# 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 September 30, 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**<br>**29th Floor**<br>**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 50,412,640 shares of the registrant's common stock, $0.0001 par value, outstanding as of October 27, 2025.

**AXSOME THERAPEUTICS, INC.**
**QUARTERLY REPORT ON FORM 10-Q**
**FOR THE QUARTER ENDED SEPTEMBER 30, 2025**

**TABLE OF CONTENTS**


| | | Page |
|---|---|---|
| CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS | | 3 |
| **PART I — FINANCIAL INFORMATION** | | |
| ITEM 1 | Financial Statements | 4 |
| ITEM 2 | Management's Discussion and Analysis of Financial Condition and Results of Operations | 36 |
| ITEM 3 | Quantitative and Qualitative Disclosure About Market Risk | 47 |
| ITEM 4 | Controls and Procedures | 47 |
| **PART II — OTHER INFORMATION** | | |
| ITEM 1 | Legal Proceedings | 48 |
| ITEM 1A | Risk Factors | 50 |
| ITEM 5 | Other Information | 111 |
| ITEM 6 | Exhibits | 113 |
| | Signatures | 114 |

## 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)

| | September 30, 2025 (Unaudited) | December 31, 2024 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 325,272 | $ 315,353 |
| Accounts receivable, net | 196,507 | 142,001 |
| Inventories, net | 23,774 | 15,732 |
| Prepaid and other current assets | 19,789 | 11,978 |
| Total current assets | 565,342 | 485,064 |
| Equipment, net | 605 | 584 |
| Right-of-use asset - operating lease | 21,654 | 5,383 |
| Goodwill | 12,042 | 12,042 |
| Intangible asset, net | 42,126 | 46,894 |
| Non-current inventory and other assets | 27,481 | 18,531 |
| Total assets | $ 669,250 | $ 568,498 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 54,227 | $ 71,997 |
| Accrued expenses and other current liabilities | 225,632 | 147,987 |
| Operating lease liability, current portion | 736 | 1,835 |
| Contingent consideration, current | 9,695 | 8,285 |
| Short-term borrowings | 70,000 | — |
| Total current liabilities | 360,290 | 230,104 |
| Contingent consideration, non-current | 89,870 | 91,680 |
| Loan payable, long-term | 117,642 | 180,710 |
| Operating lease liability, long-term | 23,041 | 6,046 |
| Finance lease liability, long-term | 4,680 | 2,943 |
| Total liabilities | 595,523 | 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, 50,307,834 and 48,667,587 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively) | 5 | 5 |
| Additional paid-in capital | 1,351,124 | 1,179,797 |
| Accumulated deficit | (1,277,402) | (1,122,787) |
| Total stockholders' equity | 73,727 | 57,015 |
| Total liabilities and stockholders' equity | $ 669,250 | $ 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 September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2025 | 2024 | 2025 | 2024 |
| Revenues: | | | | |
| Product sales, net | $ 169,784 | $ 103,736 | $ 439,101 | $ 264,352 |
| Royalty revenue | 1,208 | 1,026 | 3,396 | 2,575 |
| Total revenues | 170,992 | 104,762 | 442,497 | 266,927 |
| Operating expenses: | | | | |
| Cost of revenue (excluding amortization and depreciation) | 11,912 | 8,437 | 35,149 | 22,789 |
| Research and development | 40,162 | 45,388 | 134,488 | 132,071 |
| Selling, general and administrative | 150,235 | 95,564 | 401,302 | 298,088 |
| Loss in fair value of contingent consideration | 13,185 | 16,391 | 6,595 | 17,139 |
| Intangible asset amortization | 1,607 | 1,606 | 4,768 | 4,785 |
| Total operating expenses | 217,101 | 167,386 | 582,302 | 474,872 |
| Loss from operations | (46,109) | (62,624) | (139,805) | (207,945) |
| Interest expense, net | (1,120) | (1,978) | (5,385) | (4,359) |
| Loss on debt extinguishment | — | — | (10,385) | — |
| Loss before income taxes | (47,229) | (64,602) | (155,575) | (212,304) |
| Income tax benefit | — | — | 960 | — |
| Net loss | $ (47,229) | $ (64,602) | $ (154,615) | $ (212,304) |
| Net loss per common share, basic and diluted | $ (0.94) | $ (1.34) | $ (3.13) | $ (4.45) |
| Weighted average common shares outstanding, basic and diluted | 50,021,851 | 48,140,519 | 49,449,220 | 47,703,508 |

*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 |
| Stock-based compensation | — | — | 21,709 | — | 21,709 |
| Issuance of common stock upon exercise of options and under employee stock purchase plan | 160,724 | — | 6,741 | — | 6,741 |
| Issuance of common stock upon vesting of RSUs | 27,404 | — | — | — | — |
| Issuance of common stock upon financing | 148,875 | — | 11,039 | — | 11,039 |
| Shares tendered for withholding taxes | — | — | (1,328) | — | (1,328) |
| Net loss | — | — | — | (79,345) | (79,345) |
| Balance at June 30, 2024 | 47,801,578 | 5 | 1,086,120 | (983,273) | 102,852 |
| Stock-based compensation | — | — | 21,992 | — | 21,992 |
| Issuance of common stock upon exercise of options | 475,830 | — | 20,290 | — | 20,290 |
| Issuance of common stock upon vesting of RSUs | 10,440 | — | — | — | — |
| Issuance of common stock upon financing | 148,260 | — | 12,839 | — | 12,839 |
| Shares tendered for withholding taxes | — | — | (473) | — | (473) |
| Net loss | — | — | — | (64,602) | (64,602) |
| Balance at September 30, 2024 | 48,436,108 | 5 | 1,140,768 | (1,047,875) | 92,898 |
| 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 |
| Stock-based compensation | — | — | 24,954 | — | 24,954 |
| Issuance of common stock upon exercise of options and under employee stock purchase plan | 276,280 | — | 11,661 | — | 11,661 |
| Issuance of common stock upon vesting of RSUs | 15,776 | — | — | — | — |
| Issuance of common stock upon financing | 306,486 | — | 32,116 | — | 32,116 |
| Shares tendered for withholding taxes | — | — | (888) | — | (888) |
| Net loss | — | — | — | (47,973) | (47,973) |
| Balance at June 30, 2025 | 49,815,301 | 5 | 1,303,243 | (1,230,173) | 73,075 |
| Stock-based compensation | — | — | 23,442 | — | 23,442 |
| Issuance of common stock upon exercise of options | 389,542 | — | 15,524 | — | 15,524 |
| Issuance of common stock upon vesting of RSUs | 14,479 | — | — | — | — |
| Issuance of common stock upon financing | 88,512 | — | 9,757 | — | 9,757 |
| Shares tendered for withholding taxes | — | — | (842) | — | (842) |
| Net loss | — | — | — | (47,229) | (47,229) |
| Balance at September 30, 2025 | 50,307,834 | $ 5 | $ 1,351,124 | $ (1,277,402) | $ 73,727 |

