's estimate of the Fair Market Value as set forth in Sublandlord's Offer, Subtenant shall, within twenty (20) days after its receipt of Sublandlord's Offer Notice, notify Sublandlord setting forth Subtenant's estimate of the Fair Market Value of the applicable Offer Space and the parties will attempt to reach agreement on the Fair Market Value of such Offer Space for the applicable Term. If Subtenant fails to notify Sublandlord that Subtenant disagrees with Sublandlord's estimate and setting forth Subtenant's Fair Market Value estimate within such twenty (20) day period, then Subtenant will be deemed to have accepted Sublandlord's estimate of the Fair Market Value for the applicable Offer Space during the applicable Term. If Subtenant has timely given its dispute notice and the parties are unable to reach agreement thereon within twenty (20) days after the delivery of such notice by Subtenant, then either party may submit the determination of the Fair Market Value of such Offer Space to arbitration (as set forth below) by giving notice to the other party naming

the initiating party's representative within ten (10) days after the expiration of such twenty (20) day period. Within ten (10) days after receiving a notice of initiation of arbitration, the responding party shall appoint its own representative by notifying the initiating party of the responding party's representative. If the second representative shall not have been so appointed within such ten (10) day period, the initiating party shall deliver written notice of such failure to the responding party and the responding party shall have a period of ten (10) days after receipt of such notice to appoint its representative and deliver written notice thereof to the initiating party. If the responding party fails to notify the initiating party of its designated representative within the foregoing additional ten (10) day period, then the second representative shall be chosen in the same manner as described below with respect to the selection of the arbitrator. Upon the selection (or appointment, as the case may be) of the second representative, the two representatives thus appointed shall, within fifteen (15) days after the responding party's notice of appointment of the second representative, appoint an arbitrator. If the two initial representatives are unable timely to agree on the arbitrator, then either may, on behalf of both, request such appointment by the New York City office of JAMS, or its successor, or, on its failure, refusal or inability to act, by a court of competent jurisdiction. The Fair Market Value of the applicable Offer Space for the applicable Term shall be determined by the method commonly known as "baseball arbitration," whereby Sublandlord's selected representative and Subtenant's selected representative (or such representative appointed on behalf of Subtenant, as applicable) shall each set forth its respective determination of the Fair Market Value of such Offer Space, and the arbitrator must select one or the other determination (it being understood and agreed that the arbitrator shall be expressly prohibited from selecting a compromise figure). Sublandlord's selected representative and Subtenant's selected representative shall deliver their determinations of the Fair Market Value of the applicable Offer Space to the arbitrator within ten (10) days of the appointment of the arbitrator, and the arbitrator shall render his or her decision within ten (10) Business Days after receipt of both determinations of the Fair Market Value of such Offer Space. The arbitrator's decision shall be binding and conclusive on both Sublandlord and Subtenant. All representatives and the arbitrator shall be commercial real estate brokers who have had at least ten (10) years' experience in first-class office space subleasing transactions in the general vicinity of the Offer Space. Representatives selected by Sublandlord or Subtenant may have been engaged by them on this Sublease or other transactions. Representatives selected by a third party on behalf of Sublandlord or Subtenant (because Sublandlord or Subtenant did not timely make a selection) and the arbitrator shall be independent of either party. Each party shall pay the fees of its own representative, and the fees of the arbitrator shall be shared equally by the parties. In the event the aforesaid arbitration process has been initiated and as of the Offer Space Inclusion Date the Fixed Rent for the applicable Offer Space for such applicable Term has not been determined, then Subtenant shall continue to pay Fixed Rent for such Offer Space at the same rate of Fixed Rent per rentable square foot then applicable to the initial Premises, and when the determination of the Fair Market Value for such Offer Space has been finally made, an appropriate retroactive adjustment shall be made as of the Offer Space Inclusion Date if necessary. If such determination shall result in an underpayment by Subtenant of any Fixed Rent, Subtenant shall pay any such amounts of underpayment to Sublandlord within thirty (30) days following such determination. If such determination shall result in an overpayment by Subtenant of any Fixed Rent, the overpayment shall be

credited against the next installments of Fixed Rent for the Premises as increased by the applicable Offer Space.

(b) Availability of Offer Space. Provided (1) this Sublease shall not have been terminated, (2) Subtenant shall not then be in default in its material monetary or material non-monetary obligations under this Sublease, beyond any applicable notice or cure periods under this Sublease(or if such a default exists, then as soon as such default is cured) and (3) Named Subtenant shall occupy at least seventy-five (75%) percent of the New Premises (excluding any desk-sharing space), if at any time and from time to time during the Offer Period any Offer Space either becomes, or Sublandlord reasonably anticipates that within the next 3 to 18 months (but not later than the last day of the Offer Period) the Offer Space will become, Available, Sublandlord shall give to Subtenant notice (an "**Offer Notice**") thereof, specifying (A) the applicable portion of the Offer Space and the fixed annual rental ("**Offer Rental**") which Sublandlord is then considering for the sublease of such Offer Space, which shall be one hundred percent (100%) of the then Fair Market Value, (B) the date or estimated date (the "**Target Date**") that such Offer Space has or shall become Available and (C) such other matters as Sublandlord may reasonably deem appropriate for such Offer Notice, including without limitation, *mutatis mutandis* (together with a floor plan depicting such space if the same is available), a description of free rent, subtenant concessions, build-outs, escalation rent and other material terms Sublandlord proposes.

(c) Exercise of Offer Space Option. Provided that (1) on the date that Subtenant exercises the Offer Space Option and on the Office Space Inclusion Date, this Sublease shall not have been terminated, and (2) Subtenant shall not then be in default in its material monetary or material non-monetary obligations under this Sublease, beyond any applicable notice or cure periods under this Sublease (or if such a default exists, then as soon as such default is cured),and (3) the Named Subtenant shall occupy at least seventy-five (75%) percent of the Premises (excluding any desk-sharing space) , Subtenant shall have the option (the "**Offer Space Option**"), exercisable by notice (an "**Acceptance Notice**") given to Sublandlord on or before the date that is thirty (30) days after the giving of the Offer Notice (time being of the essence) to include the applicable Offer Space in the Premises. Sublandlord shall use all commercially reasonable efforts to remove all subtenants and occupants from the applicable Offer Space and to deliver vacant possession of any applicable Offer Space to Subtenant on the Target Date therefor (and, failing which, shall continue to use reasonable efforts to deliver vacant possession of such Offer Space to Subtenant as soon as possible thereafter), including enforcement of any holdover provisions in any existing subleases for such Offer Space, and diligently prosecuting summary eviction proceedings against all such subtenants and occupants therein if any subtenant or occupant in such Offer Space has not vacated such Offer Space within forty-five (45) days after Sublandlord has delivered notice to Subtenant of the date such Offer Space will become Available.

(d) Offer Space becomes part of the Premises upon Delivery. If Subtenant timely delivers the Acceptance Notice, then, on the date on which Sublandlord delivers vacant possession of the applicable Offer Space to Subtenant, free of all rights of possession by a third party (the "**Offer Space Inclusion Date**"), such Offer Space shall become part of the Premises, upon all of the terms and conditions set forth in this Sublease (including, without limitation, the Renewal Option) except (1) Fixed Rent shall be increased by the Offer Rental, (2) Subtenant's Share shall be determined with respect to such Offer Space in accordance with the calculation for Subtenant's Share set forth in the Sublease, as amended, provided that the numerator shall be the

number of rentable square feet of such Offer Space to be included in the Premises, and (3) the term of such Offer Space shall be coterminous with the term of the remainder of the Premises, and (4) Subtenant shall be entitled to additional condenser water with respect to such Offer Space in an amount not to exceed the proportionate amount based on twenty-three (23) tons of condenser water per full floor of the Building. Electricity charges for such Offer Space shall be measured by a submeter for such Offer Space only. If there is not submeter already installed, the cost of installing same shall be a factor in determining the Offer Rent and shall be paid for by the appropriate party. Condenser water shall be furnished to Subtenant, at Subtenant's cost and expense at the rates set forth herein, in accordance with the terms and conditions of this Sublease.

(e) Sublandlord Inability to Deliver Possession of Offer Space. If notwithstanding Sublandlord's exercise of such reasonable efforts, Sublandlord is unable to deliver possession of the applicable Offer Space to Subtenant on or before the Target Date as set forth in the Offer Notice, the Offer Space Inclusion Date shall be the date on which Sublandlord is able to so deliver possession and Sublandlord shall have no liability to Subtenant therefor (except as otherwise set forth herein) and this Sublease shall not in any way be impaired, and the Fixed Rent and Additional Rent payable with respect to such portion of the Offer Space shall be abated and the applicable commencement date shall be postponed until Sublandlord shall deliver to Subtenant vacant possession of such Offer Space. If the Offer Space Inclusion Date does not occur within thirty (30) days after the Target Date (as such date shall be extended for Force Majeure, the "**Outside ROFO Date**"), then Subtenant shall be entitled to an abatement of Fixed Rent, which abatement shall be equal to one (1) day of Fixed Rent with respect to applicable Offer Space for each day of delay (but in no event to exceed sixty (60) days) after the Outside ROFO Date until the Offer Space Inclusion Date shall occur. If the Offer Space Inclusion Date does not occur within ninety (90) days after the Target Date, then Subtenant may elect in its discretion, upon thirty (30) days' notice to Sublandlord, to rescind and terminate its Acceptance Notice with respect to the applicable Offer Space that is the subject of the Offer Notice, and, unless such Offer Space is delivered to Subtenant within such thirty (30) day period, such Offer Space shall not become part of the Premises (and Subtenant shall not be entitled to the abatement set forth in the immediately preceding sentence, but Sublandlord shall pay Subtenant's reasonable out-of-pocket expenses in connection with such Offer Space). This Section (e) constitutes "an express provision to the contrary" within the meaning of Section 223(a) of the New York Real Property Law and any other law of like import now or hereafter in effect.

