UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2025

OR

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

Commission File Number: 001-39199



Scienture Holdings, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**46-3673928**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
20 Austin Blvd. Commack, NY 11725	**33634**
(Address of principal executive offices)	(Zip code)

(631) 670-6039
(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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, $0.00001 Par Value Per Share	SCNX	**The NASDAQ Stock Market LLC** (The NASDAQ Capital Market)

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

None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's

executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $10,203,000.

There were 40,630,815 shares of the registrant's common stock outstanding on March 27, 2026.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2026 annual meeting of stockholders (the "2026 Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K (this "Annual Report") where indicated. The 2026 Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Annual Report relates.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains statements that constitute forward-looking statements which are subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Statements that are not historical are forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Some of the statements in this Annual Report constitute forward-looking statements because they relate to future events or our future performance or future financial condition. These forward-looking statements are not historical facts, but rather are based on current expectations, estimates and projections about our company, our industry, our beliefs and our assumptions. Our forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. In some cases, the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "should," or the negative of these terms or other similar expressions, may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These forward-looking statements are subject to known and unknown risks, uncertainties and assumptions about us that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by such forward-looking statements.

Actual performance or results could differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

- risks related to our history of operating losses and that our operations may not become profitable;
- claims relating to alleged violations of intellectual property rights of others;
- our ability to manage our growth;
- regulatory and licensing requirement risks;
- risks related to changes in the U.S. healthcare environment;
- risks associated with the operations of our more established competitors;
- our ability to respond to general economic conditions, including financial market volatility and disruption, elevated levels of inflation, and declining economic conditions in the United States;
- changes in laws or regulations relating to our operations;
- our growth strategy;
- compliance with the continued listing requirements of the Nasdaq Stock Market LLC ("Nasdaq");
- risks relating to the liquidity and trading of our common stock;
- our ability to raise financing in the future;
- demand for our products and services may decline;
- data security breaches, cyber-attacks or other network outages; and
- other risks disclosed below under "*Risk Factors*."

The forward-looking statements contained in this Annual Report are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements.

These risks and uncertainties include, but are not limited to, those factors described under the section of this Annual Report entitled "*Risk Factors*". Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements.

We have based the forward-looking statements included in this Annual Report on information available to us on the date of this Annual Report, and we assume no obligation to update any such forward-looking statements. Although we undertake no obligation to revise or update any forward-looking statements in this Annual Report, whether as a result of new information, future events or otherwise, you are advised to consult any additional disclosures that we may make directly to you or through reports that we may file in the future with the Securities and Exchange Commission (the "SEC"), including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K.

SUMMARY OF RISK FACTORS

Our business is subject to numerous risks and uncertainties, many of which are beyond our control, including those highlighted in the section titled "*Risk Factors*" in this Annual Report. These risks include, among others, the following:

- We operate a clinical-stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate its current business and predict its future success and viability.
- We need additional capital which may not be available when needed or on commercially acceptable terms, thereby casting substantial doubt on our ability to continue as a going concern. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our product candidates.
- Due to the significant resources required to develop our product pipeline, and depending on our ability to access capital, we must prioritize the development of certain product candidates over others and we may fail to expend our limited resources on product candidates or indications that may have been more profitable or for which there is a greater likelihood of success.
- Our business is highly dependent on the success of certain product candidates. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize one or more of our product candidates, or if we experience delays in doing so, our business will be materially harmed.
- We may seek to collaborate with third parties and may not be able to implement these collaborations on commercially acceptable terms, if at all. The success of certain of our product candidates may depend in significant part on the success of such collaborations.
- The successful development of our pharmaceutical products involves a lengthy and expensive process and is highly uncertain.
- We are subject, directly or indirectly, to federal and state healthcare, fraud, abuse false claims, and other laws and regulations as well as health data privacy and security laws and regulations, contractual obligations and self-regulatory schemes. If we are unable to comply, or have not fully complied, with such laws, we could face investigations and substantial penalties. Furthermore, it may be difficult and costly for us to comply with the extensive government regulations to which our business is subject.
- We may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our business and results of operations.
- Even if we obtain regulatory approval for any of our product candidates, we will be subject to ongoing regulatory requirements, which may result in significant additional expenses. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.
- Even if we obtain FDA approval for a product candidate in the United States, we may never obtain approval for or successfully commercialize that candidate outside of the United States, which would limit our ability to realize a product's full market potential.
- Even if we are able to commercialize any of our product candidates, the third-party payor coverage and reimbursement status of newly-approved products are uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates could limit our ability to market those products and decrease our ability to generate revenue.
- We are developing a drug-device combination product, which may result in additional regulatory risks.
- Our third party collaborators and service providers are, or may become, subject to a variety of stringent and evolving privacy and data security laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to privacy and data security. Any actual or perceived failure to comply with such obligations could expose us to significant fines or other penalties and otherwise harm our business and operations.
- Healthcare legislative reform measures may have a negative impact on our business and results of operations.
- We may not be able to protect our intellectual property and trade secret rights throughout the world. If our efforts to protect our intellectual property rights are inadequate, we may not be able to compete effectively in our market.
- We depend on in-licensed intellectual property. If we fail to comply with our obligations under intellectual property licenses with third parties, we could lose license rights that are important to our business.
- If we or our licensors are unable to obtain and maintain patent protection for our product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to our product candidates, and our ability to successfully commercialize our product candidates may be adversely affected. Furthermore, we do not intend to seek patent protection for one of our products, SCN-106.
- Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies. Our patent protection could be reduced or eliminated for non-compliance with these requirements.
- Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.
- We may be subject to claims challenging the inventorship or ownership of our intellectual property or asserting that we violated intellectual property rights of others, the outcome of which would be uncertain. These claims could be extremely costly to defend, could require us to pay significant damages and limit our ability to operate, and could distract our personnel from normal responsibilities.
- European patents and patent applications could be challenged in the recently created Unified Patent Court for the European Union.
- Our use, or the use by our third party collaborators and service providers, of new and evolving technologies, such as artificial intelligence ("AI") and machine learning ("ML"), may result in spending additional resources and present new risks and challenges that can impact our business, including by posing security and other risks to our sensitive data. As a result, we may be exposed to reputational harm, other adverse consequences, and liability.
- If our trademarks and trade names are not adequately protected then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.
- We may not be able to comply with Nasdaq's continued listing standards.
- Our common stock has in the past been a "penny stock" under SEC rules, and may be subject to the "penny stock" rules in the future. It may be more difficult to resell securities classified as "penny stock."
- The exercise of outstanding warrants, options and other securities that are exercisable into shares of our common stock will be dilutive to our existing stockholders.
- We have not historically paid or declared any dividends on our common stock and do not expect to pay or declare cash dividends in the future on a regular basis, if at all.
- Our common stock price is likely to be highly volatile because of several factors, including a limited public float.
- There may not be sufficient liquidity in the market for our securities in order for investors to sell their shares. The market price of our common stock may continue to be volatile.
- Stockholders may be diluted significantly through our efforts to obtain financing and satisfy obligations through the issuance of additional shares of our common stock.

PART I

ITEM 1. BUSINESS

INTRODUCTION

This information included in this Annual Report should be read in conjunction with the consolidated financial statements and related notes in "*Item 8. Financial Statements and Supplemental Data*" of this Annual Report.

Our logo and some of our trademarks and tradenames are used in this Annual Report. This Annual Report may also include trademarks, tradenames and service marks that are the property of others. Solely for convenience, trademarks, tradenames and service marks referred to in this Annual Report may appear without the ®, ™ and SM symbols. References to our trademarks, tradenames and service marks are not intended to indicate in any way that we will not assert to the fullest extent under applicable law our rights or the rights of the applicable licensors if any, nor that respective owners to other intellectual property rights will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend the use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

The market data and certain other statistical information used throughout this Annual Report are based on independent industry publications, reports by market research firms or other independent sources that we believe to be reliable sources. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We are responsible for all of the disclosures contained in this Annual Report, and we believe these industry publications and third-party research, surveys and studies are reliable. While we are not aware of any misstatements regarding any third-party information presented in this Annual Report, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under the section entitled "*Risk Factors*" of this Annual Report. These and other factors could cause our future performance to differ materially from our assumptions and estimates. Some market and other data included herein, as well as the data of competitors as they relate to us, are also based on our good faith estimates.

Our fiscal year ends on December 31st. Interim results are presented on a quarterly basis for the quarters ended March 31st, June 30th, and September 30th, the first quarter, second quarter and third quarter, respectively, with the quarter ending December 31st being referenced herein as our fourth quarter. "Fiscal 2025" means the Fiscal year ended December 31, 2025, whereas "Fiscal 2024" means the year ended December 31, 2024.

Unless the context requires otherwise, references to the "Company," "we," "us," and "our" refer specifically to Scienture Holdings, Inc., and its consolidated subsidiaries.

Available Information

We file annual, quarterly, and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at http://www.sec.gov and are available for download, free of charge, soon after such reports are filed with or furnished to the SEC, on the "Investors" page of our website at www.scientureholdings.com. Copies of documents filed by us with the SEC are also available from us without charge, upon oral or written request to our Secretary, who can be contacted at the address and telephone number set forth on the cover page of this Annual Report. Our website addresses are www.scientureholdings.com, www.scienture.com, www.trxadehealth.com and www.rxintegra.com. The information on, or that may be accessed through, our websites is not, and shall not be deemed to be, part of this Annual Report or incorporated by reference into any other filings we make with the SEC, except as expressly set forth by specific reference in any such filings. All website addresses in this Annual Report are intended to be inactive textual references only.

Current Business – Scienture LLC

Overview

Scienture LLC was originally incorporated in Delaware and commenced operations in 2019. In connection with our acquisition in July 2024, Scienture LLC became a wholly owned subsidiary of the Company. Scienture's principal executive offices are located in Commack, New York.

Scienture LLC is a specialty pharmaceutical company focused on the commercialization and development of products for the treatment of cardiovascular ("CVS") and Central Nervous System ("CNS") diseases. Scienture LLC launched its first commercial product for hypertension and is in the process of commercializing its second product for the treatment of opioid overdose. Its development pipeline consists of a broad range of novel product candidates including new potential treatments for migraine, thrombosis, pain and other related disorders.

Scienture LLC's Strategy

Scienture LLC's mission is to improve the lives of patients suffering from CNS and CVS diseases. Scienture LLC's vision is to be a leader in the industry by commercializing and developing new medicines for the treatment of CNS and CVS diseases. Key elements of Scienture LLC's strategy to achieve this vision include:

- *Advance product candidates through clinical studies and toward commercialization.* Scienture LLC is in various stages of clinical development for the product candidates in its pipeline, and it intends to move these programs efficiently toward being commercially available to patients, subject to approval by the U.S. Food and Drug Administration (the "FDA"). Scienture LLC obtained regulatory approval of its first product candidate, SCN-102 (*Arbli*^{TM}) in the first quarter of 2025.

- *Drive growth and profitability.* Using dedicated sales and marketing resources in the U.S., Scienture LLC will seek to drive the revenue growth of its product candidates approved for marketing by the FDA and will also evaluate and seek additional commercial ready product opportunities through acquisitions and partnerships to expand its marketed portfolio. Scienture, LLC completed the acquisition of the commercial ready product asset *REZENOPY*^{TM} in the first quarter of 2025.

- *Target strategic business development opportunities.* Scienture LLC is exploring a broad range of strategic opportunities. This may include acquiring, in-licensing and entering into co-promotion partnerships for commercial products to expand its marketed portfolio.

- *Continue to grow its development pipeline.* Scienture LLC will continue to evaluate and seek to develop additional product candidates that it believes have significant commercial potential through Scienture LLC's internal research and development efforts and through co-development partnerships.

Commercial Product Portfolio

Scienture LLC is committed to building and leveraging its strong commercial platform and infrastructure to launch its FDA approved product candidates in the U.S. The progress of Scienture LLC's products through this process is represented in the table below.



Arbli™ (SCN-102 - Losartan Potassium Oral Suspension, 10mg/mL)

Arbli™ (SCN-102) is an oral liquid formulation of losartan potassium in development under the 505(b)(2) pathway, for (i) treatment of hypertension, to lower blood pressure in adults and children greater than 6 years old, (ii) reduction of the risk of stroke in patients with hypertension and left ventricular hypertrophy, and (iii) treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria in patients with type 2 diabetes and a history of hypertension. Currently, there are no FDA-approved liquid formulations of losartan potassium.

Arbli™ (SCN-102) is the first and only FDA approved oral liquid formulation of losartan on the market. Scienture LLC submitted an Investigational New Drug ("IND") application to the FDA in September 2022. Multiple human pharmacokinetics studies were performed, showing close comparability with the oral solid dosage form. In October 2023, Scienture LLC submitted a New Drug Application ("NDA") for losartan potassium oral suspension to the FDA. In December 2023, the FDA accepted the NDA for review and assigned a Prescription Drug User Fee Act ("PDUFA") target action date of August 19, 2024. Despite responding during the FDA's review to information requests related to chemistry, manufacturing, and controls ("CMC"), pharmacovigilance, clinical, microbiology and labeling, the FDA issued a Complete Response Letter to Scienture LLC focused on the CMC information submitted. Scienture LLC prepared the requested information and resubmitted the NDA to the FDA on September 17, 2024. In October 2024, the FDA accepted the resubmitted NDA for review and assigned a PDUFA target action date of March 17, 2025. On March 13, 2025, the FDA approved the SCN-102 NDA to be launched as ARBLI™ (losartan potassium) Oral Suspension, 10mg/mL. Scienture LLC commercially launched the product in the third quarter of 2025. Arbli™ (SCN-102) is the first FDA approved oral liquid formulation of losartan on the market.

A Phase I PK study has shown that SCN-102 has close comparability to the immediate-release tablet as depicted in the data below:

Summary of Statistical Results for Losartan Potassium Oral Liquid 10 mg/ml (T) versus Losartan Potassium Immediate Release Tablets 100 mg (R) – For Losartan

PK Parameter	N	Geometric Means of treatment: Test (T)	Geometric Means of treatment: Reference (R)	Ratio (%)	Intra-subject %CV	90% CI of Ratio	SABE Result – Bound	SABE SWR
Log C_{max} (ng/ml)	44	1317.6955	974.6741	135.19	39.6	122.19 – 149.58	0.070	0.3361
LogAUC_{0-t} (ng.hr/ml)	44	1590.6271	1581.0602	100.61	13.2	97.25 – 104.08	-0.014	0.1576
LogAUC_{0-inf} (ng.hr/ml)	44	1615.4717	1605.3052	100.63	13.0	97.34 – 104.03	-0.014	0.1549

Summary of Statistical Results for Losartan Potassium Oral Liquid 10 mg/ml (T) versus Losartan Potassium Immediate Release Tablets 100 mg (R) – For Carboxylic Acid Metabolite

PK Parameter	N	Geometric Means of treatment: Test (T)	Geometric Means of treatment: Reference (R)	Ratio (%)	Intra-subject %CV	90% CI of Ratio	SABE Result – Bound	SABE SWR
Log C_{max} (ng/ml)	44	1160.0978	1056.3253	109.82	25.5	102.91 – 117.20	-0.028	0.2828
LogAUC_{0-t} (ng.hr/ml)	44	6775.8841	6726.8952	100.73	10.3	98.11 – 103.42	-0.006	0.1099
LogAUC_{0-inf} (ng.hr/ml)	44	6872.6739	6823.3736	100.72	10.2	98.13 – 103.39	-0.006	0.1071

Specifically, the Phase I PK study showed that SCN-102 was comparable to immediate release tablets based on the following:

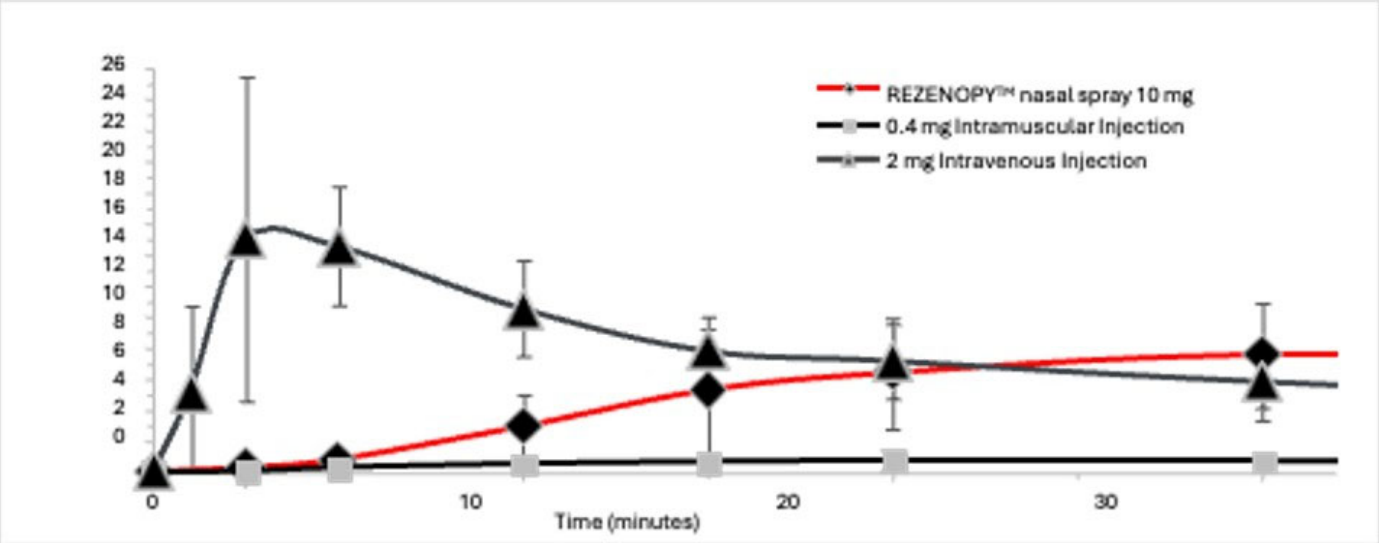
- The overall exposure for the Carboxylic Acid metabolite (EXP-3174) meet the confidence interval 80-125% range.
- The overall exposure for Losartan were within the 90% confidence interval.
- The Cmax for Losartan analyte, a pro-drug, for SCN-102 was slightly higher than the immediate release tablets (122.19 - 149.58%). This is due to the fact that the SCN-102 (oral liquid) and the reference product are two different dosage forms. SCN-102 is an oral liquid formulation and therefore it is expected to have an earlier Cmax than the immediate release tablet. Based on the discussion above, we believe that the impact of this Cmax difference will be minimal.
- The data obtained in the study is similar to the PK study data for the immediate release tablet.