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

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

| | Nine months ended September 30, | |
|---|---|---|
| | 2025 | 2024 |
| **Cash flows from operating activities** | | |
| Net loss | $ (154,615) | $ (212,304) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation expense | 71,022 | 63,232 |
| Amortization of intangible asset | 4,768 | 4,785 |
| Amortization of debt discount | 1,142 | 1,932 |
| Loss on debt extinguishment | 10,385 | — |
| Depreciation | 389 | 403 |
| Loss in fair value of contingent consideration | 6,595 | 17,139 |
| Gain from lease modification | (2,250) | — |
| Non-cash lease expense | 2,249 | 1,042 |
| Right-of-use asset amortization for finance lease | 1,633 | 697 |
| Change in operating lease liability | (373) | (235) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, net | (54,506) | (29,276) |
| Inventories, net | (7,020) | 1,873 |
| Prepaid expenses and other current assets | (7,811) | (5,296) |
| Non-current inventory and other assets | (5,159) | (169) |
| Accounts payable | (17,770) | 23,574 |
| Accrued expenses and other current liabilities | 76,569 | 30,395 |
| Net cash used in operating activities | (74,752) | (102,208) |
| **Cash flows from investing activities** | | |
| Purchases of equipment | (409) | (240) |
| Net cash used in investing activities | (409) | (240) |
| **Cash flows from financing activities** | | |
| Proceeds from draw down of debt | 260,000 | — |
| Payment of debt issuance costs | (3,638) | — |
| Repayment of debt | (261,988) | — |
| Payments on principal portion of finance lease obligation | (1,583) | (660) |
| Proceeds from issuance of common stock upon financing | 62,229 | 24,365 |
| Cash paid for common stock issuance costs | (1,099) | (487) |
| Proceeds from issuance of common stock upon exercise of options and under employee stock purchase plan | 44,220 | 29,532 |
| Payment of contingent consideration | (6,995) | (5,735) |
| Payments of tax withholdings on stock awards | (6,066) | (3,419) |
| Net cash provided by financing activities | 85,080 | 43,596 |
| Net increase (decrease) in cash | 9,919 | (58,852) |
| Cash at beginning of period | 315,353 | 386,193 |
| Cash at end of period | $ 325,272 | $ 327,341 |
| **Supplemental disclosures of cash flow information:** | | |
| Interest paid | $ 11,576 | $ 14,935 |
| 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 | 4,395 | 4,890 |
| 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 comprised of multiple late-stage development programs addressing a broad range of serious neurological and psychiatric conditions that collectively impact over 150 million people in the United States.

In May 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 announced the commercial availability of Symbravo in the U.S. in June 2025.

The Company refers herein to Auvelity, Sunosi, Symbravo (also referred to as "AXS-07"), AXS-12, AXS-14, and its programs to develop additional indications for AXS-05 and solriamfetol as the Company's products.

The accompanying unaudited interim consolidated financial statements have been prepared by the Company in accordance with accounting principles generally accepted in the United States ("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 and nine months ended September 30, 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 September 30, 2025, the Company had an accumulated deficit of $1,277.4 million.

The Company's primary sources of cash have been proceeds from the sales of Auvelity, Sunosi, Symbravo, 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, Sunosi, and 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, Sunosi, and Symbravo 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. 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 September 30, 2025, the balance of cash and cash equivalents was $325.3 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 September 30, 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 of Sunosi (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 September 30, 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 nine months ended September 30, 2025. The balance of goodwill was $12.0 million at both September 30, 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 nine months ended September 30, 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, short-term 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 contingent warrant liability using the Black-Scholes model based on key assumption and inputs. The Company utilized 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, was considered Level 3 within the fair value hierarchy. The Company accounted for warrants anticipated to be issued in the future under the Loan Agreement as liabilities and measured them at fair value using the Black-Scholes valuation model. In the second quarter of 2025, the Company derecognized the fair value of contingent warrant liability upon extinguishment of the Hercules Loan Agreement.

**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. 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 September 30, 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. Costs that are directly attributable to the issuance of revolving credit facilities are capitalized and ratably amortized over the term of the revolving credit facility.

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 and nine months ended September 30, 2025, advertising costs were $41.4 million and $105.1 million, respectively. For the three and nine months ended September 30, 2024, advertising costs were $20.7 million and $75.0 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 since it is projecting losses and has incurred year to date losses in all significant jurisdictions from which the Company does not benefit due to the full valuation allowance position against the Company's deferred tax assets. The Company did not record a tax expense or benefit for the three months ended September 30, 2025. The Company recorded a tax benefit for the nine months ended September 30, 2025 due to favorable return to provision adjustments attributable to certain foreign tax returns filed during July 2025 that was recorded as a discrete income tax benefit in the second quarter of 2025.

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 September 30, 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 2025 Long-Term Incentive Plan share pool that was adopted by the Board in April 2025 and approved by the stockholders in June 2025. 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, PSUs, 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 and nine months ended September 30, 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 adopted this guidance effective January 1, 2025, and will provide the required disclosures in the Company's annual report on Form 10-K for the year ended December 31, 2025. The adoption of this guidance is not expected to have a material impact on the 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:

| | September 30, 2025 | December 31, 2024 |
|---|---|---|
| Trade receivables | $ 215,848 | $ 155,505 |
| Less: Reserves for variable consideration | (19,341) | (13,504) |
| Accounts receivable, net | $ 196,507 | $ 142,001 |

**Note 4. Inventory**

Inventory consisted of the following:

| | September 30, 2025 | December 31, 2024 |
|---|---|---|
| Raw materials | $ 12,436 | $ 9,541 |
| Work in process | 12,851 | 7,723 |
| Finished goods | 10,349 | 8,986 |
| Total | $ 35,636 | $ 26,250 |

There were no material inventory reserves or write downs of any excess and obsolete inventory as of September 30, 2025. Non-current inventory, which consists of raw materials and work in process 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:

| | September 30, 2025 | December 31, 2024 |
|---|---|---|
| Balance sheet classification | | |
| Inventories, net | $ 23,774 | $ 15,732 |
| Non-current inventory and other assets | 11,862 | 10,518 |
| Total | $ 35,636 | $ 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 September 30, 2025 | | | | |
| Finite-lived intangible asset | $ 63,800 | $ 21,674 | $ 42,126 | 7-years |

Based on the finite-lived intangible asset recorded as of September 30, 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 | $ 1,607 |
| 2026 | 6,375 |
| 2027 | 6,375 |
| 2028 | 6,392 |
| 2029 | 6,375 |
| Thereafter | 15,002 |
| Total | $ 42,126 |

**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 $9.7 million and non-current contingent consideration liability of $89.9 million in the consolidated balance sheet as of September 30, 2025.

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

| | September 30, 2025 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Assets: | | | | |
| Cash and cash equivalents - money market funds | $ 240,099 | $ — | $ — | $ 240,099 |
| Liabilities: | | | | |
| Contingent consideration | $ — | $ — | $ 99,565 | $ 99,565 |

| | 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 September 30, 2025. Changes in fair value of the contingent consideration liabilities as of September 30, 2025 are as follows:

| | Contingent consideration |
|---|---|
| Balance at December 31, 2024 | $ 99,965 |
| Adjustment to fair value | 6,595 |
| Payments | (6,995) |
| Balance at September 30, 2025 (Level 3) | $ 99,565 |

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

| | | | As of September 30, 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 | 12.9% | 12.0% |
| | | Revenue discount rate | 17.7% - 20.7% | 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:

| | September 30, 2025 | December 31, 2024 |
|---|---|---|
| Accrued research and development | $ 12,657 | $ 14,431 |
| Accrued compensation | 27,798 | 28,225 |
| Accrued selling, general, and administrative | 36,163 | 17,498 |
| Accrued sales discounts, rebates, and allowances | 139,471 | 73,952 |
| Accrued royalties | 7,001 | 9,958 |
| Accrued interest | 45 | 1,542 |
| Accrued taxes | — | 960 |
| Finance lease liability, current | 2,497 | 1,421 |
| Total | $ 225,632 | $ 147,987 |

**Note 8. Loan and Security Agreement**

*Blackstone Alternative Credit Advisors LP and Blackstone Life Sciences Advisors L.L.C.*