(f) Subtenant's failure to Timely Give an Acceptance Notice. If Subtenant fails timely to give an Acceptance Notice, then (1) Sublandlord may enter into one or more subleases or occupancy agreements of the applicable Offer Space with third parties on such terms and conditions as Sublandlord shall determine, the Offer Space Option with respect to such Offer Space described in the Offer Notice shall be null and void and of no further force and effect and Sublandlord shall have no further obligation to offer solely the specified Offer Space subject to the Offer Notice to Subtenant, and (2) Subtenant shall, upon written demand by Sublandlord, execute an instrument confirming Subtenant's waiver of, and extinguishing, the Offer Space Option with respect to the Offer Space described in the Offer Notice, but the failure by Subtenant to execute any such instrument shall not affect the provisions of clause (1) above. However, the Offer Space Option shall continue to apply to any other Offer Space that has not been the subject of an Offer Notice.

(g) Instrument Documenting Offer Space. Promptly after the occurrence of the Offer Space Inclusion Date, Sublandlord and Subtenant shall confirm the occurrence thereof and the inclusion of the applicable Offer Space in the Premises by executing an instrument reasonably satisfactory to Sublandlord and Subtenant (including without limitation, (i) a description of the Offer Space in question and the addition of the same to the Premises; (ii) the applicable commencement date; (iii) the increased Subtenant's Share in respect of the Offer Space in question; and (iv) the increase in Fixed Rent resulting from such inclusion); provided, that failure by Sublandlord or Subtenant to execute such instrument shall not affect the inclusion of such Offer Space in the Premises in accordance with this Section 12.

(h) Nullification of Offer Space Option. Anything in this Sublease to the contrary notwithstanding, the provisions of this Paragraph granting to Subtenant the Offer Space Option shall be null and void and of no force or effect if (1) the Named Subtenant is no longer the Subtenant under this Sublease or (2) the Named Subtenant is not then in occupancy of at least 75% of the Premises (excluding any desk-sharing space).

13. Freight Elevator and Loading Dock Access. Section 30(f) of the Original Sublease is deleted and replaced with the following "Notwithstanding anything herein contained to the contrary, in connection with Subtenant's move into the New Premises and the delivery of furniture and equipment prior thereto, Sublandlord shall provide 35 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 35 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."

14. Security. Section 20 of the Original Sublease is hereby modified to provide as follows:

(a) the LC Amount shall be increased by [*****] so that within one (1) month of the Effective Date of this Amendment, Subtenant shall deliver a Letter of Credit (at Subtenant's election, by either an amendment to the Letter of Credit or replacement Letter of Credit) in the amount of [*****]. If Subtenant is unable to supply such an amendment to the Letter of Credit or such replacement Letter of Credit within one (1) month of the Effective Date, Subtenant shall post a cash deposit in the increased amount of [*****], which cash security shall be returned to Sublandlord when Subtenant delivers such amendment to the Letter of Credit or replacement Letter of Credit in the amount of [*****];

(b) if Subtenant delivers a replacement Letter of Credit, Sublandlord shall return the original Letter of Credit to Subtenant within two (2) Business Days after Sublandlord's receipt of the replacement Letter of Credit.

(c) the first sentence of Original Sublease Section 20(b) is hereby deleted and replaced with the following: "If Subtenant has not been in material 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 (5th)

anniversary of the RP Commencement Date, the LC Amount shall be allowed to be reduced to [*****]; and

(d) the last sentence of Original Sublease Section 20(b) is hereby deleted and replaced with the following: "If any time thereafter, during the Term and after the reduction of the LC Amount, Subtenant is in material 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 full amount of [*****]".

15. New Premises Condition. Subtenant shall accept the New Premises "as is," on the New Premises Commencement Date without any warranty or recourse to Sublandlord, subject to the following:

(a) Delivery of Possession. Sublandlord, at its cost, shall deliver the New 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 the New Premises Sublandlord's Work (as defined on **Exhibit D**) substantially completed (all of the items in this Section 15(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 herein 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 New Premises, the use to which the New 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.

16. Landlord's Consents.

(a) This Amendment 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**"), including without limitation, the items described in Section 9(b)(vi) hereof. 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 Amendment pursuant to the then executory provisions of the Sublease. Any delay in Prime Landlord's furnishing the Landlord's Consent shall not postpone or extend the Expiration Date. If Landlord's Consent is denied, Sublandlord shall immediately notify Subtenant of same, and either party shall have the right to give a termination notice with respect to this Amendment as described in Section 16(b) hereof, in which case the Sublease shall remain in full force and effect. 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.

(b) If the Landlord's Consent has not been obtained on or before thirty (30) days from the date hereof or Landlord's Consent is denied within such thirty (30) day period, subject to Force Majeure, 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 with respect to this Amendment. 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, if Subtenant has delivered the increased Letter of Credit or cash security deposit, to Sublandlord, Sublandlord shall promptly return to Subtenant the increased amount of the Letter of Credit or cash security deposit and upon such return this Amendment 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 Amendment, except to the extent that the provisions of this Amendment expressly survive the termination of this Amendment, but the Sublease shall survive. If the Landlord's Consent shall be obtained after the giving of any termination notice under this Section 16(b) but prior to the termination of this Amendment under this Section 16(b), then such termination notice shall automatically be deemed withdrawn (and of no effect whatsoever).

17. Delivery of Possession of New Premises

(a) Sublandlord Failure to Deliver New 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 16(b) and 17(b) hereof), if Sublandlord is unable to deliver to Subtenant possession of the New 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 Amendment shall not be impaired, (3) the same shall not be construed to extend the Term and (4) the Term with respect to the New Premises shall commence on, and the New Premises Commencement Date shall be, the date on which Sublandlord delivers possession of the New Premises to Subtenant in the Premises Condition.

(b) Notwithstanding anything to the contrary contained herein, if any time after the Landlord's Consent has been obtained, (a) the New Premises Commencement Date has not occurred by thirty (30) days from the date Landlord's Consent has been obtained, subject to Force Majeure (the "**Outside Date**"), then the RP Rent Commencement Date and IP 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 New Premises Commencement Date. If Sublandlord has not caused the New Premises Commencement Date to occur on or before sixty (60) days after the Outside Date, subject to Force Majeure, then Subtenant shall have the right at any time thereafter (but prior to the New Premises Commencement Date) to terminate this Amendment by giving written notice of termination to Sublandlord, and upon such termination, (1) this Amendment shall be of no further force or effect, (2) the Sublease shall survive, and (3) if Subtenant has delivered the increased Letter of Credit or cash security deposit,

to Sublandlord, Sublandlord shall promptly return to Subtenant the increased amount of the Letter of Credit or cash security deposit.

(c) The provisions of this Section 17 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.

18. Renewal Option. For the avoidance of doubt, the parties agree that the Renewal Option shall continue to apply.

19. Sublandlord and Subtenant's Representations. Sublandlord represents, to the best of Sublandlord's knowledge and belief, to Subtenant that Sublandlord's representations in Section 29 of the Original Sublease are true, complete and correct as of the date of execution and delivery of this Amendment, including with respect to the New Premises. Subtenant represents, to the best of Subtenant's knowledge and belief, to Sublandlord that Subtenant's representations in Section 29 of the Original Sublease are true, complete and correct as of the date of execution and delivery of this Amendment.

20. HVAC Supplemental Units. Section 30(b) of the Original Sublease is deleted and replaced with the following: "The New Premises are exclusively serviced by the 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 New Premises Commencement Date."

21. Physical Security. Sublandlord advises Subtenant that the current access cards it has for the 22nd floor may be used for the 29th and 30th floors. Sublandlord will provide additional access cards, as requested by Subtenant, at Subtenant's sole cost and expense.

22. Building Telecommunications. The first sentence of Section 30(e) of the Original Sublease is hereby deleted and replaced with the following: "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 29th and 30th floors of the Building."

23. Fire Stairs. Sublandlord grants Subtenant its right to use the fire stairs between the 29th and the 30th floors as permitted in the Lease.

24. Sub-subletting: Original Sublease Section 9(c)(ix) shall be deleted and replaced with the following: "There shall not be more than four (4) rental units per floor of the New Premises."

25. Condenser Water and Sprinklers. The first sentence of Original Sublease Section 23 shall be deleted and replaced with the following: "From and after the date that Subtenant first occupies the New Premises for the conduct of Subtenant's business, 23 tons of condenser water per floor 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 Amendment is $885.00 per ton per annum."

26.Right of First Refusal.

(a) First Refusal Notice**.** Until February 28, 2025, if Sublandlord receives an offer pursuant to a letter of intent to sublease that it is willing to accept (the "**Proposed Sublease**") for any of the currently vacant premises on the 28th and/or 31st floors of the Building (the "**Additional Space**"), Subtenant shall have a right of first refusal to sublease that part of the Additional Space made the subject of the Proposed Sublease (the "**ROFR Space**") in accordance with this Section 26, and Sublandlord may not enter into the Proposed Sublease unless Sublandlord first delivers to Subtenant a notice (the "**First Refusal to Sublease Notice**") setting forth: (a) intentionally omitted, (b) the rental amount and each of the material terms of the Proposed Sublease as set forth on the letter of intent; (c) a description of the ROFR Space and (d) any other terms set forth in the letter of intent that Sublandlord is willing to sublease the Additional Space upon (the "**Sublease Terms**").

(b) Response Period**.** For the ten (10) business day period beginning on Subtenant's receipt of the First Refusal to Sublease Notice (the "**Additional Space ROFR Response Period**"), Subtenant has the exclusive right to sublease the ROFR Space on the Sublease Terms, by notifying Sublandlord of its election to exercise its right of first refusal (the "**ROFR Exercise Notice**") on or before the last day of the Additional Space ROFR Response Period. Sublandlord is then bound to sublease to Subtenant the ROFR Space on the Sublease Terms. Within ten (10) days after Subtenant's delivery of the ROFR Exercise Notice, Sublandlord and Subtenant shall execute an amendment to the existing Sublease, on the Sublease Terms for the ROFR Space. Notwithstanding the foregoing, the term for Subtenant's sublease of the ROFR Space will be coterminous with the Sublease Term.