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REZENOPY™ (SCN-110 – Naloxone HCl Nasal Spray, 10mg)

Scienture LLC entered into an Exclusive Commercial and Supply Agreement (the "Kindeva Agreement") with Summit Biosciences Inc., a wholly-owned subsidiary of Kindeva, on March 4, 2025, pursuant to which Kindeva granted Scienture LLC an exclusive, non-transferrable, non-sublicensable right and license to commercialize REZENOPY™ (Nalaxone HCl nasal spray 10mg/0.11mL) within the United States and its territories. Scienture LLC intends to use the exclusive right and license to price, launch, promote, market, distribute, and educate the public on REZENOPY™.

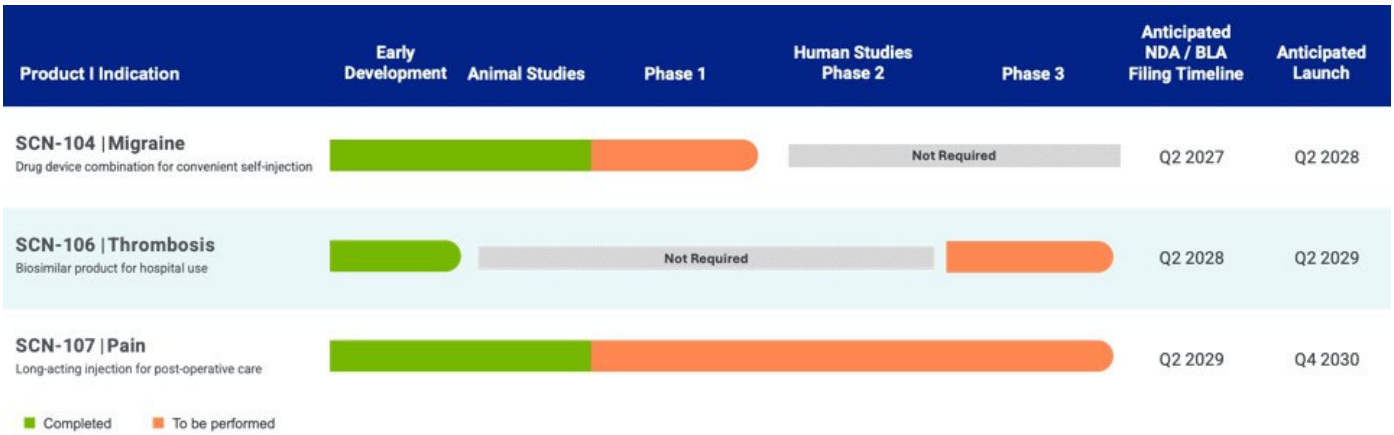
In a pharmacokinetic study in 30 healthy adult subjects, the relative bioavailability of one nasal spray of a 10 mg total dose (0.11 mL of 91 mg/mL naloxone hydrochloride solution) was compared to a single dose of 0.4 mg naloxone hydrochloride intramuscular injection and a single dose of 2 mg naloxone hydrochloride intravenous injection. The studies showed that REZENOPY™ provided exposures comparable to the reference treatments, supporting the efficacy of the product. The studies further demonstrated the safety and tolerability of the product, including testing to evaluate nasal irritation and impact on olfactory ability.



Parameter	REZENOPY nasal spray 10 mg (n=29)	Naloxone HCl 0.4 mg Intramuscular Injection (n=30)	Naloxone HCl 2 mg Intravenous Injection (n=23)
t_{max} (h)	0.75 (0.25, 1.03)	0.50 (0.17, 2.00)	0.08 (0.02, 0.18)
C_{max} (ng/mL)	9.11 (35.45)	0.74 (36.63)	18.41 (46.08)
AUCt (h·ng/mL)	19.19 (24.81)	1.92 (19.75)	12.18 (24.30)
$AUC_{0-\infty}$ (h·ng/mL)	19.52 (24.78)	1.98 (19.18)	12.25 (24.22)
Dose normalized absolute BA vs. IV	0.34 (30.53)	0.84 (29.06)	-

Research and Development Pipeline

Scienture LLC is committed to the development of innovative product candidates in the CNS and CVS therapeutic areas. The process by which Scienture LLC intends to bring its product candidates to market and the anticipated launch dates of its product candidates is depicted in the following table.



Scienture LLC is engaged in a variety of research and development efforts including development of a pipeline of novel product candidates for the treatment of various disease conditions. Scienture LLC has devoted and will continue to devote significant resources to research and development activities, and expects to incur significant expenses as it continues advancing its product candidates towards FDA approval and expanding product indications for approved products and its intellectual property portfolio. Scienture LLC's expectations regarding its research and development programs are subject to risks, including the risk that Scienture LLC's financial condition and results of operations may be materially and adversely affected by delays and failures in the completion of clinical development of its product candidates, which could increase its costs or delay or limit our ability to generate revenues.

SCN-104 (Multi-dose Dihydroergotamine Mesylate ("DHE") injection pen)

The SCN-104 injection pen is a disposable, multiple fixed dose, single entity combination product comprised of a small molecule drug, SCN-104, which is administered using a customized injection pen. SCN-104 is a drug product containing DHE as the active ingredient. The mechanism of action of SCN-104 is mediated through DHE and is exactly the same as that of DHE. DHE is available in the market as a single dose nasal spray, which has a high degree of variability in clinical outcomes. DHE is also available in the market as single dose ampoules for injection, however, Scienture LLC believes that the process of dose withdrawal from the ampoule followed by self-injection at the time of intense need is cumbersome and difficult for the patient.

Scienture LLC believes that the SCN-104 multi-dose self-injection pen is easy to use and provides enhanced patient convenience. Furthermore, Scienture LLC believes that the SCN-104 injection pen provides for consistent and accurate delivery of every dose which results in better exposure compared to the nasal spray formulation. The SCN-104 injection pen is being developed via the 505(b)(2) regulatory pathway. The SCN-104 injection pen is in development for the acute treatment of migraine headaches with or without aura and the acute treatment of cluster headache episodes.

As shown in third party studies of DHE, SCN-104's mechanism of action for its antimigraine effect is due to its potential action as an agonist at the serotonin 5-HT1D receptors. SCN-104 is intended for subcutaneous administration. SCN-104 is also intended for acute use and is not intended for chronic administration.

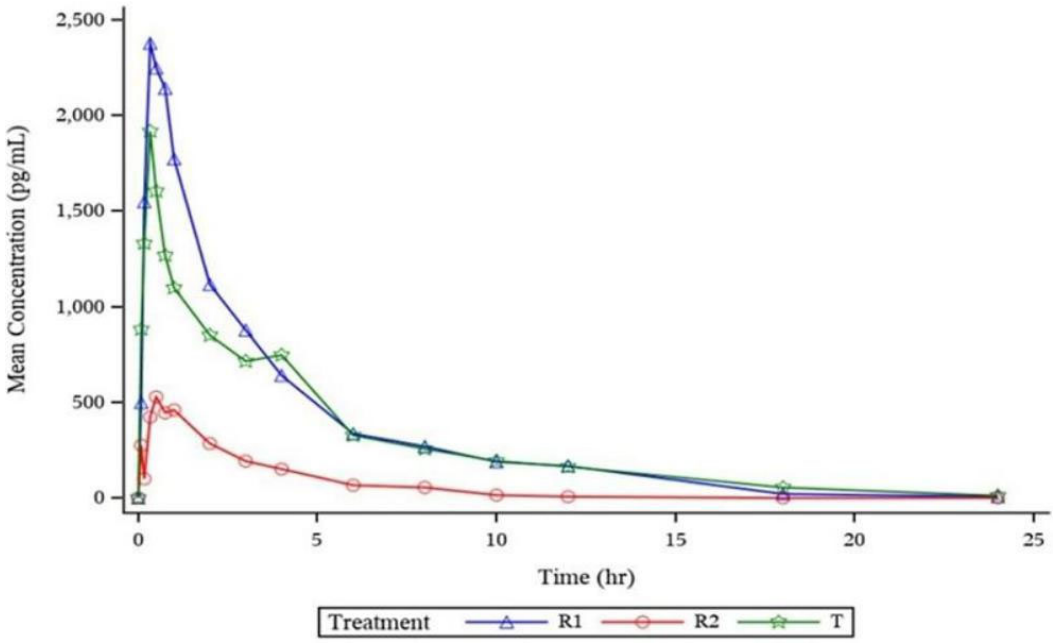
Scienture LLC has conducted two preclinical studies of SCN-104 and the SCN-104 injection pen: (i) a 30-day repeated dose toxicity study of dimethyl sulfoxide and caffeine following thrice daily, 3 times per week subcutaneous administration in Sprague-Dawley rats and (ii) a 30-day repeated dose toxicity study of dimethyl sulfoxide and caffeine following thrice daily, 3 times per week subcutaneous administration in Göttingen minipigs. The objective of each study was to evaluate the safety and tolerability of the test items with and without DHE to the subject animals, providing information on important potential toxic effects, target organs, progressive toxic effects, characterization of a possible dose-response relationship, and an estimate of the No-Observed-Adverse-Effect Level. Both studies were designed for the qualification of the excipients. The animals treated either with DHE + Dimethyl Sulfoxide ("DMSO") + caffeine or DMSO + caffeine formulations did not reveal any changes attributable to treatment at the end of the treatment/recovery periods. As such, both studies support a conclusion that SCN-102 is considered to have no toxicological significance across the following attributes – Hematology, Coagulation Parameters, Clinical Chemistry and Urinalysis.

Scienture LLC believes the SCN-104 injection pen may offer a significant improvement, in terms of usability and patient acceptability, to the current standard of care in the market (ampoules for injection). The intended pen delivery system was designed with patients in mind to carry multiple doses, have a lower volume of injection, and utilize shielded needles to avoid unnecessary exposure.

Scienture LLC has had initial discussions with the FDA to align on a path forward for this development program. As a result of these discussions, Scienture LLC learned that its proposed plan for manufacturing NDA registration batches and that the reference product and dose selection of the reference product that Scienture LLC selected for a comparative regulatory study are acceptable. Scienture LLC also received guidance from the FDA on nonclinical safety studies and stability testing. The formulation has been scaled up to enable future commercial scale production and the pen has been optimized for commercial use. As shown below, several pharmacokinetics studies have shown comparability between SCN-104 and the currently available marketed injection product.

PK Parameter (Units)	Dihydroergotamine					
	Treatment T (Test)	N	Treatment R_1 (Reference)	N	Treatment R_2 (Reference)	N
C_{max} (pg/mL)	2842.42 (2488.634)	18	2526.03 (469.296)	17	819.28 (1111.011)	18
AUC_{0-t} (h*pg/mL)	6773.54 (1363.241)	18	7684.24 (1381.049)	17	1587.43 (1270.019)	17
$AUC_{0-\infty}$ (h*pg/mL)	8097.35 (1871.544)	18	8956.95 (1664.083)	17	2709.05 (1318.836)	12
*T_{max} (hr)	0.33 (0.08, 4.00)	18	0.50 (0.33, 1.00)	17	0.50 (0.00, 1.00)	18
Kel (1/h)	0.13 (0.055)	18	0.15 (0.061)	17	0.28 (0.193)	12
Thalf (h)	6.66 (3.405)	18	6.42 (4.962)	17	3.34 (1.618)	12
AUC Ratio (%)	84.13 (6.562)	18	86.33 (7.999)	17	73.33 (12.923)	12
AUC Extrapolation (%)	15.87 (6.562)	18	13.67 (7.999)	17	26.67 (12.923)	12

PK Parameter	Least Squares Geometric Means of Treatment:		Ratio (%)	Intra-subject %CV	90% CI of Ratio
	Test (T)	Reference (R_1)			
Log C_{max} (ng/mL)	2397.74	2484.55	96.51	41.75	75.68 - 123.06
LogAUC_{0-t} (h*pg/mL)	6519.81	7534.81	86.53	15.89	78.63 - 95.23
LogAUC_{0-inf} (h*pg/mL)	7681.74	8788.14	87.41	17.79	78.54 - 97.29



Scienture LLC is initiating manufacturing activities and planning to conduct bioequivalence studies. Scienture LLC plans to initiate a Phase 1 single dose study in healthy adults in 2026, following submission of an IND, if the IND is cleared by the FDA.

SCN-106 (Potential Biosimilar)

Scienture LLC is developing a potential biosimilar, SCN-106, based on Cathflo Activase, a reference product that is a thrombolytic agent that binds to fibrin in clots and converts entrapped plasminogen to plasmin. SCN-106 is a sterile, purified glycoprotein that is synthesized using the complementary DNA for natural human tPA obtained from a Chinese hamster ovary cell-line.

Scienture LLC is working with Anthem Biosciences Pvt, Ltd. ("Anthem") to develop a biosimilar product that utilizes the same mechanism(s) of action for the proposed condition of use, and has the same route of administration, dosage form, and strength as the reference product. In this regard, Scienture LLC entered into a Master Services Agreement with Anthem on October 29, 2024 (the "Anthem Agreement"). The following is a summary of the Anthem Agreement, which is qualified in its entirety by the full text of the Anthem Agreement, which is filed as an exhibit to this Annual Report.

Under the Anthem Agreement, Anthem has agreed to diligently complete the services associated with SCN-106 as included in work orders to be attached to the Anthem Agreement. In performing these services, Anthem has agreed to strictly comply with the specifications in the Anthem Agreement, the work order, standard operating procedures approved in writing by Scienture LLC, and relevant professional standards, and any regulatory authority requirements, including current Good Laboratory Practices ("GLPs") and current Good Manufacturing Practices ("GMPs") promulgated by the FDA, and any other applicable laws, rules, and regulations. In carrying-out its services, Anthem will only allow those employees and personnel under Anthem's direct control to perform such services and will obtain Scienture LLC's consent prior to delegating or subcontracting any portion of the services. Anthem is required to provide prompt written reports to Scienture LLC on the status of the services provided by Anthem under the Anthem Agreement and any work order. Under the Anthem Agreement, Scienture LLC is responsible for paying Anthem the amounts designated on any attached work order. These amounts are to be paid on the schedule stated on the work order and Anthem is responsible for invoicing Scienture LLC for such amounts. Undisputed late payments incur interest at the rate of 18% per annum payable until the date of actual payment.