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

On May 8, 2025 (the "Closing Date"), the Company entered into a loan agreement (the "Blackstone Loan Agreement") with Blackstone Alternative Credit Advisors LP and Blackstone Life Sciences Advisors L.L.C. (collectively, the "Blackstone Representative" and referred to herein as "Blackstone"), certain subsidiaries of the Company party thereto as guarantors, Wilmington Trust, National Association, as agent, and the lenders from time to time party thereto (collectively, the "Lenders"). The Blackstone Loan Agreement provides for loans in an aggregate principal amount of up to $570.0 million, consisting of (i) a first lien senior secured term loan in an aggregate principal amount of $120.0 million funded to the Company on the Closing Date, (ii) a $180.0 million senior secured term loan available to the Company at its option, of which $90.0 million is available until May 31, 2026, and the remaining $90.0 million is available until May 31, 2027 (the "Term Loans"), and (iii) a super senior revolving credit facility in an aggregate principal amount of up to $70.0 million available at the Company's option (the "Revolver" and, together with the Term Loans, the "Loans"). The Blackstone Loan Agreement also permits the Company, subject to the consent of the Lenders, to request incremental term loans in an aggregate principal amount of up to $200.0 million at any time and on the same terms as the initial Term Loans, except that any call protection will be determined at the time the incremental term loans are incurred. The proceeds of the Term Loans were used, together with cash on hand, to repay in full the Company's obligations under the Hercules Loan Agreement (as defined below). The improved financial terms and anticipated use of the Loans are expected to result in a significant reduction in interest expense. As of September 30, 2025, there were $120.0 million and $70.0 million of outstanding principal amounts under the Term Loans and Revolver facilities, respectively. The outstanding balance under the Revolver was classified as short-term based on the Company's intent and ability to repay this amount in the next twelve months, and included in short-term borrowings on the accompanying consolidated balance sheets. In October 2025, the Company repaid the entire outstanding balance as of September 30, 2025 under the Revolver.

The Term Loans bear interest at a rate equal to the Term SOFR ("Secured Overnight Financing Rate") plus a margin of 4.75%. The effective interest rate on the Term Loans was 9.58% for the nine months ended September 30, 2025. The Revolver bears interest at SOFR plus a margin of 4.00%. If an Event of Default occurs and is continuing, all amounts outstanding under the Blackstone Loan Agreement will bear an additional 2.00% interest. The weighted-average interest rate on the Revolver was 8.00% as of September 30, 2025. The Loans mature and the principal amount (including any interest and fees) must be repaid on the date that is five years from the Closing Date. Fees and costs that were directly attributable to the Revolver have been capitalized as deferred assets and will be ratably expensed over the life of the Revolver. Deferred assets are included in non-current inventory and other assets on the accompanying consolidated balance sheets. As of September 30, 2025, the remaining unamortized balance of deferred assets was $1.0 million.

The Loans are subject to mandatory prepayment provisions that may require prepayment upon a change of control, the incurrence of certain additional indebtedness, certain asset sales, or an event of loss, subject to certain conditions set forth in the Blackstone Loan Agreement. The Company may prepay the Loans in whole at its option at any time, subject to certain yield protection premiums. The obligations under the Blackstone Loan Agreement are guaranteed by the Company's subsidiaries party thereto as guarantors and are secured by a first lien security interest in certain assets of the Company and the guarantors.

The Blackstone Loan Agreement contains customary representations and warranties, affirmative and negative covenants, and events of default applicable to the Company and the guarantors. The Blackstone Loan Agreement also contains a minimum liquidity covenant of $30.0 million, tested quarterly. If an event of default occurs and is continuing, the Lenders may declare all amounts outstanding under the Blackstone Loan Agreement to be immediately due and payable.

Concurrent with the closing of the Blackstone Loan Agreement, Blackstone purchased $15.0 million of the Company's common stock at a purchase price of $107.14 per share in a private placement transaction. The purchase agreement for the private placement contains customary representations, warranties, and covenants, and includes a lock-up period that generally prohibits, without the prior written consent of the Company, the sale, transfer, pledge, or other disposition of the securities through the period ending 120 days from the Closing Date.

In connection with the Blackstone Loan Agreement, Antecip consented to the collateral assignment of one of the license agreements, among other things, under a direct agreement among the Company, Antecip, a related party, and Blackstone.

*Hercules Capital, Inc.*

In September 2020, the Company entered into a Loan and Security Agreement for a term loan with Hercules Capital, Inc., a Maryland corporation ("Hercules"), in its capacity as administrative agent and collateral agent and as a lender, and the other financial institutions that from time to time act as lenders (the "Hercules Loan Agreement", as amended).

On May 8, 2025, the Company repaid in full its obligations under the Hercules Loan Agreement using proceeds from the Blackstone Loan Agreement. Upon repayment, the Company recorded a loss on debt extinguishment of approximately $10.4 million in the Company's consolidated statement of operations. As of September 30, 2025, there are no outstanding obligations under the Hercules Loan Agreement.

*Loan Interest Expense and Amortization*

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

| | September 30, 2025 | December 31, 2024 |
|---|---|---|
| Total outstanding debt, long-term | $ 120,000 | $ 180,000 |
| Add: accreted final payment fee | — | 4,085 |
| Less: unamortized debt discount, long-term | (2,358) | (3,375) |
| Loan payable, long-term | $ 117,642 | $ 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 September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2025 | 2024 | 2025 | 2024 |
| Interest expense | $ 3,056 | $ 4,892 | $ 11,173 | $ 14,630 |
| Amortization of final payment fee | — | 375 | 527 | 1,085 |
| Amortization of debt discount related issuance costs and warrants | 158 | 297 | 615 | 847 |

Scheduled principal payments on outstanding debt, long-term, as of September 30, 2025, are as follows:

| | |
|---|---|
| 2025 | $ — |
| 2026 | — |
| 2027 | — |
| 2028 | — |
| 2029 | — |
| Thereafter | 120,000 |
| Total principal payments outstanding | $ 120,000 |

**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 first quarter of fiscal year 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 September 30, 2025, the remaining lease term for the Company's operating lease was 5.5 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 nine months ended September 30, 2025, the Company recognized a right-of-use asset and lease liability, both, of $4.4 million in connection to this lease. As of September 30, 2025, right-of-use asset and lease liability related to the finance lease were $7.1 million and $7.2 million, respectively, and the weighted average remaining lease term was 3.0 years, with a weighted average discount rate of 9.6%.

Lease expenses recognized were as follows:

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2025 | 2024 | 2025 | 2024 |
| Operating lease expense | $ 1,261 | $ 583 | $ 3,479 | $ 1,749 |
| Finance lease expense: | | | | |
| Amortization of right-of-use assets | 684 | 324 | 1,633 | 697 |
| Interest on lease liabilities | 160 | 101 | 403 | 222 |

Future minimum lease payments of the Company's leases as of September 30, 2025 were as follows:

| | Operating lease | Finance lease |
|---|---|---|
| 2025 | $ 476 | $ 783 |
| 2026 | 2,178 | 3,007 |
| 2027 | 4,791 | 2,487 |
| 2028 | 4,807 | 1,644 |
| 2029 | 11,284 | 262 |
| Thereafter | 6,317 | — |
| Total lease payments | 29,853 | 8,183 |
| Less: imputed interest | (6,076) | (1,006) |
| Present value of lease liabilities | $ 23,777 | $ 7,177 |

**Note 10. Stockholders' Equity**

**Public Offerings**

***At-the-Market Offerings***

In March 2022, the Company entered into a sales agreement (the "March 2022 Sales Agreement") with Leerink Partners LLC ("Leerink") and filed a prospectus supplement. The March 2022 Sales Agreement supersedes the 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 December 2022, in connection with the automatic shelf registration statement (the "2022 Shelf Registration Statement"), the Company filed a new sales agreement prospectus to replace the prior prospectus supplement filed in August 2022 associated with the expired automatic shelf registration statement (the "2019 Shelf Registration Statement"), which the Company filed with the U.S. Securities and Exchange Commission (the "SEC") on December 5, 2019. 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 September 30, 2025, the Company received approximately $9.9 million in gross proceeds through the sale of 88,512 shares, of which net proceeds were approximately $9.7 million. For the nine months ended September 30, 2025, the Company received approximately $47.2 million in gross proceeds through the sale of 411,482 shares, of which net proceeds were approximately $46.3 million under the March 2022 Sales Agreement.