(c) Waiver of ROFR**.** If Subtenant either: (a) delivers written notice of rejection of the First Refusal to Sublease Notice to Sublandlord; or (b) fails to deliver the ROFR Exercise Notice, within the Additional Space ROFR Response Period, Subtenant's right of first refusal hereunder will conclusively be deemed to be waived with respect to the Proposed Sublease and Sublandlord is free to sign the Proposed Sublease.

(d) Anything in this Sublease to the contrary notwithstanding, the provisions of this Section 26 granting to Subtenant the Right of First Refusal shall be null and void and of no force or effect if the Named Subtenant is no longer the Subtenant under this Sublease.

(e) Sublandlord has advised Subtenant that there is a Sublease for the 31st floor whose term expires after February 28, 2025.

(f) Notwithstanding anything to the contrary contained herein, Sublandlord advised Subtenant on January 14, 2025 that Sublandlord is currently negotiating a Proposed Sublease for the 27th, 28th (which 28th floor is part of the ROFR Space) and 32nd floors (and possibly the 22nd floor) of the Building, and Subtenant hereby notifies Sublandlord of its election to not exercise its right of first refusal with respect to the Proposed Sublease.

27.Brokers. Sublandlord and Subtenant each hereby represents and warrants to the other that it has had no dealings with any real estate broker or agent in connection with the negotiation of this Amendment and that it knows of no real estate broker or agent who is entitled

to a commission in connection with this Amendment other than CBRE and Savills (collectively, the "**Broker**"). Sublandlord shall pay the Broker pursuant to a separate agreement. Each party agrees to indemnify and defend the other party against and hold the other party harmless from any and all claims, demands, losses, liabilities, lawsuits, judgments and costs and expenses (including, without limitation, reasonable attorneys' fees) with respect to any leasing commission or equivalent compensation alleged to be owing in connection with this Amendment on account of the indemnifying party's dealings with any real estate broker or agent. The provisions of this Section shall survive the termination of this Amendment.

28. No Further Modification. Except as set forth in this Amendment, all of the terms and provisions of the Sublease shall remain unmodified and in full force and effect.

29. Conflicts. Any conflicts between this Amendment and the Sublease shall be controlled by this Amendment. In all other respects, the Sublease continues in full force and effect.

30. Authority. Subject to obtaining Landlord's Consent, each signatory of this Amendment represents hereby that he or she has the authority to execute and deliver the same on behalf of the party hereto for which such signatory is acting.

31. Counterparts/Originals. This Amendment may be executed and delivered (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 Amendment. Sublandlord and Subtenant (i) intend to be bound by the signatures (whether original or electronic) on any document sent by electronic mail, (ii) are aware that the other party will rely on such signatures, (iii) hereby waive any defenses to the enforcement of the terms of this Amendment based on the foregoing forms of electronic signatures, and (iv) the parties further consent and agree that (1) to the extent a party signs this Amendment using electronic signature technology, by clicking "SIGN" or an equivalent, such party is signing this Amendment electronically, and (2) the electronic signatures appearing on this Amendment shall be treated, for purposes of validity, enforceability and admissibility, the same as handwritten signatures.

[SIGNATURES CONTAINED ON FOLLOWING PAGE]

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

"SUBLANDLORD"
ADVANCE MAGAZINE PUBLISHERS INC., D/B/A CONDÉ NAST

/s/ Oren Klein
Signature

Oren Klein
Name

CFO
Title

"SUBTENANT"
AXSOME THERAPEUTICS, INC.

/s/ Herriot Tabuteau
Signature

Herriot Tabuteau
Name

CEO
Title

Exhibit 10.2

AXSOME THERAPEUTICS, INC.
2015 OMNIBUS INCENTIVE COMPENSATION PLAN

NONQUALIFIED STOCK OPTION SUMMARY OF GRANT

Axsome Therapeutics, Inc., a Delaware corporation (the "Company" or "Employer"), pursuant to its 2015 Omnibus Incentive Compensation Plan (the "Plan"), hereby grants to the individual listed below (the "Participant"), a nonqualified stock option to purchase shares of common stock of the Company ("Company Stock") that may become vested and exercisable as set forth below (the "Option"). The Option is subject in all respects to the terms and conditions set forth herein, in the Nonqualified Stock Option Grant Agreement attached hereto as Exhibit A (the "Nonqualified Stock Option Grant Agreement") and the Plan, each of which is incorporated herein by reference and made part hereof. Unless otherwise defined herein, capitalized terms used in this Nonqualified Stock Option Summary of Grant (the "Summary of Grant") and the Nonqualified Stock Option Grant Agreement will have the meanings set forth in the Plan.

Participant:	[NAME]
Date of Grant:	[DATE]
Total Number of Shares Granted:	[NUMBER] of shares of Company Stock
Exercise Price:	[Fair Market Value on Date of Grant]
Exercisability of the Option:	Except as set forth herein, the Option will vest and become exercisable on the following dates (each, a "Vesting Date"), provided that the Participant continues to be employed by, or provide service to, the Employer from the Date of Grant through the applicable Vesting Date: [Insert Vesting Schedule] The Option will be fully vested and exercisable on [Insert Date] if the Participant is employed by, or providing services to, the Employer on such date.

[Signature Page Follows]

IN WITNESS WHEREOF, the Company has caused its duly authorized officers to execute and attest this Agreement, effective as of the Date of Grant.

AXSOME THERAPEUTICS, INC.

_____
Name: Herriot Tabuteau, M.D.
Title: Chief Executive Officer

I hereby acknowledge delivery of the Plan and the Plan prospectus together with this Summary of Grant and the Nonqualified Stock Option Grant Agreement. Additional copies of the Plan and the Plan prospectus are available by contacting Nick Pizzie, Chief Financial Officer at npizzie@axsome.com.

Agreed and accepted:

_____
Participant

_____
Date

EXHIBIT A

AXSOME THERAPEUTICS, INC.

NONQUALIFIED STOCK OPTION GRANT AGREEMENT
(Pursuant to the 2015 Omnibus Incentive Compensation Plan)

This Nonqualified Stock Option Grant Agreement (this "Agreement") is delivered by Axsome Therapeutics, Inc., a Delaware corporation (the "Company" or "Employer"), pursuant to the Summary of Grant delivered with this Agreement to the individual named in the Summary of Grant (the "Participant"). The Summary of Grant, which specifies the Participant, the date as of which the grant is made (the "Date of Grant"), the vesting schedule and other specific details of the grant is incorporated herein by reference.

1. **Option Grant**. Upon the terms and conditions set forth in this Agreement and in the Company's 2015 Omnibus Incentive Compensation Plan (the "Plan"), the Company hereby grants to the Participant a nonqualified stock option to purchase the number of shares of common stock of the Company ("Company Stock") set forth in the Summary of Grant (the "Option"). The Participant hereby acknowledges the receipt of a copy of the official prospectus for the Plan. Copies of the Plan and the official Plan prospectus are available by contacting Nick Pizzie, Chief Financial Officer at npizzie@axsome.com. This Agreement is made pursuant to the Plan and is subject in its entirety to all applicable provisions of the Plan. Capitalized terms used herein and not otherwise defined will have the meanings set forth in the Plan. The Participant agrees to be bound by all of the terms and conditions of the Plan.

2. **Exercisability of the Option**.

(a) The Option will become vested and exercisable as set forth in the Summary of Grant, provided that the Participant continues to be employed by, or provide service to, the Employer through the Vesting Date (as defined in the Summary of Grant).

(b) The exercisability of the Option is cumulative, but shall not exceed 100% of the shares of Company Stock subject to the Option. If the schedule set forth in the Summary of Grant would produce fractional shares of Company Stock, the number of shares of Company Stock for which the Option becomes exercisable shall be rounded down to the nearest whole share of Company Stock.

3. **Term of Option**.

(a) The Option will have a term of ten years from the Date of Grant and will terminate at the expiration of that period, unless it is terminated at an earlier date pursuant to the provisions of this Agreement or the Plan. Notwithstanding the foregoing, in the event that on the last business day of the term of the Option, the exercise of the Option is prohibited by applicable law, including a prohibition on purchases or sales of Company Stock under the Company's insider trading policy, the term of the Option shall be extended for a period of 30 days following the end of the legal prohibition, unless the Committee determines otherwise.

(b) The Option will automatically terminate upon the happening of the first of the following events:

(i) The expiration of the [NUMBER]-[PERIOD] period after the Participant ceases to be employed by, or provide service to, the Employer, if the termination is for any reason other than Disability, death or Cause.

(ii) The expiration of the one-year period after the Participant ceases to be employed by, or provide service to, the Employer on account of the Participant's Disability.

(iii) The expiration of the one-year period after the Participant ceases to be employed by, or provide service to, the Employer, if the Participant dies while employed by, or providing service to, the Employer or

within 90 days after the Participant ceases to be so employed or provide such services on account of a termination described in subsection (i) above.

(iv) The date on which the Participant ceases to be employed by, or provide service to, the Employer for Cause. In addition, notwithstanding the prior provisions of this Section 3, if the Participant engages in conduct that constitutes Cause after the Participant's employment or service terminates, the Option will immediately terminate.

Notwithstanding the foregoing, in no event may the Option be exercised after the date that is immediately before the tenth anniversary of the Date of Grant; provided, however, that if the term of the Option is extended pursuant to Section 3(a) above, in no event may the Option be exercised after the date that is immediately before the expiration of the extended term of the Option. Any portion of the Option that is not exercisable at the time the Participant ceases to be employed by, or provide service to, the Employer will immediately terminate.

4. **Exercise Procedures**.