Any project or work order in effect under the Anthem Agreement may be terminated by Scienture LLC without cause upon thirty (30) days' prior notice to Anthem. Anthem may terminate the Anthem Agreement without cause upon thirty (30) days' prior notice to Scienture LLC. However, Anthem is responsible for delivering all services and deliverables under the Anthem Agreement then required to be performed by Anthem under a work order prior to any such termination. Either party may terminate the Anthem Agreement upon the breach of the Anthem Agreement by the other party if the breach remains uncured for a period of thirty (30) days. In the event that performance by Anthem or Scienture LLC under the Anthem Agreement is delayed due to an event beyond the control of Anthem or Scienture LLC for a period of ninety (90) days, then the other party can terminate the Anthem Agreement upon written notice.

With respect to projects to be performed by Anthem under the Anthem Agreement, any and all materials relating to such projects are the property of Scienture LLC, and are to be protected as such by Anthem. Furthermore, Anthem has agreed to irrevocably assign to Scienture LLC all right, title, and interest in and to any "Program Technology" (as defined in the Anthem Agreement) and to make any assignments necessary to ensure that Scienture LLC has such ownership interest. The Anthem Agreement also contains customary confidentiality obligations, representations and warranties, indemnification provisions, and anti-assignment provisions. The Anthem Agreement may only be amended upon the written consent of both parties.

The CMC development program is focused on establishing the analytical similarity of SCN-106 to the reference product. Multiple clones of Chinese hamster ovary ("CHO") cells have been produced to synthesize lots of SCN-106 which were screened for similarity to the reference product for several key biochemical quality attributes as well as overall protein yield and finalization of a lead clone.

Scienture LLC completed a Biosimilar Initial Advisory meeting with the FDA in June 2023 to discuss the CMC, non-clinical, and clinical studies required for regulatory approval. As a result of this meeting, Scienture LLC learned that its analytical strategy for initiating analytical similarity studies between SCN-106 and a proposed biosimilar product is acceptable. Scienture LLC also learned that SCN-106 is suitable for further development and received guidance from the FDA on a comparable clinical study needed to demonstrate biosimilarity of SCN-106 and the reference product.

SCN-107 (Bupivacaine Long-Acting Injection)

SCN-107 is a long-acting injection suspension formulation of a non-opioid analgesic that is indicated for postsurgical local and regional analgesia. Scienture LLC's long-acting formulation, SCN-107, is a novel microsphere-based formulation of bupivacaine that comprises the drug in polymer-based microspheres and is intended to provide pain management over a period of 5-7 days. The product candidate is designed to potentially provide longer term post-surgical pain relief compared to the currently available products in the market.

Based on initial discussions with FDA regarding this program, Scienture LLC believes this product candidate would require at least one Phase 3 clinical trial to support submission of a marketing application.

Scienture LLC anticipates submitting an IND and, if cleared by the FDA, initiating a Phase 1 single dose study in healthy adults in 2026 to conduct an initial assessment of safety and tolerability of SCN-107.

Scienture LLC entered into a Feasibility Study and Animal Trial Material Manufacturing Agreement with Innocore Technologies, B.V. ("Innocore") on May 26, 2020 (as amended on December 2, 2022, the "Innocore License"), for certain intellectual property rights associated with SCN-107. Under the Innocore License, Innocore granted Scienture LLC a worldwide exclusive, milestone, royalty-bearing and sublicensable license to certain patent rights for the research and development of SCN-107 in postsurgical local and regional analgesia. Pursuant to the Innocore License, Scienture LLC is required to make low single-digit percentage royalty payments based on annual net sales of licensed products for the first three years of sales on a country-by-country basis, subject to a low single digit increase as of the fourth year of sales on a country-by-country basis.

Sales and Marketing

Scienture LLC intends to market its products through its own sales forces in the U.S. and seek strategic collaborations with other pharmaceutical companies to commercialize its products outside of the U.S. Scienture LLC is in the process of building a commercial sales and marketing operation in the U.S., through a partnership with a Contract Sales Organization, to support sales of Scienture LLC's products. This sales and marketing organization will include a combination of field teams, virtual sales representatives and omnichannel marketing to effectively reach health care providers and offer patient education. Scienture LLC's promotional efforts are expected to further include developing a market access strategy to obtain commercial and government payor coverage for its products. In addition, Scienture LLC intends to partner with a third-party logistics provider and have internal sales operations and analytics teams to provide state-of-the-art distribution capabilities to wholesalers, pharmacies, institutional buying groups and hospitals. Scienture LLC believes its commercial operations infrastructure, will enable it to effectively target healthcare providers to support and grow its products subsequent to market entry.

Customers

The majority of Scienture LLC's product sales, if its products are approved by the FDA, are expected to be to pharmaceutical wholesalers, specialty pharmacies, and distributors who, in turn, would sell such products to pharmacies, hospitals, long term care institutions and other customers, potentially including federal and state entities.

Market and Competition

Scienture LLC is engaged in segments of the pharmaceutical industry that are highly competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and other public and private research organizations are commercializing or pursuing the development of products utilizing the same molecules or compounds or for the same indications that Scienture LLC is currently pursuing or may target in the future.

Hypertension

Hypertension (high blood pressure) is a CVS condition, when the pressure in the blood vessels is too high (140/90 mmHg or higher). According to the Centers for Disease Control, hypertension, or high blood pressure, affects nearly half of adults in the U.S. (48.1%, or approximately 119.9 million people). Hypertension is defined as a systolic blood pressure of 140 mmHg or higher, and diastolic blood pressure of 90 mmHg or higher. Hypertension is a risk factor for stroke and heart disease, which are leading causes of death in the U.S. Factors that increase the risk of having high blood pressure include: older age, genetics, being overweight or obese, not being physically active, high-salt diet and drinking too much alcohol. Hypertension is clinically diagnosed if, when blood pressure is measured on two different days, the systolic blood pressure readings on both days is ≥140 mmHg and/or the diastolic blood pressure readings on both days is ≥ 90 mmHg.

The hypertension market has increased with the commercial launch of several branded products in recent years, as well as the launch of generic versions of branded drugs, such as Prinvil, Lotensin, Cozaar, Cardizem, Apresoline, Nitrostat and Toprol-XL. Treatment options for hypertension in the U.S. market can be broadly classified across the following product classes, Angiotensin-converting enzyme ("ACE") inhibitors, Angiotensin II receptor blockers ("ARBs"), Beta-Blockers, Diuretics and Calcium Channel Blockers.

Scienture LLC's product, Arbli™ (Losartan Oral Suspension 10mg/mL), is a ready to use oral suspension of losartan for increased patient convenience and ease of dosing. Losartan is classified as an ARB for treating hypertension and is one of the highest prescribed molecules for this indication. Current products in the market containing losartan are available only as oral solids, which can be further compounded to a liquid formulation. Scienture LLC believes that Arbli™ is the first liquid formulation of losartan on the market that does not require compounding and has reduced dosing volume and long-term shelf life at room temperature storage.

Opioid Abuse

The opioid overdose epidemic remains a significant public health issue and continues to rise exponentially in the U.S. According to the 2024 National Survey on Drug Use and Health, among people aged 12 or older in 2024, 2.7 percent (or 7.8 million people) misused opioids in the prior year. Additionally, according to the Centers for Disease Control, new preliminary data predicts that there were 71,542 drug overdose deaths for the 12 months ending in October 2025. The majority of those deaths involved highly potent synthetic opioids and their analogues. These synthetic opioids are highly powerful, with fentanyl and carfentanil estimated to be up to 100 and 10,000 times more potent than morphine, respectively. While fentanyl has been available in prescription form as an analgesic for some time, data indicates that the dramatic rise in drug overdose deaths in recent years can be attributed primarily to the influx of illicitly manufactured synthetic opioids.

Approved by the FDA in 1971, naloxone is considered the standard of care and has been shown to be effective in opioid overdose reversals. The opioid overdose reversal market (specifically for naloxone-based products) includes several branded and generic products across nasal spray, auto-injector, and injectable formulations. Most growth in recent years has been in intranasal products, such as Narcan 4mg, RiVive 3mg and Kloxxado 8mg, which are needle free and easier for bystanders and community responders to use. Real world studies suggest the need for multiple naloxone administrations ("MNA") using these products among bystanders and EMS providers continues to increase. With the increase of synthetic opioids and the rapid onset of effect, evidence is emerging suggesting the need for increased doses of naloxone to reverse opioid toxicity.

REZENOPY™ (Naloxone HCl Nasal Spray, 10mg) is the highest FDA-approved nasal spray dose available in the U.S. market. The product provides maximum naloxone protection in a single easy-to-use device and caters to the segment of patients who need multiple doses of lower strength for stabilization in emergency situations. REZENOPY™ provides potential longer duration of opioid receptor block, improves chances of quicker reversal and possible coverage against multiple abuse agents inclusive of synthetic opioids and combinations, through a single dose administration of 10mg naloxone hydrochloride. High dose REZENOPY™ improves the chances of reversing potent opioids quickly and reducing the requirement of MNA.

Migraine

Migraine is a painful, complex neurological disorder consisting of recurring painful attacks that can significantly impact quality of life. Migraine headaches are often characterized by throbbing pain, extreme sensitivity to light or sound, and potentially nausea and vomiting. The World Health Organization categorizes migraine as one of the most disabling medical illnesses worldwide. The American Research Foundation categorizes migraine as the third most prevalent illness in the world, and nearly 1 in 4 U.S. households includes someone with migraines. Migraine is estimated to affect over 39 million individuals in the U.S.

Current products in the market that are available to treat migraine headaches, include CGRP antagonists (calcitonin gene related peptide), which is a class of products first introduced in 2018 (Nurtec, Ubrelvy), Botox, branded and generic versions of triptans (Imitrex, Maxalt, Relpax), and ergot alkaloids (Ergotamine and Dihydroergotamine (DHE)).

Scienture LLC's product candidate, SCN-104, is supplied in a multi-dose pen-based delivery system for self-injection and increased patient convenience. The product candidate is in development for the acute treatment of migraine headaches with or without aura and the acute treatment of cluster headache episodes.

Thrombotically Occluded Catheter (CVAD) Management

Catheters, which are a type of a Central Venous Access Device ("CVAD"), are employed to deliver life-sustaining therapies. They can be used for short-term or long-term infusion of antibiotics, parenteral nutrition, chemotherapy, blood and blood products in patients with limited peripheral access. More than 7 million CVADs are inserted each year in patients in the United States. Occlusion of catheters while in use can complicate patient care by interrupting the administration of medications and solutions, delaying or disrupting therapies and leading to additional procedures such as catheter replacement. Occlusion is the most common noninfectious complication in the long-term use of CVADs and may occur soon after insertion of a device or develop at any time. About 58% of catheter occlusions are thrombotic, resulting from the formation of a thrombus within, surrounding, or at the tip of the catheter.

Scienture LLC's product candidate, SCN-106, is a thrombolytic agent currently in development. Scienture LLC plans to develop SCN-106 through the FDA's 351(k) pathway for biosimilars.

Postoperative Pain

Post-surgery pain, also known as postoperative pain, is pain that a patient experiences after a surgical procedure. Pain can be caused by a number of factors, including: the type of procedure, the size of the operation, and medications used during surgery. Chronic pain can negatively impact a patient's rehabilitation, quality of life, and the results of the procedure.

Current drug product treatments available in the market for treating postoperative pain include IV and oral opioids, injectable local anesthetics, and steroidal and non-steroidal analgesics. Marketed products include branded and generic versions of Celebrex, Ketalar, Exparel, Lyrica, Neurontin and Astromorph.

Scienture LLC's product candidate, SCN-107, is a microsphere based long-acting injection of Bupivacaine, a local anesthetic, in development for postsurgical analgesia. SCN-107 is designed to be a non-opioid treatment regimen with rapid onset of action and analgesia that is intended to provide coverage over a period of 5-7 days.

Manufacturing

Scienture LLC currently depends on third-party commercial manufacturing organizations ("CMOs") for all manufacturing operations, including the production of raw materials, finished dosage form product, and product packaging for both its planned commercial scale manufacturer and the products used in its preclinical and clinical research. Scienture LLC does not own or operate manufacturing facilities for the production of any of its product candidates nor does Scienture LLC have plans to develop its own manufacturing operations in the foreseeable future to support clinical trials or commercial production. Scienture LLC currently employs internal resources to manage its manufacturing contractors.

Scienture LLC is in discussion with CMOs headquartered in North America, Europe and Asia for its pipeline product candidates. These CMOs offer a comprehensive range of commercial contract manufacturing and packaging services.

If Scienture LLC fails to produce its products and product candidates in the volumes that Scienture LLC requires on a timely basis, or fails to comply with stringent regulations applicable to pharmaceutical drug manufacturers, Scienture LLC may face delays in the development and commercialization of its products and product candidates or be required to withdraw its products from the market for risks associated with manufacturing and supply of its products and product candidates.

Intellectual Property

Overview

Scienture LLC continues to build its intellectual property portfolio to provide protection for its technologies, products, and product candidates. Scienture LLC seeks patent protection, where appropriate, both in the U.S. and internationally for products and product candidates.

Scienture LLC's intended objective is to protect its innovations and proprietary products by, among other things, filing patent applications in the U.S. and abroad, including Europe, Canada, and other countries when appropriate. Scienture LLC also relies on trade secrets, know-how, proprietary knowledge, continuing technological innovation, and in-licensing opportunities to develop and maintain its proprietary position. Scienture LLC cannot be sure that patents will be granted with respect to its pending patent applications or with respect to any patent applications filed by it in the future, nor can Scienture LLC be sure that any of its existing patents or any patents that may be granted to it in the future will be commercially useful in protecting its technology or its products. Scienture LLC cannot be sure that any patents, if granted, will sustain a legal challenge.

Patent Portfolio

Arbli™ (SCN-102)

SCN-102 has two orange book listed formulation composition and method of use patents in the U.S. Patent #: 11,890,273, Issue Date: February 6, 2024, titled "LOSARTAN LIQUID FORMULATIONS AND METHODS OF USE", Expiration Date: October 7, 2041 and Patent #: 12,156,869, Issue Date: December 03, 2024, titled "LOSARTAN LIQUID FORMULATIONS AND METHODS OF USE", Expiration Date: October 7, 2041. A third application is pending (Appl. No. 18/061,819; Filing Date: December 5, 2022; Expiration: on or after October 7, 2041).

REZENOPY™ (SCN-110)

SCN-110 has an issued orange book listed formulation composition and method of use patent in the U.S. Patent #: 12,514,854, Issue Date: January 6, 2026, titled "DRUG PRODUCTS FOR INTRANASAL ADMINISTRATION AND USES THEREOF", Expiration Date: February 5, 2041. A second application is pending in the U.S. (18/602,972; Filing Date: March 12, 2024; Expiration Date: February 5, 2041).

SCN-104

SCN-104 has a formulation composition and method of use application pending in the U.S. (Appl. No. 17/757,924; Filing Date: June 23, 2022; Expiration Date: June 15, 2035).

SCN-106

SCN-106 is a potential biosimilar and considered by Scienture LLC to be part of its product development portfolio, however Scienture LLC is not pursuing patent protection for this product.

SCN-107

SCN-107 has a formulation composition and method of use application pending in the U.S. (Appl. No. 17/996,995; Filing Date: October 24, 2022; Expiration Date: on or after April 22, 2041). Applications in Canada and Europe are currently pending. As described above, Scienture LLC licenses certain patent rights from Innocore for the research and development of SCN-107.

Collaborations and Licensing Arrangements

Kindeva Drug Delivery L.P. ("Kindeva")

Scienture LLC entered into the Kindeva Agreement on March 4, 2025, pursuant to which Kindeva granted Scienture LLC an exclusive, non-transferrable, non-sublicensable right and license to commercialize REZENOPY™ (Nalaxone HCI Nasal spray 10mg/0.11mL) (the "Product") within the United States and its territories. Scienture LLC intends to use the exclusive right and license to price, launch, promote, market, distribute, and educate the public on the Product.