***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.

**Blackstone Securities Purchase Agreement**

In May 2025, the Company entered into a securities purchase agreement (the "SPA") with Blackstone or its affiliates for the private placement (the "Private Placement") of an aggregate of 140,000 shares of the Company's common stock, at a purchase price of $107.14 per share. Gross proceeds from the Private Placement were approximately $15.0 million. The closing of the Private Placement occurred contemporaneously with the closing of the Blackstone Loan Agreement.

**Shelf Registration Statement**

Contemporaneously herewith, the Company filed an automatic shelf registration statement (the "2025 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 2025 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 2025 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. In April 2025, the Company's Long-Term Incentive Plan ("2025 Plan") was adopted by the Board and approved by the stockholders in June 2025. All future equity awards will be made from the 2025 Plan and the Company does not intend to grant any future equity awards from the 2015 Plan. As of September 30, 2025, there were 2,592,462 shares available for future grant under the 2025 Plan.

**Stock Options**

The following table sets forth stock option activity as of September 30, 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 | 361,938 | 123.86 | | |
| Exercised | (938,068) | 43.17 | | |
| Forfeited/Canceled | (275,373) | 72.00 | | |
| Outstanding at September 30, 2025 | 7,587,618 | $ 49.93 | 5.9 | $ 546,116 |
| Vested and expected to vest at September 30, 2025 | 7,587,618 | $ 49.93 | 5.9 | $ 546,116 |
| Exercisable at September 30, 2025 | 5,552,310 | $ 39.63 | 5.0 | $ 454,782 |

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 $88.37 per option for the nine months ended September 30, 2025. As of September 30, 2025, there was $112.6 million of total unrecognized compensation cost related to unvested stock options which is expected to be recognized over a weighted average period of 2.1 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 September 30, 2025, total compensation cost not yet recognized related to nonvested RSUs was $73.4 million, which is expected to be recognized over a weighted-average period of 2.6 years. The intrinsic value of RSUs lapsed during the nine months ended September 30, 2025 was $17.2 million.

The following table sets forth the RSU activity for the nine months ended September 30, 2025:

| | Number of shares | Weighted average grant date fair value |
|---|---|---|
| Nonvested at December 31, 2024 | 906,944 | $ 59.48 |
| Granted | 468,455 | 120.84 |
| Vested | (295,835) | 51.71 |
| Forfeited | (72,580) | 91.81 |
| Nonvested at September 30, 2025 | 1,006,984 | $ 87.98 |

**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 September 30, 2025, total compensation cost not yet recognized related to nonvested PSUs was $4.9 million, which is expected to be recognized over a weighted-average period of 2.5 years.

The following table sets forth the PSU activity for the nine months ended September 30, 2025:

| | Number of shares | Weighted average grant date fair value |
|---|---|---|
| Nonvested at December 31, 2024 | — | $ — |
| Granted | 64,281 | 94.39 |
| Vested | — | — |
| Forfeited | — | — |
| Nonvested at September 30, 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 second offering period pursuant to the ESPP on June 1, 2024, and such offering ended on May 31, 2025.

During the nine months ended September 30, 2025, 59,607 common shares have been purchased and issued pursuant to the ESPP, and $0.7 million and $1.5 million of expense was recorded for the three and nine months ended September 30, 2025.

**Stock-based Compensation Expense**

Stock-based compensation expense recognized was as follows:

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2025 | 2024 | 2025 | 2024 |
| Research and development | $ 6,807 | $ 5,868 | $ 20,207 | $ 15,508 |
| Selling, general and administrative | 16,296 | 15,792 | 50,815 | 47,724 |
| Total | $ 23,103 | $ 21,660 | $ 71,022 | $ 63,232 |

Stock-based compensation expense capitalized into inventory totaled $0.3 million and $1.0 million for the three and nine months ended September 30, 2025, respectively, and $0.3 million and $1.0 million for the three and nine months ended September 30, 2024, respectively. 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 nine months ended September 30, 2025:

| | Warrants | Weighted average exercise price |
|---|---|---|
| Outstanding at December 31, 2024 | 79,220 | $ 56.80 |
| Issued | — | — |
| Exercised | — | — |
| Outstanding at September 30, 2025 | 79,220 | $ 56.80 |

*Outstanding Warrants*

In connection with the entry into the Third Amendment to the Hercules Loan Agreement, 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. Upon full repayment of the Company's obligations under the Hercules Loan Agreement, no additional warrants are issuable under the Hercules Loan Agreement.

**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 September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2025 | 2024 | 2025 | 2024 |
| Basic and diluted net loss per common share: | | | | |
| Net loss | $ (47,229) | $ (64,602) | $ (154,615) | $ (212,304) |
| Weighted average common shares outstanding—basic and diluted | 50,021,851 | 48,140,519 | 49,449,220 | 47,703,508 |
| Net loss per common share—basic and diluted | $ (0.94) | $ (1.34) | $ (3.13) | $ (4.45) |

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

| | September 30, | |
|---|---|---|
| | 2025 | 2024 |
| Stock options | 7,587,618 | 8,453,826 |
| Restricted stock units | 1,495,986 | 899,277 |
| Performance stock units | 64,281 | — |
| Warrants | 79,220 | 79,220 |
| ESPP | 83,477 | 69,761 |
| Total | 9,310,582 | 9,502,084 |

**Note 13. Revenues**

The Company sells Auvelity, Sunosi, and Symbravo 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 nine months ended September 30, 2025, the Company's three largest customers represented approximately 34%, 30%, and 26% 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 September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2025 | 2024 | 2025 | 2024 |
| Product sales, net | | | | |
| Auvelity | $ 136,102 | $ 80,378 | $ 351,975 | $ 198,798 |
| Sunosi | 31,611 | 23,358 | 84,645 | 65,554 |
| Symbravo | 2,071 | — | 2,481 | — |
| Total product sales, net | 169,784 | 103,736 | 439,101 | 264,352 |
| Sunosi royalty revenue | 1,208 | 1,026 | 3,396 | 2,575 |
| Total revenues | $ 170,992 | $ 104,762 | $ 442,497 | $ 266,927 |

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

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2025 | 2024 | 2025 | 2024 |
| Product sales, net | | | | |
| United States | $ 169,176 | $ 102,810 | $ 435,035 | $ 261,525 |
| Outside of the United States | 608 | 926 | 4,066 | 2,827 |
| Total product sales, net | 169,784 | 103,736 | 439,101 | 264,352 |
| Royalty revenue | | | | |
| Outside of the United States | 1,208 | 1,026 | 3,396 | 2,575 |
| Total revenues | $ 170,992 | $ 104,762 | $ 442,497 | $ 266,927 |

For the nine months ended September 30, 2025, product sales, net includes adjustments for provisions for product sales made in 2024 resulting from changes in estimates of $0.9 million for Auvelity and $0.8 million for Sunosi. For the nine months ended September 30, 2024, product sales, net includes adjustments for provisions for product sales made in 2023 resulting from changes in estimates of $1.0 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 $1.2 million and $1.0 million for the three months ended September 30, 2025 and 2024, respectively, and $3.4 million and $2.6 million for the nine months ended September 30, 2025 and 2024, respectively, related to Pharmanovia's sales of Sunosi. No other development or sales-based milestones were recognized during the nine months ended September 30, 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 and nine months ended September 30, 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 nine months ended September 30, 2025 and 2024, the Company recorded royalty expense of $10.6 million and $6.0 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 Blackstone Loan Agreement, Antecip consented to the collateral assignment of one of the license agreements, among other things, under a direct agreement among the Company, Antecip and Blackstone.