(a) Subject to the provisions of Sections 2 and 3 above, the Participant may exercise part or all of the exercisable Option by giving the Company written notice of intent to exercise in the manner provided in this Agreement, specifying the number of shares of Company Stock as to which the Option is to be exercised. At such time as the Committee shall determine, the Participant shall pay the Exercise Price (i) in cash, (ii) unless the Committee determines otherwise, by delivering shares of Company Stock owned by the Participant, which shall be valued at their Fair Market Value on the date of exercise, or by attestation (on a form prescribed by the Committee) to ownership of shares of Company Stock having a Fair Market Value on the date of exercise at least equal to the Exercise Price, (iii) by payment through a broker in accordance with procedures permitted by Regulation T of the Federal Reserve Board, (iv) by withholding shares of Company Stock subject to the exercisable Option, which have a Fair Market Value on the date of exercise equal to the Exercise Price, or (v) by such other method as the Committee may approve, to the extent permitted by applicable law. The Committee may impose from time to time such limitations as it deems appropriate on the use of shares of Company Stock to exercise the Option.

(b) The obligation of the Company to deliver shares of Company Stock upon exercise of the Option shall be subject to all applicable laws, rules, and regulations and such approvals by governmental agencies as may be deemed appropriate by the Committee, including such actions as Company counsel shall deem necessary or appropriate to comply with relevant securities laws and regulations. The Company may require that the Participant (or other person exercising the Option after the Participant's death) represent that the Participant is purchasing shares of Company Stock for the Participant's own account and not with a view to or for sale in connection with any distribution of the shares of Company Stock, or such other representation as the Committee deems appropriate.

(c) All obligations of the Company under this Agreement shall be subject to the rights of the Company as set forth in the Plan to withhold amounts required to be withheld for any taxes, if applicable. Subject to Committee approval, the Participant may elect to satisfy any tax withholding obligation of the Employer with respect to the Option by having shares of Company Stock withheld up to an amount that does not exceed the applicable withholding tax rate for federal (including FICA), state and local tax liabilities. Unless the Committee determines otherwise, the fair market value (measured at the time of the transaction) of the shares withheld for taxes shall not exceed the Participant's minimum applicable tax withholding amount.

(d) Upon exercise of the Option (or portion thereof), the Option (or portion thereof) will terminate and cease to be outstanding.

5. **No Shareholder Rights**. Neither the Participant, nor any person entitled to exercise the Participant's rights in the event of the Participant's death, shall have any of the rights and privileges of a stockholder with respect to the shares of Company Stock subject to the Option, until certificates for shares of Company Stock have been issued upon the exercise of the Option.

6. **Change of Control**. The provisions of the Plan applicable to a Change of Control will apply to the Option, and, in the event of a Change of Control, the Committee may take such actions as it deems appropriate

pursuant to the Plan; provided that, if the Option continues in effect after a Change of Control and the Participant's employment or service is terminated by the Employer without Cause upon or within 12 months following the Change in Control, any unvested portion of the Option shall become fully vested upon such cessation of employment or service.

7. **Restrictions on Exercise**. Except as the Committee may otherwise permit pursuant to the Plan, only the Participant may exercise the Option during the Participant's lifetime and, after the Participant's death, the Option will be exercisable (subject to the limitations specified in the Plan) solely by the legal representatives of the Participant, or by the person who acquires the right to exercise the Option by will or by the laws of descent and distribution, to the extent that the Option is exercisable pursuant to this Agreement.

8. **Entire Agreement**. This Agreement contains the entire agreement of the parties with respect to the Option granted hereby and may not be changed orally but only by an instrument in writing signed by the party against whom enforcement of any change, modification or extension is sought.

9. **Grant Subject to Plan Provisions**. This grant is made pursuant to the Plan, the terms of which are incorporated herein by reference, and in all respects will be interpreted in accordance with the Plan. This grant is subject to interpretations, regulations and determinations concerning the Plan established from time to time by the Committee in accordance with the provisions of the Plan, including, but not limited to, provisions pertaining to (a) rights and obligations with respect to withholding taxes, (b) the registration, qualification or listing of the shares, (c) changes in capitalization of the Company and (d) other requirements of applicable law. The Committee will have the authority to interpret and construe this grant pursuant to the terms of the Plan, and its decisions will be conclusive as to any questions arising hereunder.

10. **Assignment and Transfers**. Except as the Committee may otherwise permit pursuant to the Plan, the rights and interests of the Participant under this Agreement may not be sold, assigned, encumbered or otherwise transferred except, in the event of the death of the Participant, by will or by the laws of descent and distribution. In the event of any attempt by the Participant to alienate, assign, pledge, hypothecate, or otherwise dispose of the Option or any right hereunder, except as provided for in this Agreement, or in the event of the levy or any attachment, execution or similar process upon the rights or interests hereby conferred, the Company may terminate the Option by notice to the Participant, and the Option and all rights hereunder will thereupon become null and void. The rights and protections of the Company hereunder will extend to any successors or assigns of the Company and to the Company's parents, subsidiaries, and affiliates. This Agreement may be assigned by the Company without the Participant's consent.

11. **No Employment or Other Rights**. This Agreement will not confer upon the Participant any right to be retained in the employment of the Company and will not interfere in any way with the right of the Company to terminate the Participant's employment at any time. The right of the Company to terminate at will the Participant's employment at any time for any reason is specifically reserved.

12. **Notice**. Any notice to the Company provided for in this instrument will be addressed to the Company in care of Nick Pizzie, Chief Financial Officer at the Company's corporate headquarters, and any notice to the Participant will be addressed to such Participant at the current address shown on the payroll records of the Company, or to such other address as the Participant may designate to the Company in writing. Any notice will be delivered by hand, sent by telecopy or enclosed in a properly sealed envelope addressed as stated above, registered and deposited, postage prepaid, in a post office regularly maintained by the United States Postal Service.

13. **Recoupment Policy**. The Participant agrees that, subject to the requirements of applicable law, if the Participant breaches any restrictive covenant agreement between the Participant and the Employer or otherwise engages in activities that constitute Cause either while employed by, or providing service to, the Employer or within two years thereafter, the Option shall terminate, and the Company may rescind any exercise of the Option and delivery of shares upon such exercise, as applicable on such terms as the Committee shall determine, including the right to require that in the event of any such rescission, (a) the Participant shall return to the Company the shares received upon the exercise of the Option or, (b) if the Participant no longer owns the shares, the Participant shall pay to the Company the amount of any gain realized or payment received as a result of any sale or other disposition of the shares (or, in the event the Participant transfers the shares by gift or otherwise without consideration, the fair

market value (as determined by the Committee) of the shares on the date of the breach of any restrictive covenant agreement or activity constituting Cause), net of the price originally paid by the Participant for the shares. The Participant agrees that payment by the Participant shall be made in such manner and on such terms and conditions as may be required by the Committee and the Employer shall be entitled to set off against the amount of any such payment any amounts otherwise owed to the Participant by the Employer. In addition, the Participant agrees that the Option shall be subject to any applicable clawback or recoupment policies, share trading policies and other policies that may be implemented by the Board from time to time.

14. **Applicable Law**. The validity, construction, interpretation and effect of this Agreement will be governed by and construed in accordance with the laws of the State of Delaware, without giving effect to the conflicts of laws provisions thereof.

15. **Application of Section 409A of the Code**. This Agreement is intended to be exempt from section 409A of the Code and to the extent this Agreement is subject to section 409A of the Code, it will in all respects be administered in accordance with section 409A of the Code.

Exhibit 10.3

Axsome Therapeutics, Inc.

Stock Unit Notice
under the
Axsome Therapeutics, Inc.
2015 Omnibus Incentive Compensation Plan

Name of Grantee: _____

This Notice evidences the award of restricted Stock Units (each, an "***RSU***," and collectively, the "***RSUs***") of Axsome Therapeutics, Inc., a Delaware corporation (the "***Company***"), that have been granted to you pursuant to the Axsome Therapeutics, Inc. 2015 Omnibus Incentive Compensation Plan (the "***Plan***") and conditioned upon your agreement to the terms of the attached Stock Unit Agreement (the "***Agreement***"). This Notice constitutes part of and is subject to the terms and provisions of the Agreement and the Plan, which are incorporated by reference herein. Each RSU is equivalent in value to one share of the Company Stock and represents the Company's commitment to issue one share of Company Stock at a future date, subject to the terms of the Agreement and the Plan. The RSUs are credited to a separate account maintained for you on the books and records of the Company (the "***Account***"). All amounts credited to the Account will continue for all purposes to be part of the general assets of the Company.

Grant Date: _____

Number of RSUs:

Vesting Schedule: All of the RSUs are nonvested and forfeitable as of the Grant Date. So long as your employment or service is continuous from the Grant Date through the applicable date upon which vesting is scheduled to occur:

> twenty-five percent (25%) of the RSUs will be exercisable on the first anniversary of the Grant Date (the "Initial Vesting Date") and as to an additional twenty-five percent (25%) of the original number of RSUs at the end of each successive full twelve (12) month period following the Initial Vesting Date such that 100% of the RSUs will be vested and nonforfeitable on the fourth anniversary of the Grant Date.

Notwithstanding the foregoing, if your employment or service with the Company is terminated coincident with or within one year following a Change of Control by the Company or its successor without Cause, the RSUs that are unvested as of the date of termination will immediately become 100% exercisable.

Axsome Therapeutics, Inc. Date

I acknowledge that I have carefully read the Agreement and the prospectus for the Plan. I agree to be bound by all of the provisions set forth in those documents. I also consent to electronic delivery of all notices or other information with respect to the RSUs or the Company.

Axsome Therapeutics, Inc. Date

Axsome Therapeutics, Inc.

Stock Unit Agreement
under the
Axsome Therapeutics, Inc.
2015 Omnibus Incentive Compensation Plan

1. Terminology. Unless otherwise provided in this Agreement, capitalized terms used herein are defined in the Glossary at the end of this Agreement.

2. Vesting. All of the RSUs are nonvested and forfeitable as of the Grant Date. So long as your service or employment is continuous from the Grant Date through the applicable date upon which vesting is scheduled to occur, the RSUs will become vested and nonforfeitable in accordance with the vesting schedule set forth in the Notice. Except for the circumstances, if any, described in the Notice, none of the RSUs will become vested and nonforfeitable after your service or employment ceases.