Unless earlier terminated, the term of the Kindeva Agreement will remain in effect for 10 years from the date of first commercial sale of the Product in the United States and its territories to an unaffiliated third-party. The Kindeva Agreement will automatically renew for successive 1-year periods unless either party terminates the agreement in accordance with its terms. Either party may terminate the Kindeva Agreement if (i) the other party materially breaches the Kindeva Agreement and has not cured such breach during a period of 90 days following notice of the breach, (ii) the Product is withdrawn from the market as a result of any ruling or requirement by the FDA, a voluntary recall by the FDA is issued, or there are material safety concerns that could significantly impact the commercial viability of the Product, or (iii) the Product is the subject of a mass tort liability action or is subject to material health and public safety concerns. Scienture LLC may terminate the Kindeva Agreement upon 120 days prior written notice if Scienture LLC determines that the Product is compromised by an adverse and material change in the market or other adverse and material business conditions. The Kindeva Agreement is also terminable by either party upon the occurrence of certain bankruptcy related events pertaining to the other party.

Pursuant to the Kindeva Agreement, Scienture LLC is exclusively responsible, at its expense, for the commercializing the Product in the United States and its territories in a manner that maximizes the net sales of the Product. Scienture LLC has final and sole authority for the pricing of the Product, but has agreed to not reduce the sale price of the Product for reasons other than the impact of market demand for the Product, after taking into account all relevant factors.

Pursuant to the Kindeva Agreement, Kindeva will retain control of all activities associated with manufacturing the Product, and be responsible for any non-clinical or clinical studies regarding the Product. Kindeva will provide a copy of the NDA for the Product to Scienture LLC as well as all related information and data necessary for Scienture LLC to commercialize the Product. Once the NDA is transferred to Scienture LLC, Scienture LLC will be responsible for maintaining the NDA and deal with any regulatory authorities regarding the advertising and marketing of the Product as well as any adverse drug experience reports for the Product that Scienture LLC directly receives. The initial supply price for the Product to Scienture LLC is $9.20 per unit. Kindeva may increase that price not more than once each calendar year after the launch of the Product to account for any increased manufacturing costs.

Under the Kindeva Agreement, Scienture LLC and Kindeva agreed to form a joint steering committee within 30 days to oversee and coordinate their respective activities under the Kindeva Agreement with respect to any additional regulatory or development requirements needed to obtain any regulatory approvals needed for Scienture LLC to fulfill its commercialization responsibilities. The joint steering committee will be comprised of four members, with 2 members to be appointed by each of Scienture LLC and Kindeva. The joint steering committee is responsible for establishing timelines for the launch of the Product, overseeing the development and commercialization of the Product, providing strategic direction and performance criteria, and resolving disputes that might arise under and in connection with the Kindeva Agreement. The joint steering committee will meet 4 times per year, unless Scienture LLC and Kindeva agree to a different schedule. The joint steering committee must act by unanimous vote of the members present at a meeting, provided that at least 1 member from each of Scienture LLC and Kindeva must be present at such meeting, or may otherwise act by a written consent signed by all members.

In exchange for the exclusive rights to develop and commercialize the Products, Scienture LLC agreed to pay Kindeva certain milestone payments, net sales share payments, and NDA cost reimbursements, including:

- A one-time commercial milestone payment of between $2.5 million and $10 million based on the achievement of certain pre-defined annual net sales targets;
- Milestone payments totaling $1 million, $200,000 of which was due upon executing the Kindeva Agreement, $300,000 of which is due within 3 months of executing the Kindeva Agreement, $250,000 of which is due upon delivery of the initial commercial supply of the Product, and $250,000 of which is due 3 months after receipt of such commercial supply;

- Profit-sharing payments representing 10% of the net sales by Scienture LLC of the Product, which will be reduced to 8% of the net sales on the market entry of a third party generic ANDA for the Product; and
- Additional profit-sharing payments representing 5% of the net sales until the total cumulative payments equals Kindeva's cost of developing and receiving NDA approval of the Product, which was $12.8 million as of the date of the Kindeva Agreement.

Under the Kindeva Agreement, Scienture LLC agreed to place minimum order quantities of the Product of 3 batches of 450,000 units per year beginning in 2027 or, alternatively, pay Kindeva $1.242 million per year unless Scienture LLC elects to terminate the Kindeva Agreement pursuant to its terms.

Kesin Pharma Corporation ("Kesin")

Scienture LLC entered into exclusive license and commercial agreements on August 28, 2022 and April 24, 2023, with Kesin, a related party, pursuant to which Scienture LLC granted the exclusive license rights to commercialize SCN-102 and SCN-104, respectively, to Kesin for use in the United States (together, the "Kesin Agreement"). In consideration of the rights granted, Scienture LLC received milestone payments and reimbursement of costs actually incurred related to SCN-102 and SCN-104.

On March 13, 2024, the parties terminated the Kesin Agreement by entering a Confidential Termination Agreement (the "Kesin Termination Agreement"), and the parties agreed that Scienture LLC would pay Kesin a total gross amount of $1.285 million upon commercialization of either SCN-102 or SCN-104 via a royalty arrangement. The Kesin Termination Agreement also requires that if the full $1.285 million has not been repaid within two years of the earlier of (i) commercial launch of a product or (ii) 120 days after FDA approval of a product, then interest will accrue prospectively at a rate of 8% annually on the unpaid balance.

In August 2024, Kesin demanded immediate payment of the full amount under the Kesin Termination Agreement, alleging the full amount is payable in connection with the consummation Scienture LLC's business combination with the Company. Scienture LLC has disputed that the amount is payable, and the parties entered into discussions to resolve the issue.

On March 11, 2025, Kesin filed a complaint against Scienture LLC in the United States District Court for the Eastern District of New York seeking payment of the disputed $1.285 million. The case was voluntarily dismissed on October 1, 2025. The Company and Kesin entered into a Settlement Agreement and Release on October 27, 2025, whereby Kesin agreed to unconditionally release and discharge the Company from all actions related to the complaint in exchange for the Company paying $1.285 million plus 8% interest from March 13, 2025, and legal fees and costs related to the complaint according to a payment schedule through December 2026.

Government Regulation

U.S. Drug Development Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act (the "FDCA") and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Scienture LLC, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory authorities of the countries in which Scienture LLC wishes to conduct studies or seek approval of its product candidates. Failure to comply with applicable United States requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending applications, withdrawal of an approval, warning or untitled letters, clinical holds, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, civil penalties, and criminal prosecution.

FDA approval is required before any new unapproved product or a product with certain changes to a previously approved product, including a new use of a previously approved drug, can be marketed in the United States. The steps required to be completed by the FDA before a drug may be marketed in the United States generally include the following:

- completion of preclinical laboratory tests, animal studies, and formulation studies performed in accordance with the FDA's Good Laboratory Practice ("GLP") regulations;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent institutional review board ("IRB") or ethics committee at each clinical site before the clinical trial is commenced;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practices ("GCPs") requirements and other clinical-trial related regulations to establish the safety and efficacy of the proposed drug for each indication;
- preparation and submission to the FDA of an NDA or biologics license application ("BLA"), after completion of all pivotal clinical trials, which includes not only the results of the clinical trials, but also, detailed information on the chemistry, manufacture and quality controls for the product candidate and proposed labeling;
- satisfactory completion of an FDA Advisory Committee review, if applicable;

- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed drug is produced to assess compliance with current good manufacturing practices ("GMPs") regulations and of selected clinical trial sites to assess compliance with GCPs; and
- FDA review and approval of the NDA or BLA to permit commercial marketing of the product for particular indications for use in the United States.

Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical and Clinical Development

Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLP. The results of preclinical testing are submitted to the FDA as part of an IND application along with other information, including information about the product candidate, chemistry, manufacturing and controls, any available human data or literature to support the use of the product candidate and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

An IND application must become effective before human clinical trials may begin. The IND application automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises safety concerns or questions relating to one or more proposed clinical trials and places the clinical trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns, non-compliance or other issues affecting the integrity of the trial. Accordingly, submission of an IND application may or may not result in the FDA allowing clinical trials to commence and, once begun, issues may arise that could cause the trial to be suspended or terminated.

Clinical trials involve the administration of the investigational drug product to human subjects under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with GCP, an international standard meant to protect the rights and health of clinical research participants and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on United States patients and subsequent protocol amendments must be submitted to the FDA as part of the IND. Furthermore, an independent IRB or ethics committee for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits.

Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objects. The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial is not being conducted in accordance with FDA requirements. Further, an IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. Some trials also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may recommend a clinical trial to be halted if it determines that there is an unacceptable safety risk for subjects or other grounds, such as futility.

Clinical trials to support an NDA or BLA for marketing approval are typically conducted in three sequential phases, but the phases may overlap or be combined. In Phase 1 clinical trials, the investigational product is typically introduced into a limited population of healthy human subjects or patients with the target disease or condition. These trials are designed to test the safety, dosage tolerance, pharmacokinetics and pharmacological actions of the investigational product, to identify side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. Phase 2 clinical trials usually involve administering the investigational product to a limited patient population with the specified disease or condition to evaluate the preliminarily efficacy, dosage tolerance, and optimum dosage, and to identify possible adverse effects and safety risks. Phase 3 clinical trials are typically undertaken in a larger number of patients, typically at geographically dispersed clinical trial sites, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population. These clinical trials are intended to permit the FDA to evaluate the overall benefit-risk relationship of the investigational product and to provide adequate information for the labeling of the product candidate.

In reviewing an NDA or BLA, the FDA will consider all information submitted in the application, including the results of all clinical trials conducted. In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the NDA or BLA. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and further document clinical benefit in the case of drugs approved under accelerated approval regulations. Failure to exhibit due diligence with regard to conducting Phase 4 clinical trials could result in the withdrawal of approval for products.

Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with current GMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical study investigators. Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the product candidate, findings from animal or in vitro testing that suggest a significant risk for human subjects, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

NDA and BLA Submission and Review

Assuming successful completion of the required clinical testing in accordance with all applicable regulatory requirements, an NDA or BLA application which includes, among other information, the results of product development, preclinical studies and clinical trials is submitted to the FDA. FDA approval of the application is required before marketing of the product may begin in the United States. The application must include, among other things, the results of all trials and preclinical testing, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, controls and proposed labeling. The cost of preparing and submitting an NDA or BLA is substantial.

The FDA has 60 days from its receipt of an NDA or BLA to either issue a Refuse to File Letter or accept the NDA or BLA for filing, indicating that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs and BLAs. Under applications subject to the performance goals of the PDUFA, the FDA has a goal of responding to standard review NDAs and BLAs within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing, but this timeframe can be extended, such as by the submission of major amendments by applicants during the review period. The FDA reviews an application to determine, among other things, whether the product is safe and effective and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency.

The FDA may refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an application, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. Additionally, the FDA will inspect the facility or the facilities at which the proposed product is manufactured. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates the application and conducts inspections of the manufacturing facilities where the investigational product and/or its drug substance will be produced, it issues either an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with approved prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter generally outlines the deficiencies in the submission, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response Letter without first conducting required inspections or reviewing proposed labeling. In issuing the Complete Response Letter, the FDA may require substantial additional clinical data and/or other significant, expensive, and time-consuming requirements related to clinical trials, preclinical studies and/or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, withdraw the application or request a hearing. The FDA has committed to reviewing resubmissions of the NDA or BLA addressing such deficiencies in two or six months depending on the type of information included. Even if such data are submitted, however, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for a particular indication(s) and may include limitations on the indicated use(s) for which such product may be marketed. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the application on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. As a condition of NDA or BLA approval, the FDA may require a risk evaluation and mitigation strategy ("REMS") to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for REMS can materially affect the potential market and profitability of the product. Moreover, product approval may also be conditioned on substantial post-approval testing, such as Phase 4 post-market studies, and surveillance to monitor the product's safety or efficacy, and the FDA may limit further marketing of the product based on the results of these post-approval studies. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or BLA, or NDA or BLA supplement before the change can be implemented. An NDA or BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA and BLA supplements as it does in reviewing NDAs and BLAs. As with new NDAs and BLAs, the review process is often significantly extended by requests for additional information or clarification.

505(b)(2) NDA Approval Process

Section 505(b)(2) of the FDCA provides an alternate regulatory pathway for the FDA to approve a new product and permits reliance for such approval on published literature or an FDA finding of safety and effectiveness for a previously approved drug product. Specifically, section 505(b)(2) permits the filing of an NDA where one or more of the investigations relied upon by the applicant for approval were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Typically, 505(b)(2) applicants must perform additional trials to support the change from the previously approved drug and to further demonstrate the new product's safety and effectiveness. The FDA may then approve the new product candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication sought by the section 505(b)(2) applicant.

Regulation of Combination Products in the United States

Certain products may be comprised of components, such as drug components and device components, that would normally be regulated under different types of regulatory authorities, and frequently by different centers at the FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

- a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;
- a drug, or device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, or device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
- any investigational drug, or device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Under the FDCA and its implementing regulations, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The designation of a lead center generally eliminates the need to receive approvals from more than one FDA component for combination products, although it does not preclude consultations by the lead center with other components of FDA. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a drug-device combination product is attributable to the drug product, the FDA center responsible for premarket review of the drug product would have primary jurisdiction for the combination product. The FDA has also established an Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute.

A combination product with a drug primary mode of action generally would be reviewed and approved pursuant to the drug approval processes under the FDCA. In reviewing the NDA application for such a product, however, FDA reviewers in the drug center could consult with their counterparts in the device center to ensure that the device component of the combination product met applicable requirements regarding safety, effectiveness, durability and performance. In addition, under FDA regulations, combination products are subject to current GMP requirements applicable to both drugs and devices, including the Quality System regulations applicable to medical devices.

Post-Approval Requirements

Once an NDA or BLA is approved, a product will be subject to pervasive and continuing regulation by the FDA including, among other things, requirements relating to current GMPs, quality controls, record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by Scienture LLC and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the practice of medicine by physicians or their choice of treatments. The FDA does, however, regulate manufacturer's communications on the subject of off-label use of their products.

In addition, quality control, drug manufacture, packaging, and labeling procedures must continue to conform to current GMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA, and certain state agencies for compliance with current GMPs, which impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from current GMPs and impose reporting requirements upon Scienture LLC and any third-party manufacturers that Scienture LLC may decide to use. NDA or BLA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. Drug manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and notify the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. The discovery of violative conditions, including failure to conform to current GMPs, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with current GMPs.

The FDA may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards or is not maintained, if problems occur following initial marketing, or if previously unrecognized problems are subsequently discovered. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;

- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

U.S. Patent Term Restoration

Depending upon the timing, duration and specifics of the potential FDA approval of Scienture LLC's product candidates, some of its U.S. patents may be eligible for limited patent term extension. The Hatch-Waxman Amendments permit a patent restoration term, often referred to as patent term extension, of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves or denies the application for any patent term extension or restoration.

U.S. Marketing Exclusivity

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain marketing applications, including 505(b)(2) applications. The FDA provides three years of marketing exclusivity for an NDA (including a 505(b)(2) application), or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. Three-year exclusivity is typically awarded to innovative changes to a previously-approved drug product, such as new indications, dosage forms or strengths. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving applications for drugs that do not have the innovative change, such as generic copies of the original, unmodified drug product. Three-year exclusivity blocks approval of 505(b)(2) applications and Abbreviated New Drug Applications, but will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the nonclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness. Orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances. Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods, including exclusivity attaching to certain patent certifications. This six-month exclusivity, which runs from the end of other exclusivity protection and patent terms, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining.

Biosimilars and Exclusivity

The ACA, which was signed into law in March 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"). The BPCIA established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. A biosimilar is a biological product that is highly similar to an existing FDA-licensed "reference product." The FDA has issued multiple guidance documents outlining an approach to review and approval of biosimilars. Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. Since the passage of the BPCIA, many states have passed laws or amendments to laws, including laws governing pharmacy practices, which are state regulated, to regulate the use of biosimilars.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition—generally a disease or condition with either a patient population that affects fewer than 200,000 individuals in the United States or a patient population greater than 200,000 individuals in the United States and there is no reasonable expectation that the cost of developing and making available the drug will be recovered from sales of the drug in the United States. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the generic identity of the product and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The first applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same product for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of the patients with the disease or condition for which the product was designated. Orphan drug exclusivity does not prevent the FDA from approving a different product for the same disease or condition, or the same product for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA or BLA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan drug designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Fast Track Designation and Breakthrough Therapy Designation

The FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life-threatening disease or condition which demonstrate the potential to address unmet medical needs for the condition, and accordingly, the FDA has established the fast track designation and breakthrough therapy designation programs.