**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 September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2025 | 2024 | 2025 | 2024 |
| Loss before income taxes | $ (47,229) | $ (64,602) | $ (155,575) | $ (212,304) |
| Income tax benefit | — | — | 960 | — |
| Effective tax rate | —% | —% | (0.6)% | —% |

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 or benefit for the three months ended September 30, 2025. The Company recorded a tax benefit for the nine months ended September 30, 2025 of $1.0 million due to favorable return-to-provision adjustments attributable to certain foreign tax returns filed during July 2025 that was recorded as a discrete income tax benefit in the second quarter of 2025. The Company did not have any unrecognized tax benefits as of September 30, 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.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted in the U.S. The OBBBA includes significant provisions, such as the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act, modifications to the international tax framework and the restoration of favorable tax treatment for certain business provisions. The legislation has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. The Company does not expect material tax impacts from the legislation on its consolidated financial statements.

**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. The Company recorded royalty expense of $10.6 million and $6.0 million for the nine months ended September 30, 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 September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2025 | 2024 | 2025 | 2024 |
| Total revenues | $ 170,992 | $ 104,762 | $ 442,497 | $ 266,927 |
| Less: | | | | |
| Cost of revenue (excluding amortization and depreciation) | 11,912 | 8,437 | 35,149 | 22,789 |
| Research and development expense (excluding share-based compensation expense): | | | | |
| Solriamfetol | 9,518 | 13,711 | 32,094 | 37,908 |
| AXS-05 | 13,855 | 14,802 | 42,896 | 44,090 |
| AXS-07 | 4,825 | 2,512 | 15,379 | 9,457 |
| AXS-12 | 1,873 | 1,911 | 6,019 | 7,035 |
| AXS-14 | (1,460) | 3,516 | 5,951 | 9,886 |
| Other research and development[(a)] | 4,744 | 3,067 | 11,942 | 8,186 |
| General and administrative expense (excluding share-based compensation expense) | 19,739 | 11,587 | 44,623 | 36,427 |
| Selling and marketing expense (excluding share-based compensation expense) | 114,200 | 68,186 | 305,864 | 213,938 |
| Share based compensation expense | 23,103 | 21,660 | 71,022 | 63,232 |
| Loss in fair value of contingent consideration | 13,185 | 16,391 | 6,595 | 17,139 |
| Interest expense, net[(b)] | 1,120 | 1,978 | 5,385 | 4,359 |
| Other segment items[(c)] | 1,607 | 1,606 | 14,193 | 4,785 |
| Segment net loss | (47,229) | (64,602) | (154,615) | (212,304) |
| | | | | |
| Reconciliation of net loss | | | | |
| Adjustments and reconciling items | — | — | — | — |
| Consolidated net loss | (47,229) | (64,602) | (154,615) | (212,304) |

(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 $1,120 for the three months ended September 30, 2025 comprises (i) consolidated interest expense of $3,375 and (ii) consolidated interest income of $2,255. Interest expense, net of $5,385 for the nine months ended September 30, 2025 comprises (i) consolidated interest expense of $12,719 and (ii) consolidated interest income of $7,334. Interest expense, net of $1,978 for the three months ended September 30, 2024 comprises (i) consolidated interest expense of $5,666 and (ii) consolidated interest income of $3,688. Interest expense, net of $4,359 for the nine months ended September 30, 2024 comprises (i) consolidated interest expense of $16,151 and (ii) consolidated interest income of $11,792.
(c) Other segment items included in Segment net loss include intangible asset amortization, loss on debt extinguishment, 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. We initiated the commercial launch of Symbravo in the United States in June 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 submitted a supplemental NDA (sNDA) to the FDA for AXS-05 in AD agitation supported by four completed 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 a novel, oral, investigational DNRI, TAAR1 agonist, and 5-HT1A 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"). In March 2025, we announced topline results from the FOCUS Phase 3 trial of solriamfetol in ADHD in adults, and in April 2025, we announced topline results from 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. In May 2025, we announced that we submitted an NDA to the FDA for AXS-14 for the management of fibromyalgia. In June 2025, we received a Refusal to File letter from the FDA for the NDA. To address the FDA's feedback, Axsome will conduct an additional controlled trial, which will use a fixed-dose paradigm and a 12-week primary endpoint as requested by the FDA.

Since our incorporation in January 2012, our operations to date have included organizing and staffing our company, business planning, raising capital, developing our compounds, engaging in other discovery and preclinical activities, and the commercial launches of Auvelity, Sunosi, and 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, Sunosi, and 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 $154.6 million and $212.3 million for the nine months ended September 30, 2025 and 2024, respectively. Our accumulated deficit as of September 30, 2025 was $1,277.4 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 $171.0 million and $104.8 million in the three months ended September 30, 2025 and 2024, respectively, and $442.5 million and $266.9 million in the nine months ended September 30, 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 $1.2 million and $1.0 million for the three months ended September 30, 2025 and 2024, respectively, and $3.4 million and $2.6 million for the nine months ended September 30, 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 September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2025 | 2024 | 2025 | 2024 |
| Revenues: | | | | |
| Product sales, net | $ 169,784 | $ 103,736 | $ 439,101 | $ 264,352 |
| Royalty revenue | 1,208 | 1,026 | 3,396 | 2,575 |
| Total revenues | 170,992 | 104,762 | 442,497 | 266,927 |
| Operating expenses: | | | | |
| Cost of revenue (excluding amortization and depreciation) | 11,912 | 8,437 | 35,149 | 22,789 |
| Research and development | 40,162 | 45,388 | 134,488 | 132,071 |
| Selling, general and administrative | 150,235 | 95,564 | 401,302 | 298,088 |
| Loss in fair value of contingent consideration | 13,185 | 16,391 | 6,595 | 17,139 |
| Intangible asset amortization | 1,607 | 1,606 | 4,768 | 4,785 |
| Total operating expenses | 217,101 | 167,386 | 582,302 | 474,872 |
| Loss from operations | (46,109) | (62,624) | (139,805) | (207,945) |
| Interest expense, net | (1,120) | (1,978) | (5,385) | (4,359) |
| Loss on debt extinguishment | — | — | (10,385) | — |
| Loss before income taxes | (47,229) | (64,602) | (155,575) | (212,304) |
| Income tax benefit | — | — | 960 | — |
| Net loss | $ (47,229) | $ (64,602) | $ (154,615) | $ (212,304) |
| Net loss per common share, basic and diluted | $ (0.94) | $ (1.34) | $ (3.13) | $ (4.45) |
| Weighted average common shares outstanding, basic and diluted | 50,021,851 | 48,140,519 | 49,449,220 | 47,703,508 |

*Product sales, net.* Auvelity U.S. net sales were $136.1 million and $352.0 million for the three and nine months ended September 30, 2025, respectively, as compared to $80.4 million and $198.8 million for the same periods in 2024. Sunosi net sales were $31.6 million and $84.6 million for the three and nine months ended September 30, 2025, respectively, as compared to $23.4 million and $65.6 million for the same periods in 2024. We began commercial sales of Symbravo in June 2025 and had U.S. net sales of $2.1 million and $2.5 million for the three and nine months ended September 30, 2025. There were no Symbravo sales recorded in 2024, which reflects the timing of the Symbravo approval and launch. The increases in both comparable periods were primarily due to the increase in unit sales volume for both Auvelity and Sunosi, and commercial launch of Symbravo in June 2025.

The following table summarizes the activity of our sales allowance and reserves as of and for the nine months ended September 30, 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 | 268,243 | 104,756 | 68,512 | 441,511 |
| Payments/credits | (238,407) | (98,919) | (32,830) | (370,156) |
| Balance at September 30, 2025 | $ 85,248 | $ 19,341 | $ 54,220 | $ 158,809 |

*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 $1.2 million and $3.4 million for the three and nine months ended September 30, 2025, respectively, as compared to $1.0 million and $2.6 million for the same periods in 2024 attributable to Pharmanovia sales of Sunosi in the out-licensed markets. The increases in both comparable periods were in line with the increase in unit sales volume of Sunosi in certain ex-U.S. markets.