3. Termination of Employment or Service. Unless otherwise provided in the Notice, if your service or employment with the Company ceases for any reason, all RSUs that are not then vested and nonforfeitable will be forfeited to the Company immediately and automatically upon such cessation without payment of any consideration therefor and you will have no further right, title or interest in or to such RSUs or the underlying shares of Company Stock.

4. Restrictions on Transfer. Neither this Agreement nor any of the RSUs may be assigned, transferred, pledged, hypothecated or disposed of in any way, whether by operation of law or otherwise, and the RSUs shall not be subject to execution, attachment or similar process. All rights with respect to this Agreement and the RSUs shall be exercisable during your lifetime only by you or your guardian or legal representative. Notwithstanding the foregoing, the RSUs may be transferred upon your death by last will and testament or under the laws of descent and distribution.

5. Settlement of RSUs.

(a) Manner of Settlement. You are not required to make any monetary payment (other than applicable tax withholding, if required) as a condition to settlement of the RSUs. The Company will issue to you, in settlement of your RSUs and subject to the provisions of Section 6 below, the number of whole shares of Company Stock that equals the number of whole RSUs that become vested, and such vested RSUs will terminate and cease to be outstanding upon such issuance of the shares. Upon issuance of such shares, the Company will determine the form of delivery (e.g., a stock certificate or electronic entry evidencing such shares) and may deliver such shares on your behalf electronically to the Company's designated stock plan administrator or such other broker-dealer as the Company may choose at its sole discretion, within reason.

(b) Timing of Settlement. Your RSUs will be settled by the Company, via the issuance of Company Stock as described herein, on the date that the RSUs become vested and nonforfeitable. However, if a scheduled issuance date falls on a Saturday, Sunday or federal holiday, such issuance date shall instead fall on the next following day that the principal executive offices of the Company are open for business. In all cases, the issuance and delivery of shares under this Agreement is intended to comply with Treasury Regulation 1.409A-1(b)(4) and shall be construed and administered in such a manner.

6. Tax Withholding. On or before the time you receive a distribution of the shares subject to your RSUs, or at any time thereafter as requested by the Company, you hereby authorize any required withholding from the Company Stock issuable to you and/or otherwise agree to make adequate provision in cash for any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or any Affiliate which arise in connection with your RSUs (the "***Withholding Taxes***"). Additionally, the Company may, in its sole discretion, satisfy all or any portion of the Withholding Taxes obligation relating to your RSUs by any of the following means or by a combination of such means: (i)

withholding from any compensation otherwise payable to you by the Company; (ii) causing you to tender a cash payment; (iii) permitting you to enter into a "same day sale" commitment with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "***FINRA Dealer***") whereby you irrevocably elect to sell a portion of the shares to be delivered under the Agreement to satisfy the Withholding Taxes and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Withholding Taxes directly to the Company; or (iv) withholding shares of Company Stock from the shares of Company Stock issued or otherwise issuable to you in connection with the RSUs with a fair market value (measured as of the end of trading on the trading date immediately prior to the date on which shares of Company Stock are issued to you pursuant to Section 5) equal to the amount of such Withholding Taxes; provided, however, that the number of such shares of Company Stock so withheld shall not exceed the amount necessary to satisfy the Company's required tax withholding obligations using the minimum statutory withholding rates for federal, state, local and foreign tax purposes, including payroll taxes, that are applicable to supplemental taxable income. Unless the tax withholding obligations of the Company are satisfied, the Company shall have no obligation to deliver to you any Company Stock. In the event the Company's obligation to withhold arises prior to the delivery to you of Company Stock or it is determined after the delivery of Company Stock to you that the amount of the Company's withholding obligation was greater than the amount withheld by the Company, you agree to indemnify and hold the Company harmless from any failure by the Company to withhold the proper amount.

7. Adjustments for Corporate Transactions and Other Events.

(a) Stock Dividend, Stock Split and Reverse Stock Split. Upon a stock dividend of, or stock split or reverse stock split or other event described in Section 4(d) of the Plan affecting, the Company Stock, the number of outstanding RSUs shall, without further action of the Administrator, be adjusted to reflect such event; provided, however, that any fractional RSUs resulting from any such adjustment shall be eliminated. Adjustments under this paragraph will be made by the Administrator, whose determination as to what adjustments, if any, will be made and the extent thereof will be final, binding and conclusive.

(b) Merger, Consolidation and Other Events. If the Company shall be the surviving or resulting corporation in any merger or consolidation and the Company Stock shall be converted into other securities, the RSUs shall pertain to and apply to the securities to which a holder of the number of shares of Company Stock subject to the RSUs would have been entitled. If the stockholders of the Company receive by reason of any distribution in total or partial liquidation or pursuant to any merger of the Company or acquisition of its assets, securities of another entity or other property (including cash), then the rights of the Company under this Agreement shall inure to the benefit of the Company's successor, and this Agreement shall apply to the securities or other property (including cash) to which a holder of the number of shares of Company Stock subject to the RSUs would have been entitled, in the same manner and to the same extent as the RSUs.

8. Non-Guarantee of Employment or Service Relationship. Nothing in the Plan or this Agreement shall alter your at-will or other employment status or other service relationship with the Company, nor be construed as a contract of employment or service relationship between the Company and you, or as a contractual right of you to continue in the employ of, or in a service relationship with, the Company for any period of time, or as a limitation of the right of the Company to discharge you at any time with or without cause or notice and whether or not such discharge results in the forfeiture of any nonvested and forfeitable RSUs or any other adverse effect on your interests under the Plan.

9. Rights as Stockholder. You shall not have any of the rights of a stockholder with respect to any shares of Company Stock that may be issued in settlement of the RSUs until such shares of Company Stock have been issued to you.

10. The Company's Rights. The existence of the RSUs shall not affect in any way the right or power of the Company or its stockholders to make or authorize any or all adjustments, recapitalizations, reorganizations, or other changes in the Company's capital structure or its business, or any merger or consolidation of the Company, or any issue of bonds, debentures, preferred or other stocks with preference ahead of or convertible into, or otherwise affecting the Company Stock or the rights thereof, or

the dissolution or liquidation of the Company, or any sale or transfer of all or any part of the Company's assets or business, or any other corporate act or proceeding, whether of a similar character or otherwise.

11. Restrictions on Issuance of Shares. The issuance of shares of Company Stock upon settlement of the RSUs shall be subject to and in compliance with all applicable requirements of federal, state, or foreign law with respect to such securities. No shares of Company Stock may be issued hereunder if the issuance of such shares would constitute a violation of any applicable federal, state, or foreign securities laws or other law or regulations or the requirements of any stock exchange or market system upon which the Company Stock may then be listed. The inability of the Company to obtain from any regulatory body having jurisdiction the authority, if any, deemed by the Company's legal counsel to be necessary to the lawful issuance of any shares subject to the RSUs shall relieve the Company of any liability in respect of the failure to issue such shares as to which such requisite authority shall not have been obtained. As a condition to the settlement of the RSUs, the Company may require you to satisfy any qualifications that may be necessary or appropriate, to evidence compliance with any applicable law or regulation, and to make any representation or warranty with respect thereto as may be requested by the Company.

12. Notices. All notices and other communications made or given pursuant to this Agreement shall be given in writing and shall be deemed effectively given upon receipt or, in the case of notices delivered by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company, or in the case of notices delivered to the Company by you, addressed to the Administrator, care of the Company for the attention of its Secretary at its principal executive office or, in either case, if the receiving party consents in advance, transmitted and received via telecopy or via such other electronic transmission mechanism as may be available to the parties. Notwithstanding the foregoing, the Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this award of RSUs by electronic means or to request your consent to participate in the Plan or accept this award of RSUs by electronic means. You hereby consent to receive such documents by electronic delivery and, if requested, to agree to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

13. Entire Agreement. This Agreement, together with the relevant Notice and the Plan, contains the entire agreement between the parties with respect to the RSUs granted hereunder. Any oral or written agreements, representations, warranties, written inducements, or other communications made prior to the execution of this Agreement with respect to the RSUs granted hereunder shall be void and ineffective for all purposes.

14. Amendment. This Agreement may be amended from time to time by the Administrator in its discretion; provided, however, that this Agreement may not be modified in any manner that would have a materially adverse effect on the RSUs as determined in the discretion of the Administrator, except as provided in the Plan or in a written document signed by each of the parties hereto.

15. Recoupment Policy. You agree that, subject to the requirements of applicable law, if you breach any restrictive covenant agreement between you and the Company or you otherwise engage in activities that constitute Cause either while employed by, or providing service to, the Company or within two years thereafter, the RSU shall terminate, and the Company may rescind any delivery of shares upon vesting or settlement, as applicable on such terms as the Committee shall determine, including the right to require that in the event of any such rescission, (a) you shall return to the Company the shares received upon settlement of the RSU or, (b) if you no longer owns the shares, you shall pay to the Company the amount of any gain realized or payment received as a result of any sale or other disposition of the shares (or, in the event you transfer the shares by gift or otherwise without consideration, the fair market value (as determined by the Administrator) of the shares on the date of the breach of any restrictive covenant agreement or activity constituting Cause). You agree that payment shall be made in such manner and on such terms and conditions as may be required by the Committee and you shall be entitled to set off against the amount of any such payment any amounts otherwise owed to you by the Company. In addition, you agree that the RSU shall be subject to any applicable clawback or recoupment

policies, share trading policies and other policies that may be implemented by the Board from time to time.

409A Savings Clause. This Agreement and the RSUs granted hereunder are intended to either fit within the "short-term deferral" exemption from Section 409A of the Code as set forth in Treasury Regulation Section 1.409A-1(b)(4) or comply with Section 409A. Notwithstanding the foregoing, if it is determined that the RSUs fail to satisfy the requirements of the short-term deferral rule and are otherwise deferred compensation subject to Section 409A, and if you are a "Specified Employee" (within the meaning set forth Section 409A(a)(2)(B)(i) of the Code) as of the date of your separation from service (within the meaning of Treasury Regulation Section 1.409A-1(h)), then the issuance of any shares that would otherwise be made upon the date of the separation from service or within the first six (6) months thereafter will not be made on the originally scheduled date(s) and will instead be issued in a lump sum on the date that is six (6) months and one day after the date of the separation from service, but if and only if such delay in the issuance of the shares is necessary to avoid the imposition of additional taxation on you in respect of the shares under Section 409A of the Code. Each installment of shares that vests is intended to constitute a "separate payment" for purposes of Section 409A of the Code and Treasury Regulation Section 1.409A-2(b)(2).