A product candidate is eligible for fast track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. Under the fast track program, the sponsor of a drug candidate may request that the FDA designate the candidate for a specific indication as a fast track product concurrent with, or after, the filing of the IND for the candidate. The FDA must determine if the product candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request. Fast track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review of sections of the applicant's NDA or BLA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing an application does not begin until the last section of the application is submitted. Additionally, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Under the FDA's breakthrough therapy program, a sponsor may seek FDA designation of its product candidate as a breakthrough therapy if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough therapy designation comes with all of the benefits of fast track designation. The FDA may take other actions appropriate to expedite the development and review of the product candidate, including intensive guidance on an efficient product development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Priority Review

A product is eligible for priority review if it has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Under the current PDUFA agreement, these six-and ten-month review periods are measured from the "filing" date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast track designation are also likely to be considered appropriate to receive a priority review.

Pediatric Information

Under the Pediatric Research Equity Act (the "PREA"), NDAs and BLAs, or supplements to NDAs and BLAs, must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs and combination products, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. The Final Rule on ClinicalTrials.gov registration and reporting requirements became effective in 2017, and both the National Institutes of Health and the FDA have signaled the government's willingness to begin enforcing those requirements against non-compliant clinical trial sponsors.

Other Regulatory Requirements

Health Care Laws

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business that may constrain the financial arrangements and relationships through which Scienture LLC researches, as well as sell, market and distribute any products for which Scienture LLC obtains marketing authorization. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, and transparency laws and regulations related to drug pricing and payments and other transfers of value made to physicians and other healthcare providers. If Scienture LLC's operations are found to be in violation of any of such laws or any other governmental regulations that apply, Scienture LLC may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations, exclusion from participation in federal and state healthcare programs and responsible individuals may be subject to imprisonment. Scienture LLC may be subject to:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the purchase, lease, order, arrangement, or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The Medicare program is a national health insurance program that primarily provides health insurance for Americans aged 65 and older as well as some younger people with disability status as determined by the Social Security Administration and people with end stage renal disease and amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease). The Medicaid program is a federal and state health insurance program that helps with medical costs for some people with limited income and resources, and offers benefits not normally covered by Medicare, including nursing home care and personal care services. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil monetary penalties;

- The federal civil and criminal false claims laws and civil monetary penalty laws, such as the federal False Claims Act, which impose criminal and civil penalties and authorize civil whistleblower or qui tam actions, against individuals or entities for, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false statement of record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery;

- The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information. Individually identifiable information means information that is a subset of health information, including demographic information collected from an individual, and: (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (a) that identifies the individual; or (b) with respect to which there is reasonable basis to believe the information can be used to identify the individual.

  HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;

- The U.S. federal transparency requirements under the ACA, including the provision commonly referred to as the Physician Payments Sunshine Act, and its implementing regulations, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the Centers for Medicare & Medicaid Services ("CMS"), information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other licensed health care practitioners and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;

- Federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products; and

- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, Scienture LLC is subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and False Claims Act, and may apply to Scienture LLC's business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. There are ambiguities as to what is required to comply with these state requirements and if Scienture LLC fails to comply with an applicable state law requirement Scienture LLC could be subject to penalties. State and foreign laws, including for example the European Union General Data Protection Regulation, which became effective in May 2018, also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state requirements and if Scienture LLC fails to comply with an applicable state law requirement Scienture LLC could be subject to penalties.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Ensuring that Scienture LLC's internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that Scienture LLC's business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If Scienture LLC's operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, Scienture LLC may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm, and the curtailment or restructuring of Scienture LLC's operations, as well as additional reporting obligations and oversight if Scienture LLC becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, defending against any such actions can be costly and time consuming, and may require significant financial and personnel resources. Therefore, even if Scienture LLC is successful in defending against any such actions that may be brought against it, its business may be impaired. If any of the physicians or other providers or entities with whom Scienture LLC expects to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, Scienture LLC's ability to operate its business and its results of operations could be adversely affected.

Healthcare Reform

Payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new technologies such as gene therapy and therapies addressing rare diseases such as those Scienture LLC is developing. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact Scienture LLC's ability to sell its products profitably. In particular, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA") was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government's comparative effectiveness research.

In addition, other legislative and regulatory changes have been proposed and adopted in the United States since the ACA was enacted.

- The Budget Control Act of 2011 and subsequent legislation, among other things, created measures for spending reductions by Congress that include aggregate reductions of Medicare payments to providers of 2% per fiscal year, which remain in effect through 2031. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation. The U.S. American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

- On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs.

In August 2022, the Inflation Reduction Act of 2022 (the "IRA"), was signed into law. The IRA includes several provisions that may impact Scienture LLC's business, depending on how various aspects of the IRA are implemented. Provisions that may impact Scienture LLC's business include a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, the imposition of new manufacturer financial liability on most drugs in Medicare Part D, permitting the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, requiring companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay until January 1, 2032 the implementation of the U.S. Department of Health and Human Services ("HHS") rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on Scienture LLC's business and the healthcare industry in general is not yet known.

Former President Biden issued multiple executive orders that sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from former President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. A number of these and other proposed measures may require authorization through additional legislation to become effective, and the Trump administration may reverse or otherwise change these measures. However, Congress has indicated that it will continue to seek new legislative measures to control drug costs.

Scienture LLC expects that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. Federal Government will pay for healthcare drugs and services, which could result in reduced demand for Scienture LLC's drug candidates or additional pricing pressures.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm Scienture LLC's business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for Scienture LLC's drugs or put pressure on its drug pricing, which could negatively affect its business, financial condition, results of operations and prospects.

Pharmaceutical Coverage, Pricing, and Reimbursement

The success of Scienture LLC's product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors. Scienture LLC cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, its product candidates or assure that coverage and reimbursement will be available for any product that it may develop. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require Scienture LLC to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of Scienture LLC's products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Even if Scienture LLC obtains coverage for a given product, the resulting reimbursement payment rates might not be adequate for Scienture LLC to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates, once approved. Patients are unlikely to use Scienture LLC's product candidates, once approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of their cost. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for Scienture LLC's product candidates.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Scienture LLC cannot be sure that reimbursement will be available for any product candidate that it commercializes and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives.

Scienture LLC expects that 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 Scienture LLC receives for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent Scienture LLC from being able to generate revenue, attain profitability, or commercialize Scienture LLC's products. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. Scienture LLC cannot be sure whether additional legislative changes will be enacted, or whether existing regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals or clearances of Scienture LLC's product candidates, if any, may be.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of Scienture LLC's product candidates. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Environmental Matters

The Company and Scienture LLC's operations and those of its third-party manufacturers and suppliers are subject to national, state and local environmental laws. Scienture LLC has made, and intends to continue to make, expenditures and undertake efforts to comply with applicable laws. Scienture LLC believes the safety procedures utilized by it for the handling and disposing hazardous materials comply with the standards prescribed by applicable laws and regulations.

Human Capital

The Company's success begins and ends with its people. The Company's solid progress to date reflects the talent and hard work of all of its employees. The Company considers the intellectual capital of its employees to be an essential driver of its business and key to its future prospects. Attracting, developing, and retaining talented people in technical, marketing, sales, research, and other positions is crucial to executing its strategy and its ability to compete effectively.

Talent Acquisition, Retention and Development

The Company's key human capital objectives are to attract, retain and develop the highest quality talent. The Company employs various human resource programs in support of these objectives. The Company's ability to recruit and retain such talent depends on a number of factors, including compensation and benefits, talent development and career opportunities, and the work environment.

The Company attracts and rewards its employees by providing market competitive compensation and benefit packages, including incentives and recognition plans that extend to all levels in its organization. To that end, Scienture LLC offers a comprehensive total rewards program aimed at health, home-life, and financial needs of its employees. Scienture LLC's total rewards package includes market-competitive pay, broad-based stock grants, bonuses, healthcare benefits, retirement savings plans, paid time off and family leave, an Employee Assistance Program, and mental health services.

The Company is committed to the safety, health, and security of its employees. The Company believes a hazard-free environment is critical for the success of its business. Throughout the Company's operations, it strives to ensure that all its employees have access to safe workplaces that allow them to succeed in their jobs. The Company's experience and continuing focus on workplace safety has enabled it to preserve business continuity without sacrificing its commitment to keeping its colleagues and workplace visitors safe.

Facilities

The Company's corporate headquarters is located at 20 Austin Blvd, Commack, NY 11725, which is 2,000 square feet of office space with a lease termination date of July 31, 2026. The Company believes its facilities are sufficient to meet its current needs for the foreseeable future.

Legal Proceedings

From time to time, the Company may be involved in various claims and legal proceedings.

On March 11, 2025, Kesin filed a complaint against Scienture LLC in the United States District Court for the Eastern District of New York stemming from exclusive license and commercial agreements that Scienture LLC entered into on August 28, 2022 and April 24, 2023, with Kesin, a related party, pursuant to which Scienture LLC granted the exclusive license rights to commercialize SCN-102 and SCN-104, respectively to Kesin for use in the United States of America (together, the "Kesin Agreement"). In consideration of the rights granted, Scienture LLC received milestone payments and reimbursement of costs actually incurred related to SCN-102 and SCN-104.

On March 13, 2024, the parties terminated the Kesin Agreement by entering a Confidential Termination Agreement (the "Kesin Termination Agreement"), and the parties agreed that Scienture LLC would pay Kesin a total gross amount of $1.285 million upon commercialization of either SCN-102 or SCN-104 via a royalty arrangement. The Kesin Termination Agreement also requires that if the full $1.285 million has not been repaid within two years of the earlier of (i) commercial launch of a product or (ii) 120 days after FDA approval of a product, then interest will accrue prospectively at a rate of 8% annually on the unpaid balance.

In August 2024, Kesin demanded immediate payment of the full amount under the Kesin Termination Agreement, alleging the full amount is payable in connection with the consummation Scienture LLC's business combination with the Company. Scienture LLC disputed that the amount was payable, and the parties entered into discussions to resolve the issue. Nevertheless, Kesin filed its complaint on March 11, 2025, seeking payment of the disputed $1.285 million. The case was voluntarily dismissed on October 1, 2025. The Company and Kesin entered into a Settlement Agreement and Release on October 27, 2025, whereby Kesin agreed to unconditionally release and discharge the Company from all actions related to the complaint in exchange for the Company paying $1.285 million plus 8% interest from March 13, 2025, and legal fees and costs related to the complaint according to a payment schedule through December 2026.

Employees

Currently, the Company and Scienture LLC collectively employ approximately four (4) full-time employees and five (5) part-time employees. We are not a party to any collective bargaining agreements and have not experienced any strikes or work stoppages. We consider our relations with our employees and consultants to be satisfactory.

Seasonality

Our business is not directly affected by seasonal fluctuations but is affected indirectly by the fall and winter flu season, to the extent it leads to an increased demand for certain generic pharmaceuticals.

Subsidiaries

We currently exist as a holding company directly owning 100% of the equity interests of Scienture LLC. Scienture LLC is a specialty pharmaceutical company focused on the commercialization and development of products for the treatment of Cardiovascular (CVS) and Central Nervous System (CNS) diseases. Scienture LLC launched its first commercial product for hypertension and is in the process of commercializing its second product for the treatment of opioid overdose. Its development pipeline consists of a broad range of novel product candidates including new potential treatments for migraine, thrombosis, pain and other related disorders.

Dispositions

SOSRx, LLC

SOSRx, LLC ("SOSRx") was formed on February 15, 2022. The Company entered into a relationship with Exchange Health, LLC ("Exchange Health"), a technology company providing an online platform for manufacturers and suppliers to sell and purchase pharmaceuticals, pursuant to which SOSRx, a Delaware limited liability company, was formed, which was owned 51% by the Company and 49% by Exchange Health. SOSRx did not generate material revenue and in February 2023 the Company voluntarily withdrew from the joint venture agreement.

Community Specialty Pharmacy, LLC and Alliance Pharma Solutions, LLC

On January 20, 2023, the Company entered into Membership Interest Purchase Agreements to sell 100% of the outstanding membership interests of the Company's former subsidiaries, Community Specialty Pharmacy, LLC and Alliance Pharma Solutions, LLC (d.b.a DelivMeds). The Company also agreed to enter into a Master Service Agreement to operate the businesses prior to closing. The transactions contemplated by the Membership Interest Purchase Agreements closed on August 22, 2023.

Superlatus Inc.

On July 14, 2023, the Company entered into an Amended and Restated Agreement and Plan of Merger (the "Superlatus Merger Agreement") with Superlatus Inc., a diversified food technology company, and Foods Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of the Company ("Merger Sub").

On July 31, 2023, the Company completed its acquisition of Superlatus in accordance with the terms and conditions of the Superlatus Merger Agreement (the "Superlatus Merger"), pursuant to which the Company acquired Superlatus by way of a merger of the Merger Sub with and into Superlatus, with Superlatus being a wholly owned subsidiary of the Company and the surviving entity in the Superlatus Merger.

Under the terms of the Superlatus Merger Agreement, at the closing of the Superlatus Merger (the "Closing"), shareholders of Superlatus received an aggregate of 136,441 shares of the Company's common stock and 306,855 shares of the Company's Series B Preferred Stock, par value $0.00001 per share (the "Series B Preferred Stock"), convertible into 100 shares of the Company's common stock. At Closing, the value of the Company's common stock was $7.30 per share, resulting in a total value of $225,000,169.

On October 13, 2023, the Company announced that Superlatus PD Holding Company, Inc., a purported subsidiary of Superlatus, entered into a supplier agreement with Rainforest Distribution Corp, a New York corporation ("Rainforest"), pursuant to which Superlatus allegedly appointed Rainforest as its exclusive distributor for Superlatus' portfolio of consumer packaged goods brands in certain markets. The Company later learned and announced that neither the Company's management nor the Company's Board of Directors authorized or approved the organization of Superlatus PD Holding Company, Inc. or the entry into the supplier agreement. Instead, the Company's management determined that certain representatives of a former subsidiary of the Company likely unilaterally took actions related to the supplier agreement.

On January 8, 2024, the Company entered into Amendment No. 1 to the Amended and Restated Agreement and Plan of Merger (the "Superlatus Amendment") as not all of the closing conditions of the Superlatus Merger Agreement were met. Under the terms of the Superlatus Amendment, the merger consideration to the shareholders of Superlatus was adjusted to the aggregate of 136,441 shares of the Company's common stock and 15,759 shares of the Company's Series B Preferred Stock, resulting in a total value of $12,500,089. Additionally, the shareholders of Superlatus agreed to surrender back to the Company 291,096 shares of the Company's Series B Preferred Stock.

On March 5, 2024, the Company entered in a Stock Purchase Agreement ("Superlatus SPA") with Superlatus Foods Inc. (the "Buyer"). Pursuant to the Superlatus SPA, the Company sold all of the issued and outstanding stock of Superlatus to the Buyer. A $1.00 purchase price was delivered to the Company at the closing, which occurred simultaneously with the execution of the Superlatus SPA. As a result of the transaction Superlatus is no longer a subsidiary of the Company, and the rights and assets of Superlatus together with various liabilities and obligations that were specific to Superlatus became rights and obligations of the Buyer.

Other Legacy Subsidiaries

The Company also previously owned 100% of Softell Inc. (f/k/a Trxade Inc.) ("Softell"), Integra Pharma Solutions, LLC ("IPS"), Bonum Health, Inc., and Bonum Health, LLC.

Softell & IPS Entities

On October 4, 2024, the Company and Softell entered into an Assignment and Assumption of Membership Interests (the "IPS Assignment Agreement"), pursuant to which the Company transferred, and Softell accepted, 100% of the membership interests of IPS. As a result, IPS became a wholly-owned subsidiary of Softell.

On April 8, 2025, the Company entered into a Membership Interest Purchase Agreement (the "IPS MIPA") with Tollo Health, Inc. ("Tollo"), pursuant to which Tollo agreed to purchase and the Company agreed to sell all of the Company's membership interests in IPS. Suren Ajjarapu, the Company's former Chief Executive Officer, and Prashant Patel, the Company's former President and Chief Operating Officer, each have a beneficial interest in Tollo.