*Cost of revenue.* Cost of revenue was $11.9 million and $35.1 million for the three and nine months ended September 30, 2025, respectively, as compared to $8.4 million and $22.8 million for the same periods in 2024. The increase was in line with the increase in sales of Auvelity and Sunosi, and commercial launch of Symbravo in June 2025.

*Research and development.* The following table summarizes our research and development expenses for our primary products for the three and nine months ended September 30, 2025 and 2024 (in thousands):

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2025 | 2024 | 2025 | 2024 |
| Solriamfetol | $ 9,518 | $ 13,711 | $ 32,094 | $ 37,908 |
| AXS-05 | 13,855 | 14,802 | 42,896 | 44,090 |
| AXS-07 | 4,825 | 2,512 | 15,379 | 9,457 |
| AXS-12 | 1,873 | 1,911 | 6,019 | 7,035 |
| AXS-14 | (1,460) | 3,516 | 5,951 | 9,886 |
| Other research and development (*) | 4,744 | 3,067 | 11,942 | 8,186 |
| Stock-based compensation | 6,807 | 5,869 | 20,207 | 15,509 |
| Total research and development expenses | $ 40,162 | $ 45,388 | $ 134,488 | $ 132,071 |

(*) 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 decreased by $5.2 million and increased by $2.4 million for the three and nine months ended September 30, 2025, respectively, as compared to the same periods in 2024. The decrease in the three months ended comparable period was due to the completion of trials for solriamfetol in ADHD and MDD and a refund of a regulatory filing fee related to AXS-14, partially offset by ongoing supplier validation costs for AXS-07. The increase in the nine months ended comparable period was due to the ongoing supplier validation costs for AXS-07, partially offset by lower spending due to completion of trials for MDD and ADHD for solriamfetol. We expect research and development costs to moderately increase through the end of 2025 and into 2026 as new development programs commence while certain development programs near completion.

*Selling, general and administrative.* Selling, general and administrative expenses were $150.2 million and $401.3 million for the three and nine months ended September 30, 2025, respectively, as compared to $95.6 million and $298.1 million for the same periods in 2024. The increases in both comparable periods were related to higher commercial activities for Auvelity, including a sales force expansion and a national direct-to-consumer advertising campaign, commercial launch of Symbravo, and higher personnel costs related to organizational growth, including non-cash stock-based compensation. We anticipate modest growth in SG&A expenses through 2025 and into 2026 as we increase marketing and promotional spending for Auvelity.

*Loss in Fair Value of Contingent Consideration.* The $13.2 million and $6.6 million changes for the three and nine months ended September 30, 2025, respectively, as compared to $16.4 million and $17.1 million changes for the same periods in 2024, were 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 September 30, 2025 and 2024 and $4.8 million for both the nine months ended September 30, 2025 and 2024.

*Interest expense, net.* Interest expense, net was $1.1 million and $5.4 million for the three and nine months ended September 30, 2025, respectively, as compared to $2.0 million and $4.4 million for the same periods in 2024. The decrease in the three months ended comparable period was due to the lower interest expense from the Blackstone Loan Agreement, which was partially offset by less interest income on lower cash balances. The increase in the nine months ended comparable period was mainly due to less interest income on lower cash balances.

*Income tax expense.* We did not record an income tax expense or benefit for the three months ended September 30, 2025. We recorded a tax benefit of $1.0 million for the nine months ended September 30, 2025 due to favorable return-to-provision adjustments attributable to certain foreign tax returns filed during July 2025 that were recorded as a discrete tax benefit in the second quarter of 2025. We did not record an income tax benefit or expense for the same periods in 2024.

*Net loss.* Net loss was $47.2 million and $154.6 million for the three and nine months ended September 30, 2025, respectively, as compared to $64.6 million and $212.3 million for the same periods in 2024. The decreases in both comparable periods were 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 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 September 30, 2025, we have financed our operations primarily through proceeds from equity offerings, debt borrowings, and proceeds from product sales. See discussion below.

Contemporaneously herewith, 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 2025 Shelf Registration Statement. In the future, we may conduct additional offerings of one or more of these securities utilizing the 2025 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 2025 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.

Also contemporaneously herewith, in connection with the 2025 Shelf Registration Statement, we filed a new sales agreement prospectus to replace the prior prospectus supplement filed in December 2022 associated with the 2022 Shelf Registration Statement, which would have expired in December 2025. 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.

In March 2022, we entered into a sales agreement, or the March 2022 Sales Agreement with Leerink, and filed a prospectus supplement. The March 2022 Sales Agreement supersedes the sales agreement, dated December 5, 2019, by and between us and Leerink. We exhausted sales of shares of our common stock under our prior at-the-market offering program.

Under the March 2022 Sales Agreement, for the nine months ended September 30, 2025, we received approximately $47.2 million in gross proceeds through the sale of 411,482 shares, of which net proceeds were approximately $46.3 million.

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 2025 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 2025 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 relinquished our then existing space in One World Trade Center and commenced 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.

As described below in the "Loan Agreement with Blackstone" section, on May 8, 2025, we entered into a loan agreement (the "Blackstone Loan Agreement") with Blackstone Alternative Credit Advisors LP and Blackstone Life Sciences Advisors L.L.C. (collectively, the "Blackstone Representative" and referred to herein as "Blackstone"), certain subsidiaries of our party thereto as guarantors, Wilmington Trust, National Association, as agent, and the lenders from time to time party thereto (collectively, the "Lenders"). The Blackstone Loan Agreement provides for Loans in an aggregate principal amount of up to $570.0 million.

On May 8, 2025, we repaid in full our obligations under the Hercules Loan Agreement using proceeds from the Blackstone Loan Agreement. As of September 30, 2025, there are no outstanding obligations under the Hercules Loan Agreement.

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):

| | Nine months ended September 30, | |
|---|---|---|
| | **2025** | **2024** |
| Net cash (used in) provided by: | | |
| Operating activities | $ (74,752) | $ (102,208) |
| Investing activities | (409) | (240) |
| Financing activities | 85,080 | 43,596 |
| Net increase (decrease) in cash | $ 9,919 | $ (58,852) |

*Operating Activities.* Cash used in operating activities for the nine months ended September 30, 2025 was $74.8 million, as compared to $102.2 million for the same period in 2024. The decrease of $27.4 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 related activities.

*Investing Activities.* Cash used in investing activities for the nine months ended September 30, 2025 was $409 thousand, as compared to $240 thousand for the same period in 2024. The increase was attributable to additional equipment purchases in 2025 to support our expanded office space and workforce.

*Financing Activities.* Cash provided by financing activities was $85.1 million for the nine months ended September 30, 2025, which included net proceeds of $256.4 million from draw-downs related to the Blackstone Loans and net proceeds of $61.1 million from issuance of common stock for financing purposes as well as proceeds of $44.2 million from the issuance of common stock upon the exercise of employee stock options and under the ESPP, which was partially offset by the repayment of the Hercules Loan and revolving loan commitments under the Blackstone Loan Agreement, for a total of $262.0 million, and payments of contingent consideration and tax withholdings on stock awards, for a total of $13.1 million. Cash provided by financing activities was $43.6 million for the nine months ended September 30, 2024, which included net proceeds of $23.9 million from issuance of common stock for financing purposes as well as proceeds of $29.5 million from the issuance of common stock upon the exercise of employee stock options and under the ESPP, which was partially offset by payments of contingent consideration and tax withholdings on stock awards, for a total of $9.2 million.

**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, while further investing in Auvelity, Sunosi, and Symbravo. 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 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 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 Blackstone Loan Agreement (see below), Antecip consented to the collateral assignment of one of the license agreements, among other things, under a direct agreement among us, Antecip and Blackstone.