16. No Obligation to Minimize Taxes. The Company has no duty or obligation to minimize the tax consequences to you of this award of RSUs and shall not be liable to you for any adverse tax consequences to you arising in connection with this award. You are hereby advised to consult with your own personal tax, financial and/or legal advisors regarding the tax consequences of this award and by signing the Notice, you have agreed that you have done so or knowingly and voluntarily declined to do so.

17. Conformity with Plan. This Agreement is intended to conform in all respects with, and is subject to all applicable provisions of, the Plan. Inconsistencies between this Agreement and the Plan shall be resolved in accordance with the terms of the Plan. In the event of any ambiguity in this Agreement or any matters as to which this Agreement is silent, the Plan shall govern. A copy of the Plan is available upon request to the Administrator.

18. No Funding. This Agreement constitutes an unfunded and unsecured promise by the Company to issue shares of Company Stock in the future in accordance with its terms. You have the status of a general unsecured creditor of the Company as a result of receiving the grant of RSUs.

19. Effect on Other Employee Benefit Plans. The value of the RSUs subject to this Agreement shall not be included as compensation, earnings, salaries, or other similar terms used when calculating your benefits under any employee benefit plan sponsored by the Company, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company's employee benefit plans.

20. Governing Law. The validity, construction and effect of this Agreement, and of any determinations or decisions made by the Administrator relating to this Agreement, and the rights of any and all persons having or claiming to have any interest under this Agreement, shall be determined exclusively in accordance with the laws of the State of Delaware, without regard to its provisions concerning the applicability of laws of other jurisdictions. As a condition of this Agreement, you agree that you will not bring any action arising under, as a result of, pursuant to or relating to, this Agreement in any court other than a federal or state court in the districts which include Delaware, and you hereby agree and submit to the personal jurisdiction of any federal court located in the district which includes Delaware or any state court in the district which includes Delaware. You further agree that you will not deny or attempt to defeat such personal jurisdiction or object to venue by motion or other request for leave from any such court.

21. Resolution of Disputes. Any dispute or disagreement which shall arise under, or as a result of, or pursuant to or relating to, this Agreement shall be determined by the Administrator in good faith in its absolute and uncontrolled discretion, and any such determination or any other determination by the Administrator under or pursuant to this Agreement and any interpretation by the Administrator of the terms of this Agreement, will be final, binding and conclusive on all persons affected thereby. You agree

that before you may bring any legal action arising under, as a result of, pursuant to or relating to, this Agreement you will first exhaust your administrative remedies before the Administrator. You further agree that in the event that the Administrator does not resolve any dispute or disagreement arising under, as a result of, pursuant to or relating to, this Agreement to your satisfaction, no legal action may be commenced or maintained relating to this Agreement more than twenty-four (24) months after the Administrator's decision.

22. Headings. The headings in this Agreement are for reference purposes only and shall not affect the meaning or interpretation of this Agreement.

23. Electronic Delivery of Documents. By your signing the Notice, you (i) consent to the electronic delivery of this Agreement, all information with respect to the Plan and the RSUs, and any reports of the Company provided generally to the Company's stockholders; (ii) acknowledge that you may receive from the Company a paper copy of any documents delivered electronically at no cost to you by contacting the Company by telephone or in writing; (iii) further acknowledge that you may revoke your consent to the electronic delivery of documents at any time by notifying the Company of such revoked consent by telephone, postal service or electronic mail; and (iv) further acknowledge that you understand that you are not required to consent to electronic delivery of documents.

24. No Future Entitlement. By your signing the Notice, you acknowledge and agree that: (i) the grant of a restricted stock unit award is a one-time benefit which does not create any contractual or other right to receive future grants of restricted stock units, or compensation in lieu of restricted stock units, even if restricted stock units have been granted repeatedly in the past; (ii) all determinations with respect to any such future grants and the terms thereof will be at the sole discretion of the Committee; (iii) the value of the restricted stock units is an extraordinary item of compensation which is outside the scope of your employment contract, if any; (iv) the value of the restricted stock units is not part of normal or expected compensation or salary for any purpose, including, but not limited to, calculating any termination, severance, resignation, redundancy, end of service payments or similar payments, or bonuses, long-service awards, pension or retirement benefits; (v) the vesting of the restricted stock units ceases upon termination of Service with the Company or transfer of employment from the Company, or other cessation of eligibility for any reason, except as may otherwise be explicitly provided in this Agreement; (vi) the Company does not guarantee any future value of the restricted stock units; and (vii) no claim or entitlement to compensation or damages arises if the restricted stock units decrease or do not increase in value and you irrevocably release the Company from any such claim that does arise.

25. Personal Data. For purposes of the implementation, administration and management of the restricted stock units or the effectuation of any acquisition, equity or debt financing, joint venture, merger, reorganization, consolidation, recapitalization, business combination, liquidation, dissolution, share exchange, sale of stock, sale of material assets or other similar corporate transaction involving the Company (a "***Corporate Transaction***"), you consent, by execution of the Notice, to the collection, receipt, use, retention and transfer, in electronic or other form, of your personal data by and among the Company and its third party vendors or any potential party to a potential Corporate Transaction. You understand that personal data (including but not limited to, name, home address, telephone number, employee number, employment status, social security number, tax identification number, date of birth, nationality, job and payroll location, data for tax withholding purposes and shares awarded, cancelled, vested and unvested) may be transferred to third parties assisting in the implementation, administration and management of the restricted stock units or the effectuation of a Corporate Transaction and you expressly authorize such transfer as well as the retention, use, and the subsequent transfer of the data by the recipient(s). You understand that these recipients may be located in your country or elsewhere, and that the recipient's country may have different data privacy laws and protections than your country. You understand that data will be held only as long as is necessary to implement, administer and manage the restricted stock units or effect a Corporate Transaction. You understand that you may, at any time, request a list with the names and addresses of any potential recipients of the personal data, view data, request additional information about the storage and processing of data, require any necessary amendments to data or refuse or withdraw the consents herein, in any case without cost, by contacting in

writing the Company's Secretary. You understand, however, that refusing or withdrawing your consent may affect your ability to accept a restricted stock unit award.

{*Glossary begins on next page*}

GLOSSARY

(a) "***Administrator***" means the Committee as defined in the Plan.

(b) "***Agreement***" means this document, as amended from time to time, together with the Plan which is incorporated herein by reference.

(c) ***"Cause"*** has the meaning set forth in the Plan.

(d) ***"Change of Control"*** shall have the meaning set forth in the Plan.

(e) "**Code**" means the Internal Revenue Code of 1986, as amended, and the Treasury regulations and other guidance promulgated thereunder.

(f) "**Company Stock**" shall mean common stock of the Company.

(g) " ***Company***" means Axsome Therapeutics, Inc., and shall include all its successors except where the context otherwise requires. For purposes of determining whether a Change of Control has occurred, Company shall mean only Axsome Therapeutics, Inc.

(h) "***Grant Date***" means the effective date of a grant of RSUs made to you as set forth in the relevant Notice.

(i) "***Notice***" means the statement, letter or other written notification provided to you by the Company setting forth the terms of a grant of RSUs made to you.

(j) "***Plan***" means the Axsome Therapeutics, Inc. 2015 Omnibus Incentive Compensation Plan, as in effect from time to time.

(k) "***RSU***" means the Company's commitment to issue one share of Company Stock at a future date, subject to the terms of the Agreement and the Plan.

(l) "***You***" or "***Your***" means the recipient of the RSUs as reflected on the applicable Notice. Whenever the word "you" or "your" is used in any provision of this Agreement under circumstances where the provision should logically be construed, as determined by the Administrator, to apply to the estate, personal representative, or beneficiary to whom the RSUs may be transferred by will or by the laws of descent and distribution, the words "you" and "your" shall be deemed to include such person.

{*End of Agreement*}

Exhibit 10.4

Axsome Therapeutics, Inc.

Stock Unit Notice
under the
Axsome Therapeutics, Inc.
2015 Omnibus Incentive Compensation Plan

Name of Grantee: _____

This Notice evidences the award of restricted Stock Units (each, an "***RSU***," and collectively, the "***RSUs***") of Axsome Therapeutics, Inc., a Delaware corporation (the "***Company***"), that have been granted to you pursuant to the Axsome Therapeutics, Inc. 2015 Omnibus Incentive Compensation Plan (the "***Plan***") and conditioned upon your agreement to the terms of the attached Stock Unit Agreement (the "***Agreement***"). This Notice constitutes part of and is subject to the terms and provisions of the Agreement and the Plan, which are incorporated by reference herein. Each RSU is equivalent in value to one share of the Company Stock and represents the Company's commitment to issue one share of Company Stock at a future date, subject to the terms of the Agreement and the Plan. The RSUs are credited to a separate account maintained for you on the books and records of the Company (the "***Account***"). All amounts credited to the Account will continue for all purposes to be part of the general assets of the Company.

Grant Date: _____

Number of RSUs:

Vesting Schedule: All of the RSUs are nonvested and forfeitable as of the Grant Date. So long as your employment or service is continuous from the Grant Date through the applicable date upon which vesting is scheduled to occur:

> twenty-five percent (25%) of the RSUs will be vested on the first anniversary of the Grant Date (the "Initial Vesting Date") and as to an additional twenty-five percent (25%) of the original number of RSUs on each anniversary of each such date following the Initial Vesting Date such that 100% of the RSUs will be vested and nonforfeitable on the fourth anniversary of the Grant Date.