On April 8, 2025, the Company also entered into a Stock Purchase Agreement (the "Softell SPA") with Tollo, pursuant to which Tollo agreed to purchase and the Company agreed to sell all issued and outstanding shares of common stock of Softell.

Bonum Health Entities

On April 8, 2025, the Company also entered into a Stock Purchase Agreement (the "Bonum SPA") with Tollo, pursuant to which Tollo agreed to purchase and the Company agreed to sell all issued and outstanding shares of common stock of Bonum Health, Inc.

In November 2025, the Company dissolved Bonum Health, LLC.

The divestitures described above are part of a broader strategic realignment at the Company designed to sharpen operational focus and unlock long-term value. It is aligned with the Company's commitment to streamline its core operations, optimize its portfolio, and accelerate growth in the Branded and Specialty Pharma markets. The Company intends to use the proceeds obtained from the divestment to facilitate the high-growth commercial and strategic product development activities at its Scienture LLC subsidiary.

Corporate and Organizational History

We were incorporated in Delaware on July 15, 2005, as "Bluebird Exploration Company" ("Bluebird"). Bluebird was originally formed to engage in the exploitation of mineral properties. In December 2008, Bluebird changed its name to "Xcellink International, Inc." ("XCEL"), and subsequently announced that its business plan was being expanded to include the development and marketing of platform-independent customer-centric payment systems and methodologies. XCEL was unable to raise the funds necessary to implement its business strategy, and never generated any revenue.

On November 22, 2013, Trxade Group, Inc., a Nevada corporation ("Trxade Nevada") and wholly owned subsidiary of Trxade, Inc., a Florida corporation ("Trxade Florida"), acquired a controlling interest of XCEL common stock pursuant to a Purchase and Sale Agreement dated November 7, 2013. Trxade Florida was formed in August 2010 under the name PharmaCycle LLC, a Nevada limited liability company ("PharmaCycle"). PharmaCycle was formed by Prashant Patel, our former President and Chief Operating Officer. In January 2013, PharmaCycle converted into a Florida corporation and changed its name to Trxade, Inc. In May 2013, Trxade Florida formed Trxade Nevada as a wholly owned subsidiary. Subsequently, Trxade Nevada acquired Trxade Florida pursuant to a reverse triangular merger, resulting in Trxade Florida becoming a wholly-owned subsidiary of Trxade Nevada (the "Nevada-Florida Merger"). Immediately following the Nevada-Florida Merger, Surendra Ajjarapu, the Company's former Chief Executive Officer, and Mr. Patel, the Company's former President and Chief Operating Officer, collectively owned 99% of Trxade Nevada.

On December 16, 2013, Trxade Nevada and XCEL entered into a definitive merger agreement providing for the merger of Trxade Nevada with and into XCEL, with XCEL continuing as the surviving corporation (the "XCEL Merger"). The XCEL Merger closed in January 2014. As a result of the XCEL Merger, XCEL acquired Trxade Nevada and Trxade Nevada's wholly owned subsidiaries, including IPS. In connection with the XCEL Merger, XCEL changed its name to "Trxade Group, Inc." and changed its trading symbol to "TRXD".

Our common stock was approved for listing on Nasdaq under the symbol "MEDS" on February 13, 2020.

On June 1, 2021, we changed our corporate name from "Trxade Group, Inc." to "TRxADE HEALTH, Inc."

On July 25, 2024, the Company entered into and closed an Agreement and Plan of Merger (the "Scienture Merger Agreement") with MEDS Merger Sub I, Inc., a Delaware corporation and wholly owned subsidiary of the Company ("Merger Sub I"), MEDS Merger Sub II, LLC, a Delaware limited liability company and wholly owned subsidiary of the Company ("Merger Sub II" and, together with Merger Sub I, the "Merger Subs"), and Scienture LLC. Pursuant to the Scienture Merger Agreement, (i) Merger Sub I merged with and into Scienture LLC (the "First Merger"), with Scienture LLC continuing as the surviving entity and a wholly owned subsidiary of the Company, and (ii) Scienture LLC merged with and into Merger Sub II (the "Second Merger" and, together with the First Merger and all other related transactions, the "Scienture Merger"), with Merger Sub II continuing as the surviving entity. In connection with the transactions, the Company changed its name to "Scienture Holdings, Inc." and Merger Sub II, as the surviving entity of the Second Merger, changed its name to "Scienture, LLC".

ITEM 1A. RISK FACTORS

You should be aware that there are substantial risks for an investment in our common stock. You should carefully consider these risk factors before you decide to invest in our common stock and should not consider this list to be a complete statement of all risks and uncertainties.

If any of the following risks were to occur, such as our business, financial condition, results of operations or other prospects, any of these could materially affect our likelihood of success. If that happens, the market price of our common stock, if any, could decline, and prospective investors would lose all or part of their investment in our common stock.

Risks Related to Our Business

We operate a clinical-stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate its current business and predict its future success and viability.

We hold a clinical-stage biopharmaceutical company with a limited operating history. Scienture LLC was formed in 2019 and its operations to date have been limited to organizing and staffing its company, business planning, raising capital, identifying and developing its product candidates for the treatment of central nervous system ("CNS") and cardiovascular ("CVS") diseases, securing intellectual property rights, and planning and undertaking preclinical studies and clinical trials. Scienture LLC has not yet demonstrated an ongoing ability to generate revenues, obtain regulatory approvals, manufacture any product on a commercial scale or arrange for a third party to do so on its behalf or conduct sales and marketing activities necessary for successful product commercialization. Scienture LLC's limited operating history as a company makes any assessment of its future success and viability subject to significant uncertainty. Scienture LLC encounters risks and difficulties frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields, and Scienture LLC has not yet demonstrated an ability to successfully overcome such risks and difficulties. If Scienture LLC does not address these risks and difficulties successfully, its business will suffer.

The success of our business depends primarily upon its ability to identify, develop, and commercialize product candidates, including our existing product candidates: SCN-102, SCN-104, SCN-106, and SCN-107. We only have one product candidate, SCN-102, for which it has conducted pivotal clinical studies to date, and we will be required to similarly perform pivotal clinical studies for the other products in its pipeline in order to obtain regulatory approval for these earlier stage candidates. Our business depends heavily on its ability to obtain FDA approval for SCN-102 and successfully launch this product candidate and do the same for the other products in its pipeline. We do not know whether it will be able to develop any products of commercial value. We do not have any products approved for commercial sale and have not generated any revenue from product sales to date. We will continue to incur significant research and development and other expenses related to its preclinical and clinical development and ongoing operations. As a result, we are not profitable and has incurred losses in each period since its inception. Net losses and negative cash flows have had, and likely will continue to have, an adverse effect on our financial condition. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates.

We anticipate that our expenses will increase substantially if, and as, we:

- advance our product candidates through clinical development;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- hire additional clinical, quality control, medical, scientific and other technical personnel to support the clinical development of our product candidates;
- experience an increase in headcount as we expand our research and development organization and market development and pre-commercial planning activities;
- undertake any pre-commercial or commercial activities to establish sales, marketing and distribution capabilities, including in relation to our product candidates;
- seek to identify, acquire and develop additional product candidates, including through business development efforts to invest in or in-license other technologies or product candidates;
- maintain, expand and protect our intellectual property portfolio; and
- make milestone, royalty, interest, or other payments due under any in-license, collaboration agreements; financing agreements, or other arrangements with third parties.

Biopharmaceutical product development entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, secure market access and reimbursement and become commercially viable, and therefore any investment in us is highly speculative. Accordingly, you should consider our prospects, factoring in the costs, uncertainties, delays and difficulties frequently encountered by companies in clinical development, especially clinical-stage biopharmaceutical companies such as us. Any predictions you make about our future success or viability may not be as accurate as they would otherwise be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives.

Additionally, our expenses could increase beyond our expectations if we are required by the FDA or other comparable regulatory authorities to perform clinical trials in addition to those that we currently expect, or if there are any delays in establishing appropriate manufacturing arrangements for or in completing our clinical trials or the development of any of our product candidates.

We need additional capital which may not be available when needed or on commercially acceptable terms. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our product candidates.

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Moving forward, we expect our expenses to continue to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek regulatory and marketing approval for, our product candidates. Even if our current or future product candidates are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Because of the numerous risks and uncertainties associated with research and development of product candidates, we are unable to predict the timing or amount of our working capital requirements.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations with existing cash, cash equivalents, short-term investments, and any future equity or debt financings and upfront and milestone and royalty payments, if any, received under any future licenses or collaborations. While we believe that our cash as of the date of this Annual Report will be sufficient to meet our funding requirements during the next 12 months, this belief may prove to be wrong as we could utilize available capital resources sooner than we expect. We will eventually need to raise additional capital or secure debt funding to support on-going operations. This may include raising additional financing on an opportunistic basis in the future. For example, we may seek to raise equity capital or obtain additional capital in the near term due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for current or future operating plans.

Attempting to secure additional financing may divert management from day-to-day activities, which may adversely affect our ability to develop product candidates. Our future capital requirements will depend on many factors, including but not limited to:

- the scope, timing, progress, costs and results of discovery, preclinical development and clinical trials for our current or future product candidates;
- the number of clinical trials required for regulatory approval of our current or future product candidates;
- the costs, timing and outcome of regulatory review of any of our current or future product candidates;
- the costs associated with acquiring or licensing additional product candidates, technologies or assets, including the timing and amount of any milestones, royalties or other payments due in connection with our acquisitions and licenses;
- the cost of manufacturing clinical and commercial supplies of our current or future product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- the effectiveness of our approach at identifying target patient populations and utilizing our approach to enrich our patient population in our clinical trials;
- our ability to maintain existing, and establish new, strategic collaborations or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- expenses to attract, hire and retain skilled personnel;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors;
- the effect of macroeconomic trends including inflation and rising interest rates;
- addressing any potential supply chain interruptions or delays;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invests in business, products and technologies.

We anticipate that the sources of capital available to us will be through the sale of equity and debt, which may not be available on favorable terms, if at all, and may, if sold, cause significant dilution to existing stockholders. Our ability to raise additional funds will depend on financial, economic, political and market conditions and other factors, over which we may have no or limited control. The issuance of additional securities, whether equity or debt, or the possibility of such issuance, may cause the market price of our shares to decline. If we are unable to access additional capital moving forward, it may hurt our ability to grow and to generate future revenues, our financial position, and liquidity. Furthermore, we could be forced to delay, limit, reduce or terminate product development programs, future commercialization efforts or other operations.

If we raise additional capital through the sale of equity or convertible debt securities or we issue any equity or convertible debt securities in connection with a collaboration agreement or other contractual arrangement, our stockholders' ownership interests also will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of stockholders.

Debt financing, if available, may result in increased fixed payment obligations and involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends or acquiring, selling or licensing intellectual property rights or assets, which could adversely impact the ability to conduct our business.

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 intellectual property, technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. Any of these occurrences may have a material adverse effect on our business, operating results and prospects.

Market conditions and changes in financial regulations and policies can impact the viability of financial institutions. In the event of failure of any of the financial institutions where we maintain cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position. In addition, changes in regulations governing financial institutions are beyond our control and difficult to predict; consequently, the impact of such changes on our business and results of operations is difficult to predict and may have an adverse effect on us.

Due to the significant resources required to develop our product pipeline, and depending on our ability to access capital, we must prioritize the development of certain product candidates over others and we may fail to expend our limited resources on product candidates or indications that may have been more profitable or for which there is a greater likelihood of success.

Due to the significant resources required for the development of our product candidates, we must decide which product candidates and indications to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates, therapeutic areas or indications may not lead to the development of viable commercial products and may divert resources away from better opportunities. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misread trends in the pharmaceutical industry, in particular for CNS and CVS diseases, our business, financial condition and results of operations could be materially and adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

Our acquisitions and investments in new businesses and new products, services, and technologies is inherently risky, and could disrupt our ongoing businesses.

We have invested and expect to continue to invest in new businesses, products, services, and technologies. Such endeavors may involve significant risks and uncertainties, including insufficient revenues from such investments to offset any new liabilities assumed and expenses associated with these new investments, inadequate return of capital on our investments, distraction of management from current operations, and unidentified issues not discovered in our due diligence of such strategies and offerings that could cause us to fail to realize the anticipated benefits of such investments and incur unanticipated liabilities. Because these new ventures are inherently risky, no assurance can be given that such strategies and offerings will be successful and will not adversely affect our reputation, financial condition, and operating results.

The use of resources for new businesses and new products, services, and technologies, to the extent such new businesses and new products, services, and technologies do not generate revenues or profits may take management's focus and time away from more profitable endeavors, may require us to take significant write-downs or write-offs, may take funding away from our other operations or growth opportunities, which may ultimately be more profitable, and may have a material adverse effect on our cash flows, liquidity and revenues, any or all of which may cause the value of our securities to decline in value or become worthless.

Our business is highly dependent on the success of certain product candidates. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize one or more of our product candidates, or if we experience delays in doing so, our business will be materially harmed.

Scienture LLC has completed development of SCN-102, which received FDA regulatory approval in March 2025 and commenced commercialization in the third quarter of 2025. The remaining product candidates — SCN-104, SCN-106, and SCN-107 — remain in clinical or preclinical development. Management expects SCN-104 and SCN-106 to achieve regulatory approval in 2027 or 2028, with commercialization projected to begin in 2028, and SCN-107 to achieve regulatory approval in 2028 or 2029, with commercialization projected to begin in 2029. Our future success and ability to generate revenue from Scienture LLC's product candidates is dependent on our ability to successfully develop, obtain regulatory approval for, and commercialize one or more of our remaining product candidates. If any of Scienture LLC's product candidates encounters safety or efficacy problems, development delays, regulatory issues, or other problems, our development plans and business would be materially harmed.

We may not have the financial resources to continue development of our product candidates, particularly if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, product candidates, including:

- inability to demonstrate to the satisfaction of the FDA or other comparable regulatory authorities that our product candidates are safe and effective;
- insufficiency of our financial and other resources to complete the necessary clinical trials and preclinical studies;

- negative or inconclusive results from clinical trials, preclinical studies or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional clinical trials or preclinical studies or abandon a program;
- product-related adverse events experienced by subjects in our clinical trials, including unexpected toxicity results, or by individuals using drugs or therapeutic biologics similar to our product candidates;
- delays in submitting an IND application or other regulatory submission to the FDA or other comparable regulatory authorities, or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial or a suspension or termination, or hold, of a clinical trial once commenced;
- conditions imposed by the FDA or other comparable regulatory authorities regarding the scope or design of our clinical trials;
- poor effectiveness of our product candidates during clinical trials;
- better than expected performance of control arms, such as placebo groups, which could lead to negative or inconclusive results from our clinical trials;
- delays in enrolling subjects in our clinical trials;
- high drop-out rates of subjects from our clinical trials;
- inadequate supply or quality of product candidates or other materials necessary for the conduct of our clinical trials;
- higher than anticipated clinical trial or manufacturing costs;
- unfavorable FDA or comparable regulatory authority inspection and review of our clinical trial sites;
- failure of our third-party contractors or investigators to comply with regulatory requirements or the clinical trial protocol or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policies and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our therapies in particular; or
- varying interpretations of data by the FDA or other comparable regulatory authorities.

In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. We may in the future conduct one or more clinical trials with one or more trial sites that are located outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to conditions imposed by the FDA, and there can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and could delay or permanently halt our development of the applicable product candidates.

We are dependent upon our current management, who may have conflicts of interest. Our ability to develop product candidates and our future growth depends on attracting, hiring and retaining key personnel and recruiting additional qualified personnel.

Our success depends upon the continued contributions of our key management and scientific personnel, many of whom have substantial experience with developing therapies, identifying potential product candidates and building the technologies related to the clinical development of our product candidates. However, some of officers and directors have duties and affiliations with other companies. Involvement of our officers and directors in other businesses may present a conflict of interest regarding decisions they make for us or with respect to the amount of time available for us.

Given the specialized nature of CNS and CVS diseases and our approach, there is an inherent scarcity of experienced personnel in these fields. As we continue developing product candidates, we will require personnel with medical, scientific, or technical qualifications specific to each program. The loss of any of our officers or directors, in particular our current management team consisting of Shankar Hariharan, Narasimhan Mani or Rahul Surana, could have a materially adverse effect upon our business and future prospects.