*Loan Agreement with Blackstone*

On May 8, 2025 (the "Closing Date"), we entered into a loan agreement (the "Blackstone Loan Agreement") with Blackstone Alternative Credit Advisors LP and Blackstone Life Sciences Advisors L.L.C. (collectively, the "Blackstone Representative" and referred to herein as "Blackstone"), certain subsidiaries of ours party thereto as guarantors, Wilmington Trust, National Association, as agent, and the lenders from time to time party thereto (collectively, the "Lenders"), providing for loans in an aggregate principal amount of up to $570.0 million, consisting of (i) a first lien senior secured term loan in an aggregate principal amount of $120.0 million funded to us on the Closing Date, (ii) a $180.0 million senior secured term loan which is available to us at our option, of which $90.0 million is available to us until May 31, 2026, and of which the remaining $90.0 million is available until May 31, 2027 (the "Term Loans") and (iii) a super senior revolving credit facility in an aggregate principal amount of up to $70.0 million available at our option (the "Revolver" and collectively with the Term Loans, the "Loans"). The Blackstone Loan Agreement also permits us, subject to the consent of the Lenders, to request incremental term loans in an aggregate principal amount of up to $200.0 million at any time and on the same terms as the initial Term Loans, except that any call protection will be determined at the time the incremental term loans are incurred. The proceeds of the Term Loans were used, together with cash on hand, to repay in full our obligations under the Hercules Loan Agreement, which resulted in a recording of a loss on debt extinguishment of approximately $10.4 million in the Company's consolidated statement of operations. The Term Loans bear interest at a variable SOFR plus 4.75%. The Revolver bears interest at SOFR plus 4.0%. The maturity date of the Loans is May 8, 2030. The Blackstone Loan Agreement provides for additional drawdowns at our option, subject to certain conditions, and includes customary covenants and a minimum liquidity covenant of $30.0 million. The obligations under the Blackstone Loan Agreement are secured by a first lien on certain assets of ours and our subsidiaries.

On May 8, 2025, we repaid in full our obligations under the Hercules Loan Agreement using proceeds from the Blackstone Loan Agreement. As of September 30, 2025, there are no outstanding obligations under the Hercules Loan Agreement.

*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 October 27, 2025, we had 816 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 $325.3 million and $315.4 million as of September 30, 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 or interest expense, 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 September 30, 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 nine months ended September 30, 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 September 30, 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. On October 27, 2025, the SDNY District Court preliminarily approved the terms of a settlement resolving the Securities Class Action. A settlement hearing is scheduled for February 10, 2026.

*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 SDNY 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.

On September 23, 2025, John Wickstrom filed a stockholder derivative complaint captioned Wickstrom v. Herriot Tabuteau, et al. in the Court of Chancery of the State of Delaware against the Company's current directors, certain of the Company's current and former officers, and the Company (as nominal defendant). On September 29, 2025, John Gildea filed a stockholder derivative complaint captioned Gildea v. Herriot Tabuteau, et al. in the Court of Chancery of the State of Delaware against the Company's current directors, certain of the Company's current and former officers, and the Company (as nominal defendant). The Delaware derivative complaints arise out of similar allegations as those made in the Securities Class Action and the SDNY derivative action. The plaintiffs assert claims for breach of fiduciary duties, unjust enrichment, and corporate waste against all of the defendants. The plaintiffs seek unspecified damages, fees, interest, and costs, as well as corporate governance changes.

*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, January 29, 2025, May 1, 2025, and August 15, 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; *Axsome Malta Ltd. et al v. Hetero USA Inc. et al*. 2-25-cv-00801; *Axsome Malta Ltd. & Axsome Therapeutics, Inc. v. Aurobindo Pharma USA, Inc. et al*. No. 2-25-cv-03721; and *Axsome Malta Ltd. et al v. Alkem Laboratories Ltd*. No. 2-25-cv-14694, respectively, all of which were filed in the NJ District Court.

On June 4, 2024, Axsome and the Malta Subsidiary entered into a settlement agreement with Unichem Laboratories Ltd. ("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 Inc. On September 25, 2024, Hikma Pharmaceuticals USA, Inc. ("Hikma") 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. On May 21, 2025, Axsome and the Malta Subsidiary entered into a settlement with Hetero USA, Inc., Hetero Labs Limited Unit-V, and Hetero Labs Ltd. (collectively, "Hetero") under which agreement Hetero 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. All other actions remain pending.

*Symbravo Paragraph IV Litigation*

On September 26, 2025, we commenced a patent infringement action against Apotex Inc. relating to Apotex's ANDA for Symbravo. This action is captioned *Axsome Therapeutics, Inc. v. Apotex, Inc.,* No. 1:25-CV-16038 in the NJ District Court.

## 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 facility with Blackstone, 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 Food and Drug Administration (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 $154.6 million and $212.3 million for the nine months ended September 30, 2025 and 2024, respectively. As of September 30, 2025, we had an accumulated deficit of $1,277.4 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, Sunosi, and 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 facility with Blackstone, 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.***

On May 8, 2025 (the "Closing Date"), we entered into a loan agreement (the "Blackstone Loan Agreement") with Blackstone Alternative Credit Advisors LP and Blackstone Life Sciences Advisors L.L.C. (collectively, the "Blackstone Representative" and referred to herein as "Blackstone"), certain subsidiaries party thereto as guarantors, Wilmington Trust, National Association, as agent, and the lenders from time to time party thereto (collectively, the "Lenders"), providing for loans in an aggregate principal amount of up to $570.0 million, consisting of (i) a first lien senior secured term loan in an aggregate principal amount of $120.0 million funded to us on the Closing Date, (ii) a $180.0 million senior secured term loan which is available to us at the Company's option, of which $90.0 million is available to us until May 31, 2026, and of which the remaining $90.0 million is available until May 31, 2027 (the "Term Loans") and (iii) a super senior revolving credit facility in an aggregate principal amount of up to $70.0 million available at our option (the "Revolver" and collectively with the Term Loans, the "Loans"). The Blackstone Loan Agreement also permits us, subject to the consent of the Lenders, to request incremental term loans in an aggregate principal amount of up to $200.0 million at any time and on the same terms as the initial Term Loans, except that any call protection will be determined at the time the incremental term loans are incurred. The proceeds of the Term Loans were used, together with cash on hand, to repay in full our obligations under the Hercules Loan Agreement, which resulted in a recording of a loss on debt extinguishment of approximately $10.4 million in the Company's consolidated statement of operations. The Term Loans bear interest at a variable SOFR plus 4.75%. The Revolver bears interest at SOFR plus 4.0%. The maturity date of the Loans is May 8, 2030. The Blackstone Loan Agreement provides for additional drawdowns at our option, subject to certain conditions, and includes customary covenants and a minimum liquidity covenant of $30.0 million. The obligations under the Blackstone Loan Agreement are secured by a first lien on certain assets of ours and our subsidiaries.

The Blackstone 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 Blackstone 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 Blackstone Loan Agreement could result in a default. Upon the occurrence of an event of default, 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 approval of Symbravo earlier this year, 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 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. On October 10, 2025, a cease-fire between Israel and Hamas took effect; however, there remain reports of clashes in Gaza and accusations of violations from both sides. 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, and although the US-Houthi conflict has now ceased, Yemen remains a volatile region with ongoing violence from multiple parties. 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 the U.S. and global financial and economic markets. For example, on October 1, 2025, the U.S. federal government commenced a shutdown due to an impasse over funding for the 2026 fiscal year, impacting a number of federal services, including essential services such as Medicare and Medicaid, and it is uncertain when it will end. In addition, the U.S. announced a 100% tariff, effective October 1, 2025, on any branded or patented pharmaceuticals imported into the U.S., unless the relevant drug manufacturer has or is in the process of building a manufacturing facility in the U.S. The imposition of such tariffs is currently delayed as the U.S. administration seeks to negotiate drug pricing agreements with large drug manufacturers. The outcome of such ongoing negotiations is currently unclear, and the final terms and impact remain uncertain. While we currently do not anticipate a material impact from such tariffs on our business or operations, such tariffs could have implications on drug pricing, drug production levels and patient access, and may result in supply chain or other operational disruptions. Further, if we are required to change our current manufacturing partners or suppliers now or in the future in order to avoid such tariffs, the terms of new agreements that we may enter into may not be favorable to us and related operational disruptions may heighten manufacturing and compliance risks and derail commercialization plans.