Notwithstanding the foregoing, if your employment or service with the Company is terminated coincident with or within one year following a Change of Control by the Company or its successor without Cause, the RSUs that are unvested as of the date of termination will immediately become 100% vested.

Axsome Therapeutics, Inc. _____ Date _____

I acknowledge that I have carefully read the Agreement and the prospectus for the Plan. I agree to be bound by all of the provisions set forth in those documents. I also consent to electronic delivery of all notices or other information with respect to the RSUs or the Company.

Signature of Grantee _____ Date _____

Axsome Therapeutics, Inc.

Stock Unit Agreement
under the
Axsome Therapeutics, Inc.
2015 Omnibus Incentive Compensation Plan

1. Terminology. Unless otherwise provided in this Agreement, capitalized terms used herein are defined in the Glossary at the end of this Agreement.

2. Vesting. All of the RSUs are nonvested and forfeitable as of the Grant Date. So long as your service or employment is continuous from the Grant Date through the applicable date upon which vesting is scheduled to occur, the RSUs will become vested and nonforfeitable in accordance with the vesting schedule set forth in the Notice. Except for the circumstances, if any, described in the Notice, none of the RSUs will become vested and nonforfeitable after your service or employment ceases.

3. Termination of Employment or Service. Unless otherwise provided in the Notice, if your service or employment with the Company ceases for any reason, all RSUs that are not then vested and nonforfeitable will be forfeited to the Company immediately and automatically upon such cessation without payment of any consideration therefor and you will have no further right, title or interest in or to such RSUs or the underlying shares of Company Stock.

4. Restrictions on Transfer. Neither this Agreement nor any of the RSUs may be assigned, transferred, pledged, hypothecated or disposed of in any way, whether by operation of law or otherwise, and the RSUs shall not be subject to execution, attachment or similar process. All rights with respect to this Agreement and the RSUs shall be vested during your lifetime only by you or your guardian or legal representative. Notwithstanding the foregoing, the RSUs may be transferred upon your death by last will and testament or under the laws of descent and distribution.

5. Settlement of RSUs.

(a) Manner of Settlement. You are not required to make any monetary payment (other than applicable tax withholding, if required) as a condition to settlement of the RSUs. The Company will issue to you, in settlement of your vested RSUs and subject to the provisions of Section 6 below, the number of whole shares of Company Stock that equals the number of whole RSUs that become vested, and such vested RSUs will terminate and cease to be outstanding upon such issuance of the shares. Upon issuance of such shares, the Company will determine the form of delivery (e.g., a stock certificate or electronic entry evidencing such shares) and may deliver such shares on your behalf electronically to the Company's designated stock plan administrator or such other broker-dealer as the Company may choose at its sole discretion, within reason.

(b) Timing of Settlement. Your vested RSUs will be settled by the Company, via the issuance of Company Stock as described herein, on the earliest of one of the following events: (1) Change of Control; (2) your "separation from service" as defined in Section 409A and applicable regulations and guidance thereunder ("Section 409A"), including your termination due to death or Disability; or (3) the seventh (7th) anniversary of the Grant Date. However, if a scheduled issuance date falls on a Saturday, Sunday or federal holiday, such issuance date shall instead fall on the next following day that the principal executive offices of the Company are open for business. In all cases, the issuance and delivery of shares under this Agreement is intended to comply with Section 409A and shall be construed and administered in such a manner.

6. Tax Withholding. On or before the time you receive a distribution of the shares subject to your RSUs, or at any time before or thereafter as requested by the Company, you hereby authorize any required withholding from the Company Stock issuable to you and/or otherwise agree to make adequate provision in cash for any sums required to satisfy the federal, state, local and foreign tax withholding

obligations of the Company or any Affiliate which arise in connection with your RSUs (the "***Withholding Taxes***"). Additionally, the Company may, in its sole discretion, satisfy all or any portion of the Withholding Taxes obligation relating to your RSUs by any of the following means or by a combination of such means: (i) withholding from any compensation otherwise payable to you by the Company; (ii) causing you to tender a cash payment; (iii) permitting you to enter into a "same day sale" commitment with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "***FINRA Dealer***") whereby you irrevocably elect to sell a portion of the shares to be delivered under the Agreement to satisfy the Withholding Taxes and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Withholding Taxes directly to the Company; or (iv) withholding shares of Company Stock from the shares of Company Stock issued or otherwise issuable to you in connection with the RSUs with a fair market value (measured as of the end of trading on the trading date immediately prior to the date on which shares of Company Stock are issued to you pursuant to Section 5) equal to the amount of such Withholding Taxes; provided, however, that the number of such shares of Company Stock so withheld shall not exceed the amount necessary to satisfy the Company's required tax withholding obligations using the minimum statutory withholding rates for federal, state, local and foreign tax purposes, including payroll taxes, that are applicable to supplemental taxable income. Unless the tax withholding obligations of the Company are satisfied, the Company shall have no obligation to deliver to you any Company Stock. In the event the Company's obligation to withhold arises prior to the delivery to you of Company Stock or it is determined after the delivery of Company Stock to you that the amount of the Company's withholding obligation was greater than the amount withheld by the Company, you agree to indemnify and hold the Company harmless from any failure by the Company to withhold the proper amount.

7. Adjustments for Corporate Transactions and Other Events.

(a) Stock Dividend, Stock Split and Reverse Stock Split. Upon a stock dividend of, or stock split or reverse stock split or other event described in Section 4(d) of the Plan affecting, the Company Stock, the number of outstanding RSUs shall, without further action of the Administrator, be adjusted to reflect such event; provided, however, that any fractional RSUs resulting from any such adjustment shall be eliminated. Adjustments under this paragraph will be made by the Administrator, whose determination as to what adjustments, if any, will be made and the extent thereof will be final, binding and conclusive.

(b) Merger, Consolidation and Other Events. If the Company shall be the surviving or resulting corporation in any merger or consolidation and the Company Stock shall be converted into other securities, the RSUs shall pertain to and apply to the securities to which a holder of the number of shares of Company Stock subject to the RSUs would have been entitled. If the stockholders of the Company receive by reason of any distribution in total or partial liquidation or pursuant to any merger of the Company or acquisition of its assets, securities of another entity or other property (including cash), then the rights of the Company under this Agreement shall inure to the benefit of the Company's successor, and this Agreement shall apply to the securities or other property (including cash) to which a holder of the number of shares of Company Stock subject to the RSUs would have been entitled, in the same manner and to the same extent as the RSUs.

8. Non-Guarantee of Employment or Service Relationship. Nothing in the Plan or this Agreement shall alter your at-will or other employment status or other service relationship with the Company, nor be construed as a contract of employment or service relationship between the Company and you, or as a contractual right of you to continue in the employ of, or in a service relationship with, the Company for any period of time, or as a limitation of the right of the Company to discharge you at any time with or without cause or notice and whether or not such discharge results in the forfeiture of any nonvested and forfeitable RSUs or any other adverse effect on your interests under the Plan.

9. Rights as Stockholder. You shall not have any of the rights of a stockholder with respect to any shares of Company Stock that may be issued in settlement of the RSUs until such shares of Company Stock have been issued to you.

10. The Company's Rights. The existence of the RSUs shall not affect in any way the right or power of the Company or its stockholders to make or authorize any or all adjustments, recapitalizations,

reorganizations, or other changes in the Company's capital structure or its business, or any merger or consolidation of the Company, or any issue of bonds, debentures, preferred or other stocks with preference ahead of or convertible into, or otherwise affecting the Company Stock or the rights thereof, or the dissolution or liquidation of the Company, or any sale or transfer of all or any part of the Company's assets or business, or any other corporate act or proceeding, whether of a similar character or otherwise.

11. Restrictions on Issuance of Shares. The issuance of shares of Company Stock upon settlement of the RSUs shall be subject to and in compliance with all applicable requirements of federal, state, or foreign law with respect to such securities. No shares of Company Stock may be issued hereunder if the issuance of such shares would constitute a violation of any applicable federal, state, or foreign securities laws or other law or regulations or the requirements of any stock exchange or market system upon which the Company Stock may then be listed. The inability of the Company to obtain from any regulatory body having jurisdiction the authority, if any, deemed by the Company's legal counsel to be necessary to the lawful issuance of any shares subject to the RSUs shall relieve the Company of any liability in respect of the failure to issue such shares as to which such requisite authority shall not have been obtained. As a condition to the settlement of the RSUs, the Company may require you to satisfy any qualifications that may be necessary or appropriate, to evidence compliance with any applicable law or regulation, and to make any representation or warranty with respect thereto as may be requested by the Company.

12. Notices. All notices and other communications made or given pursuant to this Agreement shall be given in writing and shall be deemed effectively given upon receipt or, in the case of notices delivered by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company, or in the case of notices delivered to the Company by you, addressed to the Administrator, care of the Company for the attention of its Secretary at its principal executive office or, in either case, if the receiving party consents in advance, transmitted and received via telecopy or via such other electronic transmission mechanism as may be available to the parties. Notwithstanding the foregoing, the Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this award of RSUs by electronic means or to request your consent to participate in the Plan or accept this award of RSUs by electronic means. You hereby consent to receive such documents by electronic delivery and, if requested, to agree to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

13. Entire Agreement. This Agreement, together with the relevant Notice and the Plan, contains the entire agreement between the parties with respect to the RSUs granted hereunder. Any oral or written agreements, representations, warranties, written inducements, or other communications made prior to the execution of this Agreement with respect to the RSUs granted hereunder shall be void and ineffective for all purposes.

14. Amendment. This Agreement may be amended from time to time by the Administrator in its discretion; provided, however, that this Agreement may not be modified in a manner that would have a materially adverse effect on the RSUs as determined in the discretion of the Administrator, except as provided in the Plan or in a written document signed by each of the parties hereto.