Despite our efforts to retain valuable employees, members of our team may terminate employment on short notice. The competition for qualified personnel in the biotechnology and biopharmaceutical industries is intense, and our future success depends upon our ability to attract, retain, and motivate highly skilled scientific, technical and managerial employees. We face competition for personnel from other companies, universities, public and private research institutions, and other organizations. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to implement our business strategy, which would have a material adverse effect on our business.

In addition, our clinical operations and research and development programs depend on our ability to attract and retain highly skilled scientists, data scientists, and engineers, particularly in New York, New Jersey, Massachusetts and Pennsylvania. There is powerful competition for skilled personnel in these geographical markets, and we may experience, difficulty in hiring and retaining employees with appropriate qualifications on acceptable terms, or at all. Many of the companies with which we compete for experienced personnel have greater resources than we do. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of stock awards decline, it may harm our ability to recruit and retain highly skilled employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects would be harmed.

We may seek to collaborate with third parties and may not be able to implement these collaborations on commercially acceptable terms, if at all. The success of certain of our product candidates may depend in significant part on the success of such collaborations.

We plan to opportunistically pursue strategic partnerships if we believe that these partnerships can accelerate the development or maximize the market potential of our product candidates. Likely collaborators may include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. In addition, if we are able to obtain regulatory approval for product candidates from foreign regulatory authorities, we may enter into partnerships or collaborations with international biotechnology or pharmaceutical companies for the commercialization of such product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a partnership or collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed partnerships or collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the potential differentiation of our product candidates from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA or other comparable regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for partnership or collaboration and whether such a partnership or collaboration could be more attractive than the one with us for our product candidate. If we elect to increase expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop product candidates or bring them to market and generate product revenue.

Partnerships and collaborations are each complex and time-consuming to negotiate and document. Further, business combinations among large pharmaceutical companies could result in a reduced number of potential future collaborators. Any partnership or collaboration agreement that we enter into in the future may contain restrictions on our ability to enter into potential partnerships or collaborations or to otherwise develop specified product candidates. We may not be able to negotiate partnerships or collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay development programs, delay potential commercialization or reduce the scope of any sales or marketing activities, or increase expenditures and undertake development or commercialization activities at our own expense.

We may have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on any future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, any future collaborators may have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms.

Collaborations involving our product candidates pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of our product candidates 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, which 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 independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, including trade secrets and intellectual property rights, contract interpretation, or the preferred course of development might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might 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;

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

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

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future collaborator is involved in a business combination, we could decide to delay, diminish or terminate the development or commercialization of any licensed product candidate.

We have relied upon and plan to continue to rely on third parties, such as Contract Research Organizations ("CROs"), clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials and expect to rely on these third parties to conduct clinical trials of any other product candidate that we develop. Our ability to complete clinical trials in a timely fashion depends on a number of key factors. These factors include protocol design, regulatory and Institutional Review Board approval, patient enrollment rates and compliance with GCPs. Generally, we rely on our third-party partners to accurately report their results. Our reliance on third parties for clinical development activities may impact or limit our control over the timing, conduct, expense and quality of our clinical trials. Moreover, the FDA requires that we to comply with GCPs for conducting, 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. The FDA enforces these GCPs through periodic inspections of clinical trial sponsors, principal investigators, clinical trial sites and Institutional Review Boards. For certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States.

We remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. Our failure or the failure of third parties to comply with the applicable protocol, legal and regulatory requirements and scientific standards can result in rejection of our clinical trial data or other sanctions. If we or our third-party clinical trial providers or third-party CROs do not successfully carry out these clinical activities, our clinical trials or the potential regulatory approval of a product candidate may be delayed or be unsuccessful. Additionally, if we or our third-party contractors fail to comply with applicable GCPs for any reason, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our product candidates, which would delay the regulatory approval process. We cannot be certain that, upon inspection, the FDA will determine that any of our clinical trials comply with GCPs. We are also required to register certain clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing development programs. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If these third parties, including clinical investigators, do not successfully carry out their contractual duties, meet expected deadlines or conduct its clinical trials in accordance with regulatory requirements or its stated protocols, we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. In such an event, our financial results and the commercial prospects for any product candidates that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired or foreclosed.

We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or regulatory approval of our product candidates or commercialization of any resulting products, producing additional losses and depriving us of potential product revenue.

In addition, we rely on wholesalers and attempt to structure our agreements with such wholesalers to ensure that we are appropriately and predictably compensated for the services we provide. We cannot control the frequency or magnitude of pharmaceutical price changes. We might be unable to renew agreements with wholesalers in a timely and favorable manner. These risks might have a materially adverse impact on our business operations and our financial positions or results of operations.

Any of the third-party organizations we utilize may terminate our engagements with us under certain circumstances. The replacement of an existing CRO or other third party may result in the delay of the affected trials or otherwise adversely affect our efforts to obtain regulatory approvals and commercialize our product candidates. We may not be able to enter into alternative arrangements or do so on commercially reasonable terms. In addition, even if there are suitable replacements for one or more of these service providers, there is a natural transition period when a new service provider begins work. As a result, delays may occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition and prospects.

Our third-party manufacturing partners may be unable to increase the scale of production or product yield of our product candidates, resulting in increased manufacturing costs and delays in commercialization of our products. Furthermore, changes in methods of manufacturing our product candidates could result in additional costs or delays.

In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of our product candidates, our third-party manufacturers will be required to increase production and optimize manufacturing processes while maintaining the quality of our product candidates. The transition to larger scale production could prove difficult. In addition, if our third-party manufacturers are not able to optimize their manufacturing processes to increase the product yield for our product candidates, or if such third party manufacturers are unable to produce increased amounts of our product candidates while maintaining the same quality, then we may not be able to meet the demands of clinical trials or market demands. This could decrease our ability to generate profits and have a material adverse impact on our business and results of operations.

Our growth depends in part on the success of our strategic relationships with third parties. Some of these third parties may be located outside of the United States.

In order to grow our business, we anticipate that we will need to continue to depend on our relationships with third parties, including our technology providers. Identifying partners, and negotiating and documenting relationships with them, requires significant time and resources. Our competitors may be effective in providing incentives to third parties to favor their products or services, or utilization of, our products and services. In addition, acquisitions of our partners by our competitors could result in a decrease in the number of our current and potential customers. If we are unsuccessful in establishing or maintaining our relationships with third parties, our ability to compete in the marketplace or to grow our revenue could be impaired and our results of operations may suffer. Even if we are successful, we cannot assure you that these relationships will result in increased customer use of our products or increased revenue.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates, and we lack the resources and the capabilities to do so. Our current strategy is to outsource all manufacturing of our product candidates to third parties, including in jurisdictions outside of the United States such as China. As such, we currently rely on third-party manufacturers to provide all of the Active Pharmaceutical Ingredients (“API”) and the final drug product formulation of all of our product candidates that are being used in our clinical trials and preclinical studies. If we were to need an alternate manufacturer, we would incur added costs and delays in identifying and qualifying any such replacement. In addition, we typically order raw materials, API and drug product and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements with any commercial manufacturer. We may not be able to timely secure needed supply arrangements on satisfactory terms, or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to complete the development of our product candidates or, to commercialize them, if approved. We may be unable to conclude agreements for commercial supply with third-party manufacturers or may be unable to do so on acceptable terms. There may be difficulties in scaling up to commercial quantities and formulation of our product candidates, and the costs of manufacturing could be prohibitive.

Many of the third-party manufacturers we rely on have only recently begun working with us and have limited or no experience manufacturing our API and final drug products. If our manufacturers have difficulty or suffer delays in successfully manufacturing material that meets our specifications, it may limit supply of our product candidates and could delay our clinical trials.

Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third-party manufacturer to comply with applicable regulatory requirements and reliance on third parties for manufacturing process development, regulatory compliance and quality assurance;
- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between parties;
- limitations on supply availability resulting from capacity and scheduling constraints of third parties;
- the failure of the third-party manufacturer to produce materials with acceptable quality on a larger scale;
- the possible breach of manufacturing agreements by third parties because of factors beyond our control;
- the possible termination or non-renewal of the manufacturing agreements by the third party, at a time that is costly or inconvenient to us; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

If we do not maintain our key manufacturing relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for our product candidates. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the FDA and other comparable regulatory authorities.

Additionally, if any third-party manufacturer with whom we contract fail to perform its obligations, we may be forced to manufacture the materials ourself, for which we may not have the capabilities or resources, or enter into an agreement with a different manufacturer. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change third-party manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce its product candidate according to the specifications previously submitted to the FDA or other comparable regulatory authorities. We may be unsuccessful in demonstrating the comparability of clinical supplies, which could require the conduct of additional clinical trials. The delays associated with the verification of a new third-party manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a third-party manufacturer may possess technology related to the manufacture of our product candidates that such third party owns independently. This would increase our reliance on such third-party manufacturer or require us to obtain a license from such third-party manufacturer in order to have another third party manufacture our product candidates.

If any of our product candidates are approved by any regulatory agency, we intend to utilize arrangements with third-party contract manufacturers for the commercial production of those products. This process is difficult and time consuming and we may face competition for access to manufacturing facilities as there are a limited number of contract manufacturers operating under cGMPs that are capable of manufacturing our product candidates. Consequently, we may not be able to reach agreement with third-party manufacturers on satisfactory terms, which could delay commercialization.

Some of our manufacturers are located outside of the United States, including in China. There is currently significant uncertainty about the future relationship between the United States and various other countries, including China, with respect to trade policies, treaties, government regulations and tariffs. Increased tariffs or pending legislation that would impose federal contracting or federal funding limitations on parties directly using or connected to those using the services or equipment of certain foreign entities with known or alleged associations with foreign adversaries could potentially disrupt our existing supply chains and impose additional costs on our business. In particular, certain Chinese biotechnology companies and commercial manufacturing organizations may become subject to trade restrictions, sanctions, and other regulatory requirements by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting our supplies and manufacturing. Additionally, it is possible further tariffs may be imposed that could affect imports of any APIs used in our product candidates in the future, or our business may be adversely impacted by retaliatory trade measures taken by China or other countries, including restricted access to such raw materials used in its product candidates. Given the unpredictable regulatory environment in China and the United States and uncertainty regarding how the U.S. or foreign governments will act with respect to tariffs, international trade agreements and policies, further governmental action related to tariffs, additional taxes, contracting matters, regulatory changes or other retaliatory trade measures in the future could occur with a corresponding detrimental impact on our business and financial condition.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or voluntary recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our contract manufacturers to manufacture our product candidates must be evaluated by the FDA. We do not control the manufacturing process of, and is completely dependent on, its contract manufacturing partners for compliance with cGMPs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other comparable regulatory authorities, we may not be able to secure and/or maintain regulatory approval for our product candidates manufactured at these facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA finds deficiencies or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates 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, obtain regulatory approval for or market our approved product candidates. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to our its product candidates and market our products, if approved.

The FDA or other comparable regulatory authorities require manufacturers to register manufacturing facilities, and also inspect these facilities to confirm compliance with cGMPs.

Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA and other comparable regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval, if obtained.

Furthermore, should we decide to use any APIs in any of our product candidates that are proprietary to one or more third parties, we would need to maintain licenses to those APIs from those third parties. If we are unable to gain or continue to access rights to such APIs prior to conducting preclinical toxicology studies intended to support clinical trials, we may need to develop alternate product candidates from these programs by either accessing or developing alternate APIs, resulting in increased development costs and delays in commercialization of these product candidates. If we are unable to gain or maintain continued access rights to the desired APIs on commercially reasonable terms or develop suitable alternate APIs, we may not be able to commercialize product candidates from these programs.

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

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as the vendors used to manufacture drug product or manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. 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 materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay or prevent completion of clinical trials, require conducting bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay or prevent approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

We may be subject to lawsuits.

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business. Such claims, even if lacking merit, could result in the expenditure of significant financial and managerial resources.

The successful development of our pharmaceutical products involves a lengthy and expensive process and is highly uncertain.

Successful development of our pharmaceutical products involves a lengthy and expensive process, is highly uncertain, and is dependent on numerous factors, many of which are beyond our control. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- clinical trial results may show the product candidates to be less effective than expected;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals, which, among other things, may be caused by patients who fail the trial screening process, slow enrollment in clinical trials, patients dropping out of trials, patients lost to follow-up, length of time to achieve trial endpoints, additional time requirements for data analysis or NDA or similar foreign application preparation, discussions with the FDA or other comparable regulatory authority, FDA or other comparable regulatory request for additional preclinical or clinical data (such as long-term toxicology studies) or unexpected safety or manufacturing issues;
- preclinical study results may show the product candidate to be less effective than desired or to have harmful side effects;
- failure to receive the necessary post-marketing approval requirements; or
- the proprietary rights of others and their competing products and technologies may prevent our product candidates from being commercialized.

Furthermore, the length of time necessary to complete clinical trials and submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one product candidate to the next and from one country or jurisdiction to the next and may be difficult to predict.

Even if a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials and/or reporting as conditions of approval. Regulators of other countries and jurisdictions have their own procedures for the approval of product candidates with which we must comply prior to marketing in those countries or jurisdictions.

Even if we are successful in obtaining marketing approval, commercial success of any approved products will also depend in large part on the availability of coverage and adequate reimbursement from third-party payors, including government payors such as the Medicare and Medicaid programs and managed care organizations in the United States or country-specific governmental organizations in foreign countries, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other healthcare payors were not to provide coverage and adequate reimbursement for our products once approved, market acceptance and commercial success would be reduced. Even if we are able to obtain coverage and adequate reimbursement for approved products, there may be features or characteristics of our products, such as dose preparation requirements, that prevent our products from achieving market acceptance by the healthcare or patient communities.

In addition, if any of our product candidates receive marketing approval, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply (or ensure that our third-party providers comply) with current cGMPs and GCPs for any clinical trials that we conduct post-approval. In addition, there is always the risk that we, a regulatory authority or a third party might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our product candidates post-approval could adversely affect our business, financial condition and results of operations.

Risks Related to Our Legal and Regulatory Requirements

We are subject, directly or indirectly, to federal and state healthcare, fraud, abuse false claims, and other laws and regulations as well as health data privacy and security laws and regulations, contractual obligations and self-regulatory schemes. If we are unable to comply, or have not fully complied, with such laws, we could face investigations and substantial penalties. Furthermore, it may be difficult and costly for us to comply with the extensive government regulations to which our business is subject.

Our operations are subject to extensive regulation by the U.S. federal and state governments. Healthcare providers and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our operations and our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations. These laws will impact, among other things, our clinical research, as well as our proposed sales and marketing programs.

We may be subject to health information privacy and security laws by the federal government, the states and other jurisdictions in which we may conduct our business. In particular, we may be subject to regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which establishes privacy and security standards that limit the use and disclosure of individually identifiable health information, known as “protected health information,” and requires the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. We are directly subject to certain provisions of the regulations as a “Business Associate” through our relationships with customers. We are also directly subject to the HIPAA privacy and security regulations as a “Covered Entity” with respect to our operations as a healthcare clearinghouse, specialty pharmacy and medical surgical supply business. If we are unable to properly protect the privacy and security of protected health information entrusted to us, we could be found to have breached our contracts with our customers. Further, if we fail to comply with applicable HIPAA privacy and security standards, we could face civil and criminal penalties. Although we have implemented and continue to maintain policies and processes to assist us in complying with these regulations and our contractual obligations, we cannot provide assurances regarding how these regulations will be interpreted, enforced or applied by the government and regulators to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level might also require us to make costly system purchases /or modifications from time to time.

We also may be subject to extensive, and frequently changing, local, state and federal laws and regulations relating to healthcare fraud, waste and abuse. Local, state and federal governments continue to strengthen their position and scrutiny over practices involving fraud, waste and abuse affecting Medicare, Medicaid and other government healthcare programs. Many of the regulations applicable to us, including those relating to marketing incentives, are vague or indefinite and have not been interpreted by the courts. The regulations may be interpreted or applied by a prosecutorial, regulatory, or judicial authority in a manner that could require us to make changes in our operations. If we fail to comply with applicable laws and regulations, we could become liable for damages and suffer civil and criminal penalties, including the loss of licenses or our ability to participate in Medicare, Medicaid and other federal and state healthcare programs.