Furthermore, 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. This pause was initially set to expire on July 9, 2025, but was extended thereafter, with significant tariff changes taking effect with certain countries on August 1, 2025. Tariffs have become a central part of the U.S. trade policy, undergoing continuous expansion and modification throughout 2025, including an announcement that starting October 1, 2025, the U.S. will impose a 100% tariff on any branded or patented pharmaceutical product, unless a company is building its pharmaceutical manufacturing plant in America. It is presently unclear 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, executive orders were signed to implement Most Favored Nation drug pricing policies designed to align certain prescription drug prices in the U.S. to lower prices available in other countries. Investigations are being conducted to examine price differentials and consider policy approaches for implementation, including through administrative action. If such Most Favored Nation policies are implemented, changes to drug pricing are expected to affect the profitability of pharmaceutical and biotech companies in the U.S. as well as in other countries, as a price referencing policy to the U.S. market could make it commercially unviable to commercialize a drug product in a price constrained market. 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 (which received a CRL and has now been approved) and for AXS-14 (which received a Refuse to File letter from the FDA, and which we plan to resubmit), 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 Note 14, we are required to pay to an entity owned by our Chief Executive Officer and Chairman of the Board certain royalty payments related to any 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, we received a Refuse to File from the FDA relating to the Company's product candidate AXS-14 for the management of fibromyalgia in June 2025. Likewise, our prior efforts have resulted in our decision not to further develop certain product candidates that, at one time, appeared to be promising. 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, we relied on the completed Phase 2 trial and Phase 3 trial to support an NDA for AXS-14 for the management of fibromyalgia; however, we received a Refuse to File from the FDA. We plan to conduct an additional Phase 3 trial to address FDA's feedback. Furthermore, although we believe that we are able to rely on the Phase 2 CONCERT trial, Phase 3 SYMPHONY trial, and Phase 3 ENCORE trial to support an NDA for AXS-12 for the treatment of cataplexy and narcolepsy, the FDA could still require additional studies to support the approval of an NDA for this and other 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 temporarily removed from the FDA website following an executive order, but was restored and reinstated the following month per a court order. However, it remains in draft form, which impacts 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. With respect to our NDA for AXS-14 for the management of fibromyalgia, the FDA stated that upon preliminary review, it found that our NDA was not sufficiently complete to permit a substantive review. To address the FDA's feedback, we plan to conduct an additional controlled trial, which will use a fixed-dose paradigm and a 12-week primary endpoint as requested 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 our other 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.

For example, in early September 2025, following a presidential memorandum directing the FDA to "take appropriate action to enforce the Federal Food, Drug, and Cosmetic Act's prescription drug advertising provisions, and otherwise ensure truthful and non-misleading information in direct-to-consumer prescription drug advertisements", the FDA issued more than 100 enforcement letters to pharmaceutical companies and compounding firms, alleging that certain promotional communications and direct-to-consumer advertisements are false and misleading. Furthermore, the Department of Health and Human Services (HHS) and FDA have stated that they are committed to a "more expansive reading" of the FDA's enforcement authorities than that taken by previous administrations.

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, 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. We settled the ensuing litigation in February 2025. 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. We have reached settlement agreements in the ensuing litigation with four of the six filers. We remain in ongoing litigation with the remaining two filers in the U.S. District Court for the District of New Jersey.

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 are approved but do 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 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 our most recent 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 Inflation Reduction Act ("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.

On April 15, 2025, the Administration issued an executive order (the "April 2025 EO") that, among other directives, directs HHS to work with Congress to align the treatment of small molecule drugs and biologics in the Medicare price setting program under the IRA. It is currently unclear how such modifications would affect the timeframe in which Medicare price setting becomes applicable for selected drugs or biologics. The April 2025 EO also directs HHS to provide recommendations within 180 days to accelerate the approval of generics, biosimilars, combination products and second-in-class medications, as well as to address Medicaid drug rebates and Medicaid drug payment methodologies, and, within one year, to develop and implement a plan to test a payment model to enable Medicare to obtain pharmaceuticals at lower cost. Other Centers for Medicare & Medicaid Services (CMS) policy changes and demonstration projects to test new care, delivery and payment models can also significantly affect how drugs, including our products, are covered and reimbursed. Legislative and regulatory proposals may also be made to expand post-approval requirements and restrict sales and promotional activities for drugs. To date, CMS has selected ten Medicare Part D drugs with prices to go into effect on January 1, 2026 and another 15 Part D drugs with prices to go into effect on January 1, 2027. Another 15 drugs from Medicare Part B or Medicare Part D will be selected by February 1, 2026, for the maximum price to be set and in effect by January 1, 2028. If any of our approved products are subject to price negotiations, it could, among other things, lead to lower revenues prior to the expiry of intellectual property protections. The Medicare drug price negotiation program is currently subject to legal challenges and, therefore, its outcome remains uncertain. We continue to evaluate the impact of the IRA on our business, operations and financial condition. 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.

Further, the ACA expanded the 340B drug discount program to additional facilities for outpatient drugs. These facilities may purchase drugs at the discounted price provided to Medicaid and dispense drugs to people with commercial insurance coverage. This program has greatly expanded over time with qualifying facilities establishing relationships with contract pharmacies, which has continued to exert downward pressure on price and profitability of outpatient medicines. Any changes to Medicaid required rebates could also affect our 340B pricing. Other aspects of the 340B program are subject to ongoing litigation, the resolution of which could impact the scope of the 340B program.

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 January 12, 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.

For example, the OBBBA reinstates the option to deduct domestic research and development expenditures in the year incurred, commencing with tax years beginning after December 31, 2024. Foreign research and development expenditures remain subject to the 15-year capitalization and amortization requirements. The OBBBA also includes other significant provisions, including tax cut extensions and modifications to the international tax framework. While we continue to evaluate the impact of these legislative changes as additional guidance becomes available, uncertainty remains regarding the timing and interpretation by tax authorities in affected jurisdictions.

Further, OBBBA has enacted, among others, changes to eligibility requirements for premium tax credits, which are expected to result in less coverage in the ACA's health insurance marketplace ("Marketplace") over the next few years. The ACA premium tax credits will expire at the end of 2025, which is expected to result in an additional loss of coverage for approximately 24 million people currently enrolled in insurance plans obtained through the Marketplace. In addition, the OBBBA has made other changes to the enrollment and eligibility requirements for Medicaid, which is expected to result in the loss of coverage for certain individuals currently enrolled in Medicaid programs.

***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 October 27, 2025, we had 816 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 October 27, 2025, our executive officers, directors, and 5% stockholders and their affiliates beneficially owned an aggregate of approximately 34% 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 October 27, 2025, we have outstanding 50,412,640 shares of common stock and 9,324,596 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, 42,498,356 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 2025 Long-Term Incentive 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 Blackstone Loan Agreement contains restrictive covenants that prohibit us from declaring or paying any dividends or making any other distributions on our common stock, except as may be expressly permitted under the facility. 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 third 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 third 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 Saad | Director | September 11, 2025[2] | March 15, 2027 | 48,577[3] |
| Nick Pizzie | Chief Financial Officer | September 15, 2025[2] | September 15, 2026 | 37,000[3] |
| Ari Maizel | Chief Commercial Officer | September 15, 2025[2] | November 30, 2026 | 27,500[3] |

(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.
(3) Represents the sale of shares underlying stock options that will be exercised prior to expiration.

**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 |
|---|---|
| 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: November 3, 2025

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

Date: November 3, 2025

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

**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: November 3, 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: November 3, 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 September 30, 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: November 3, 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 September 30, 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: November 3, 2025

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