15. Recoupment Policy. You agree that, subject to the requirements of applicable law, if you breach any restrictive covenant agreement between you and the Company or you otherwise engage in activities that constitute Cause either while employed by, or providing service to, the Company or within two years thereafter, the RSU shall terminate, and the Company may rescind any delivery of shares upon vesting or settlement, as applicable on such terms as the Committee shall determine, including the right to require that in the event of any such rescission, (a) you shall return to the Company the shares received upon settlement of the RSU or, (b) if you no longer owns the shares, you shall pay to the Company the amount of any gain realized or payment received as a result of any sale or other disposition of the shares (or, in the event you transfer the shares by gift or otherwise without consideration, the fair market value (as determined by the Administrator) of the shares on the date of the breach of any restrictive covenant agreement or activity constituting Cause). You agree that payment shall be made in such manner and on

such terms and conditions as may be required by the Committee and you shall be entitled to set off against the amount of any such payment any amounts otherwise owed to you by the Company. In addition, you agree that the RSU shall be subject to any applicable clawback or recoupment policies, share trading policies and other policies that may be implemented by the Board from time to time.

409A Savings Clause. This Agreement and the RSUs granted hereunder are intended to either fit within the "short-term deferral" exemption from Section 409A of the Code as set forth in Treasury Regulation Section 1.409A-1(b)(4) or comply with Section 409A. Notwithstanding the foregoing, if it is determined that the RSUs fail to satisfy the requirements of the short-term deferral rule and are otherwise deferred compensation subject to Section 409A, and if you are a "Specified Employee" (within the meaning set forth Section 409A(a)(2)(B)(i) of the Code) as of the date of your separation from service (within the meaning of Treasury Regulation Section 1.409A-1(h)), then the issuance of any shares that would otherwise be made upon the date of the separation from service or within the first six (6) months thereafter will not be made on the originally scheduled date(s) and will instead be issued in a lump sum on the date that is six (6) months and one day after the date of the separation from service, but if and only if such delay in the issuance of the shares is necessary to avoid the imposition of additional taxation on you in respect of the shares under Section 409A of the Code. Each installment of shares that vests and is settled is intended to constitute a "separate payment" for purposes of Section 409A of the Code and Treasury Regulation Section 1.409A-2(b)(2).

16. No Obligation to Minimize Taxes. The Company has no duty or obligation to minimize the tax consequences to you of this award of RSUs and shall not be liable to you for any adverse tax consequences to you arising in connection with this award. You are hereby advised to consult with your own personal tax, financial and/or legal advisors regarding the tax consequences of this award and by signing the Notice, you have agreed that you have done so or knowingly and voluntarily declined to do so.

17. Conformity with Plan. This Agreement is intended to conform in all respects with, and is subject to all applicable provisions of, the Plan. Inconsistencies between this Agreement and the Plan shall be resolved in accordance with the terms of the Plan. In the event of any ambiguity in this Agreement or any matters as to which this Agreement is silent, the Plan shall govern. A copy of the Plan is available upon request to the Administrator.

18. No Funding. This Agreement constitutes an unfunded and unsecured promise by the Company to issue shares of Company Stock in the future in accordance with its terms. You have the status of a general unsecured creditor of the Company as a result of receiving the grant of RSUs.

19. Effect on Other Employee Benefit Plans. The value of the RSUs subject to this Agreement shall not be included as compensation, earnings, salaries, or other similar terms used when calculating your benefits under any employee benefit plan sponsored by the Company, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company's employee benefit plans.

20. Governing Law. The validity, construction and effect of this Agreement, and of any determinations or decisions made by the Administrator relating to this Agreement, and the rights of any and all persons having or claiming to have any interest under this Agreement, shall be determined exclusively in accordance with the laws of the State of Delaware, without regard to its provisions concerning the applicability of laws of other jurisdictions. As a condition of this Agreement, you agree that you will not bring any action arising under, as a result of, pursuant to or relating to, this Agreement in any court other than a federal or state court in the districts which include Delaware, and you hereby agree and submit to the personal jurisdiction of any federal court located in the district which includes Delaware or any state court in the district which includes Delaware. You further agree that you will not deny or attempt to defeat such personal jurisdiction or object to venue by motion or other request for leave from any such court.

21. Resolution of Disputes. Any dispute or disagreement which shall arise under, or as a result of, or pursuant to or relating to, this Agreement shall be determined by the Administrator in good faith in its absolute and uncontrolled discretion, and any such determination or any other determination by the

Administrator under or pursuant to this Agreement and any interpretation by the Administrator of the terms of this Agreement, will be final, binding and conclusive on all persons affected thereby. You agree that before you may bring any legal action arising under, as a result of, pursuant to or relating to, this Agreement you will first exhaust your administrative remedies before the Administrator. You further agree that in the event that the Administrator does not resolve any dispute or disagreement arising under, as a result of, pursuant to or relating to, this Agreement to your satisfaction, no legal action may be commenced or maintained relating to this Agreement more than twenty-four (24) months after the Administrator's decision.

22. Headings. The headings in this Agreement are for reference purposes only and shall not affect the meaning or interpretation of this Agreement.

23. Electronic Delivery of Documents. By your signing the Notice, you (i) consent to the electronic delivery of this Agreement, all information with respect to the Plan and the RSUs, and any reports of the Company provided generally to the Company's stockholders; (ii) acknowledge that you may receive from the Company a paper copy of any documents delivered electronically at no cost to you by contacting the Company by telephone or in writing; (iii) further acknowledge that you may revoke your consent to the electronic delivery of documents at any time by notifying the Company of such revoked consent by telephone, postal service or electronic mail; and (iv) further acknowledge that you understand that you are not required to consent to electronic delivery of documents.

24. No Future Entitlement. By your signing the Notice, you acknowledge and agree that: (i) the grant of a restricted stock unit award is a one-time benefit which does not create any contractual or other right to receive future grants of restricted stock units, or compensation in lieu of restricted stock units, even if restricted stock units have been granted repeatedly in the past; (ii) all determinations with respect to any such future grants and the terms thereof will be at the sole discretion of the Committee; (iii) the value of the restricted stock units is an extraordinary item of compensation which is outside the scope of your employment contract, if any; (iv) the value of the restricted stock units is not part of normal or expected compensation or salary for any purpose, including, but not limited to, calculating any termination, severance, resignation, redundancy, end of service payments or similar payments, or bonuses, long-service awards, pension or retirement benefits; (v) the vesting of the restricted stock units ceases upon termination of Service with the Company or transfer of employment from the Company, or other cessation of eligibility for any reason, except as may otherwise be explicitly provided in this Agreement; (vi) the Company does not guarantee any future value of the restricted stock units; and (vii) no claim or entitlement to compensation or damages arises if the restricted stock units decrease or do not increase in value and you irrevocably release the Company from any such claim that does arise.

25. Personal Data. For purposes of the implementation, administration and management of the restricted stock units or the effectuation of any acquisition, equity or debt financing, joint venture, merger, reorganization, consolidation, recapitalization, business combination, liquidation, dissolution, share exchange, sale of stock, sale of material assets or other similar corporate transaction involving the Company (a "***Corporate Transaction***"), you consent, by execution of the Notice, to the collection, receipt, use, retention and transfer, in electronic or other form, of your personal data by and among the Company and its third party vendors or any potential party to a potential Corporate Transaction. You understand that personal data (including but not limited to, name, home address, telephone number, employee number, employment status, social security number, tax identification number, date of birth, nationality, job and payroll location, data for tax withholding purposes and shares awarded, cancelled, vested and unvested) may be transferred to third parties assisting in the implementation, administration and management of the restricted stock units or the effectuation of a Corporate Transaction and you expressly authorize such transfer as well as the retention, use, and the subsequent transfer of the data by the recipient(s). You understand that these recipients may be located in your country or elsewhere, and that the recipient's country may have different data privacy laws and protections than your country. You understand that data will be held only as long as is necessary to implement, administer and manage the restricted stock units or effect a Corporate Transaction. You understand that you may, at any time, request a list with the names and addresses of any potential recipients of the personal data, view data, request additional information about the storage and processing of data, require any necessary amendments to data or refuse or withdraw the consents herein, in any case without cost, by contacting in writing the Company's Secretary. You

understand, however, that refusing or withdrawing your consent may affect your ability to accept a restricted stock unit award.

{*Glossary begins on next page*}

GLOSSARY

(a) "***Administrator***" means the Committee as defined in the Plan.

(b) "***Agreement***" means this document, as amended from time to time, together with the Plan which is incorporated herein by reference.

(c) "***Cause****"* has the meaning set forth in the Plan.

(d) *"****Change of Control****"* shall have the meaning set forth in the Plan.

(e) "**Code**" means the Internal Revenue Code of 1986, as amended, and the Treasury regulations and other guidance promulgated thereunder.

(f) "***Company Stock***" shall mean common stock of the Company.

(g) " ***Company***" means Axsome Therapeutics, Inc., and shall include all its successors except where the context otherwise requires. For purposes of determining whether a Change of Control has occurred, Company shall mean only Axsome Therapeutics, Inc.

(h) "***Disability***" shall have the meaning in the Plan subject to the requirements of Treasury Regulation Section 1.409A-3(i)(4).

(i) "***Grant Date***" means the effective date of a grant of RSUs made to you as set forth in the relevant Notice.

(j) "***Notice***" means the statement, letter or other written notification provided to you by the Company setting forth the terms of a grant of RSUs made to you.

(k) "***Plan***" means the Axsome Therapeutics, Inc. 2015 Omnibus Incentive Compensation Plan, as in effect from time to time.

(l) "***RSU***" means the Company's commitment to issue one share of Company Stock at a future date, subject to the terms of the Agreement and the Plan.

(m) "***You***" or "***Your***" means the recipient of the RSUs as reflected on the applicable Notice. Whenever the word "you" or "your" is used in any provision of this Agreement under circumstances where the provision should logically be construed, as determined by the Administrator, to apply to the estate, personal representative, or beneficiary to whom the RSUs may be transferred by will or by the laws of descent and distribution, the words "you" and "your" shall be deemed to include such person.

{*End of Agreement*}

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 5, 2025

/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 5, 2025

/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, 2025 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 5, 2025

/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, 2025 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 5, 2025

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