In addition, we may be subject to the operating and security standards of the Drug Enforcement Administration, the FDA, various state boards of pharmacy, state health departments, the HHS, the CMS, and other comparable agencies. We are also subject to certain state laws relating to price gouging. Although we have enhanced our procedures to ensure compliance, a regulatory agency or tribunal may conclude that our operations are not compliant with applicable laws and regulations. In addition, we may be unable to maintain or renew existing permits, licenses or any other regulatory approvals or obtain without significant delay, future permits, licenses or other approvals needed for the operation of our businesses. Any noncompliance by us with applicable laws and regulations or the failure to maintain, renew or obtain necessary permits and licenses could lead to litigation and have a material adverse impact on our results of operations.

Because of the breadth of these laws and the limited statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. 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. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations.

We may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of our product candidates and adversely impact our business and results of operations.

An NDA or other similar regulatory filing requesting approval to market a product candidate must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe, effective, pure and potent for each desired indication. The NDA or other similar regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product.

The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of pharmaceutical products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, and such regulations differ from country to country. We are not permitted to market any product candidate in the United States or in any foreign countries until we receive the requisite approval from the applicable regulatory authorities of such jurisdictions.

The FDA or any foreign regulatory bodies can delay, limit or deny approval of a product candidate for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory body that the product candidate is safe and effective for the requested indication;
- the FDA's or the applicable foreign regulatory agency's disagreement with our trial protocol or the interpretation of data from preclinical studies or clinical trials;
- our inability to demonstrate that the clinical and other benefits of a product candidate outweigh any safety or other perceived risks;
- the FDA's or the applicable foreign regulatory agency's requirement for additional preclinical studies or clinical trials;
- the FDA's or the applicable foreign regulatory agency's non-approval of the formulation, labeling or specifications of a product candidate;
- the FDA's or the applicable foreign regulatory agency's failure to approve our manufacturing processes and facilities or the facilities of third-party manufacturers upon which we rely; or
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of pharmaceutical products in development, only a small percentage successfully complete the FDA or other regulatory bodies' approval processes and are commercialized.

Even if we eventually complete clinical testing and receive approval from the FDA or applicable foreign agencies for our product candidates, the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional clinical trials which may be required after approval. The FDA or the applicable foreign regulatory agency also may approve a product candidate for a more limited indication or a narrower patient population than we originally requested, and the FDA, or applicable foreign regulatory agency, may not approve it with the labeling that we believe is necessary or desirable for the successful commercialization.

Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of our product candidates and would materially adversely impact our business and prospects.

Even if we obtain regulatory approval for any of our product candidates, we will be subject to ongoing regulatory requirements, which may result in significant additional expenses. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If any of our product candidates are approved by the FDA or a comparable foreign regulatory authority, they will be subject to extensive and ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and listing, as well as continued compliance with cGMPs and GMPs for any clinical trials that we conduct post-approval. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses, including the duration of use, for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product. The FDA may also require a Risk Evaluation and Mitigation Strategy in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations and implementing tracking and tracing requirements for certain prescription pharmaceutical products. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMPs and adherence to commitments made in any approved marketing application. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

We will have to comply with requirements concerning advertising and promotion for our product candidates. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote any of our products for indications or uses for which they do not have approval. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. We also must submit new or supplemental applications and obtain approval for certain changes to the product labeling or manufacturing processes for our products, if approved.

If we discover previously unknown problems with any of our product candidates, such as adverse events of unanticipated severity or frequency, or problems with the facility where they manufactured, or if the FDA disagrees with the promotion, marketing or labeling of our products, the FDA may impose restrictions on us, including requiring withdrawal from the market. If we fail to comply with applicable regulatory requirements, the FDA and other regulatory authorities may, among other things:

- issue warning letters or other regulatory enforcement action;
- impose injunctions, fines or civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical studies;

- refuse to approve pending applications or supplements to approved applications;
- require revisions to the labeling, including limitations on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- impose a Risk Evaluation and Mitigation Strategy, which may include distribution or use restrictions;
- require the conduct of an additional post-market clinical trial or trials to assess the safety of the product;
- impose restrictions on our operations, including closing our contract manufacturers' facilities where regulatory inspections identify observations of noncompliance requiring remediation; or
- restrict the marketing of the product, require a product recall, seizure or detention, or refuse to permit the import or export of the product.

Any government action or investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our product candidates. If regulatory sanctions are applied or if regulatory approval is withdrawn, our operating results will be adversely affected.

Moreover, the policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. In addition, 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 be subject to enforcement action and we may not achieve or sustain profitability.

We intend to use certain regulatory pathways to seek regulatory approval of several of our product candidates. If the FDA concludes that our marketing applications no longer qualify for these regulatory pathways, then our applications may not be accepted by the FDA for review and approval of our products may be delayed.

We intend to seek FDA approval for certain product candidates through the Section 505(b)(2) regulatory pathway. Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (the "FDCA") was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, (the "Hatch-Waxman Amendments"), and permits the submission of an NDA where at least some of the information required for approval comes from preclinical studies or clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA interprets Section 505(b)(2) of the FDCA to permit the applicant to rely upon the FDA's previous findings of safety and efficacy for an approved product. The FDA requires submission of information needed to support any changes to a previously approved drug, such as published data or new studies conducted by the applicant or clinical trials demonstrating safety and efficacy. The FDA could require additional information to sufficiently demonstrate safety and efficacy to support approval. If the FDA later determines our applications for any of our product candidates do not meet the requirements of Section 505(b)(2), or that additional information is needed to support a marketing application for such candidates we are planning to develop under the Section 505(b)(2) pathway, we could experience delays in submitting a marketing application or in obtaining marketing approval. Moreover, even if we obtain approval for our product candidates under the Section 505(b)(2) regulatory pathway, the approval may be subject to limitations on the indicated uses for which they may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

We may seek priority review designation for our product candidates. We might not receive such designation, and even if we do, such designation may not lead to faster regulatory review or approval.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for one or more of our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status, so even if we believe a product candidate for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily result in an expedited regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

We may seek orphan drug designation from the FDA for our product candidates. We may be unable to obtain such designation or, if obtained, to maintain the benefits associated with orphan drug status, including the potential for non-patent market exclusivity.

We may seek orphan drug designation for certain of our product candidates, but we may not be able to obtain such designation or maintain the benefits associated with orphan drug designation (if obtained), including the potential for non-patent market exclusivity. Under the Orphan Drug Act, the FDA may designate a drug or biologic as an orphan drug if it is a product intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population of 200,000 or more in the United States where there is no reasonable expectation that the cost of developing the product will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Generally, if a product with an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same product and indication for that time period, except in limited circumstances. Any competitor developing the same product in the same indication with orphan drug designation may block our ability to obtain orphan drug exclusivity in the future if the competitor receives marketing approval before we do. The applicable exclusivity period is seven years in the United States.

Even if we obtain orphan drug exclusivity, that exclusivity may not effectively protect our product from competition because different products can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines 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 or if another product with the same active moiety is determined to be safer, more effective, or represents a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a product nor gives the product any advantage in the regulatory review or approval process.

If regulatory authorities approve generic versions of our products, or do not grant our products a sufficient period of market exclusivity before approving a generic version, our ability to generate revenue may be adversely affected.

Once an NDA is approved, including under the 505(b)(2) pathway, the product covered thereby becomes a “reference listed drug” in the FDA’s publication, “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly known as the Orange Book. Manufacturers may seek approval of generic versions of reference listed drugs through submission of Abbreviated New Drug Applications and may obtain therapeutical equivalence evaluations for 505(b)(2) pathway drugs under the Food and Drug Omnibus Reform Act’s expanded authorities, in the United States. In support of an Abbreviated New Drug Application, a generic manufacturer need not conduct clinical trials to assess safety and efficacy. 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 labelling 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. 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. 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.

Generic drug manufacturers may seek to launch generic products following the expiration of any applicable exclusivity period we obtain if any of our products is approved, even if we still have patent protection. In particular, competition that our lead candidate, SCN-102, could face from generic versions could materially and adversely affect our future revenue, profitability, and cash flows and substantially limit our ability to obtain a return on the investments we have made in SCN-102.

Even if we obtain FDA approval for a product candidate in the United States, we may never obtain approval for or successfully commercialize that candidate outside of the United States, which would limit our ability to realize a product's full market potential.

In order to market a candidate outside of the United States, we must obtain marketing authorizations and comply with numerous and varying regulatory requirements of other countries regarding quality, safety and efficacy. Clinical trials conducted in one country may not be accepted by foreign regulatory authorities, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional non-clinical studies or clinical trials, which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates in those countries. We do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market for our product candidates will be reduced and we would not be able to realize the full market potential of our product candidates.

Even if we are able to commercialize any of our product candidates, the third-party payor coverage and reimbursement status of newly-approved products are uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates could limit our ability to market those products and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors in the United States are essential for most patients to be able to afford treatments such as our products or product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for drug treatments by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our products, and potentially attract additional collaboration partners to invest in the development of our product candidates. We cannot be sure that adequate coverage and reimbursement in the United States, the EU or elsewhere will be available for our products or any products that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs, biologics and medical devices will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs, biologics and medical devices. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our products or product candidates.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our products or product candidates. We expect to experience pricing pressures in connection with the sale of our products and product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

We are developing a drug-device combination product, which may result in additional regulatory risks.

Our SCN-104 injection pen will be regulated as a drug-device combination product. We currently plan to develop this product as a combination of a small molecule drug product administered using a disposable, multiple fixed dose injection pen. There may be additional regulatory risks for drug-device combination products. We may experience delays in obtaining regulatory approval of SN-104 given the increased complexity of the review process when approval of the product and a delivery device is sought under a single marketing application. In the United States, each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a drug, biologic or device. The delivery device will be subject to FDA design control device requirements which comprise among other things, design verification, design validation (including human factors testing), and testing to assess performance, cleaning, and robustness. Delays in or failure of the studies conducted by us, or failure of us, our collaborators, if any, or our third-party providers or suppliers to maintain compliance with regulatory requirements could result in increased development costs, delays in or failure to obtain regulatory approval, and associated delays in SCN-104 reaching the market.

Our third party collaborators and service providers are, or may become, subject to a variety of stringent and evolving privacy and data security laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to privacy and data security. Any actual or perceived failure to comply with such obligations could expose us to significant fines or other penalties and otherwise harm our business and operations.

In the ordinary course of our business, we and the third parties upon which we rely (such as our third party CROs and other contractors and consultants) collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, sensitive third-party data, business plans, transactions, financial information and data we collect about trial participants in connection with clinical trials. Our data processing activities subject us to numerous evolving privacy and data security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to privacy and data security.

The legislative and regulatory framework for the processing of personal data worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. In the United States, numerous federal, state and local laws and regulations, including federal health information privacy laws, state information security and data breach notification laws, federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws) govern the processing of health-related and other personal data.

At the state level, numerous U.S. states—including California, Virginia, Colorado, Connecticut and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording individuals certain rights concerning their personal data. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While these states exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Additionally, we may be subject to new laws governing the privacy of consumer health data. For example, Washington's My Health My Data Act broadly defines consumer health data, creates a private right of action to allow individuals to sue for violations of the law, imposes stringent consent requirements and grants consumers certain rights with respect to their health data, including to request deletion of their information. Connecticut and Nevada have also passed similar laws regulating consumer health data. These various privacy and data security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern privacy and data security. For example, the European Union's General Data Protection Regulation and the United Kingdom's GDPR (collectively, "GDPR") impose strict requirements for processing personal data.

GDPR establishes stringent requirements regarding the processing of personal data, including (i) strict requirements relating to processing of sensitive data (such as health data), ensuring there is a legal basis or condition to justify the processing of personal data, where required, (ii) strict requirements relating to obtaining consent of individuals, (iii) expanded disclosures about how personal data is to be used, (iv) limitations on retention of information, (v) implementing safeguards to protect the security and confidentiality of personal data, where required, (vi) providing notification of data breaches, (v) maintaining records of processing activities, and (vii) documenting data protection impact assessments where there is high risk processing and taking certain measures when engaging third-party processors.

Under GDPR, companies may face temporary or definitive bans on data processing and other corrective activities, fines, and private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. Non-compliance could also result in a material adverse effect on our business, financial position and results of operations.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area ("EEA") and the United Kingdom ("UK") have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA's standard contractual clauses, the UK's International Data Transfer Agreement/Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

In addition to privacy and data security laws, we are contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to privacy and data security, and our efforts to comply with such obligations may not be successful.

We may publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding privacy and data security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Obligations related to privacy and data security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our privacy and data security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable privacy and data security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If we obtain approval of any of our product candidates and we are found to have improperly promoted off-label uses of such products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, if approved. In particular, while the FDA permits the dissemination of truthful and non-misleading information about an approved product, a manufacturer may not promote a product for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The government has also imposed consent decrees, corporate integrity agreements or permanent injunctions under which specified promotional conduct must be changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Healthcare legislative reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In 2010, the ACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry.

There are continued efforts to challenge the ACA. There are also efforts to broaden healthcare coverage. U.S. lawmakers also have explored proposals to reduce drug prices, including requiring price transparency and drug importation measures. These proposals might result in significant changes in the pharmaceutical value chain as manufacturers, pharmacy benefits managers ("PBMs", managed care organizations and other industry stakeholders look to implement new transactional flows and adapt their business models. PBMs are third-party administrator of prescription drug programs for commercial health plans, self-insured employer plans, Medicare Part D plans (prescription drug plans), the Federal Employees Health Benefits Program, and state government employee plans

Provincial governments in Canada that provide partial funding for the purchase of pharmaceuticals and independently regulate the sale and reimbursement of drugs have sought to reduce the costs of publicly funded health programs. For example, provincial governments have taken steps to reduce consumer prices for generic pharmaceuticals and, in some provinces, change professional allowances paid to pharmacists by generic manufacturers.

Many European governments provide or subsidize healthcare to consumers and regulate pharmaceutical prices, patient eligibility and reimbursement levels in order to control government healthcare system costs. Some European governments have implemented or are considering austerity measures to reduce healthcare spending. These measures exert pressure on the pricing and reimbursement timelines for pharmaceuticals and may cause our customers to purchase fewer of our products and services or influence us to reduce prices.

The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any of our product candidates, if approved;
- the ability to set a price that we believe is fair for any of our product candidates, if approved;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical and biologic products. In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

We cannot be sure whether additional legislative changes will be enacted, or whether 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 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.

We cannot predict what healthcare reform initiatives may be adopted in the future. We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government 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.

Inadequate funding for the FDA and other government agencies, including from government shutdowns, or other disruptions to these agencies' operations, could hinder such agencies' ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the United States government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Our Technology and Intellectual Property

We may not be able to protect our intellectual property and trade secret rights throughout the world. If our efforts to protect our intellectual property rights are inadequate, we may not be able to compete effectively in our market.

We may not be able to pursue patent coverage of our product candidates in certain countries outside of the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may 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. The breadth and strength of our or our licensors' patents issued in foreign jurisdictions or regions may not be the same as the corresponding patents issued in the United States. Consequently, we may not be able to prevent third parties from practicing our or our licensors' inventions in all countries outside the United States, or from selling or importing products made using our or our licensors' 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 certain territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition to seeking patents for some of our product candidates, we also rely on trade secrets, including unpatented know-how, technology, and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time consuming, and the outcome is unpredictable. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we may not be able to establish or maintain a competitive advantage in the market, which could materially adversely affect our business, operating results and financial condition. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if successful. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protections, particularly those relating to biotechnology and biopharmaceutical products. This difficulty with enforcing patents could make it difficult for us to stop the infringement of our or our licensors' patents or marketing of competing products otherwise generally in violation of our proprietary rights. 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 or our licensors' patents at risk of being invalidated or interpreted narrowly, put our or our licensors' 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 intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We depend on in-licensed intellectual property. If we fail to comply with our obligations under intellectual property licenses with third parties, we could lose license rights that are important to our business.

Scienture LLC is a party to the Innocore License, an exclusive and royalty-bearing intellectual property license agreement. In connection with our efforts to expand our pipeline of product candidates, we expect to enter into additional license agreements in the future. We expect that any future license agreements we may enter into may impose various diligence, milestone payment, royalty, insurance, and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate the relevant agreement, in which event we would not be able to develop or market the products covered by such licensed intellectual property, or to pursue other remedies.

We may not be able to obtain licenses at a reasonable cost or on reasonable terms, or at all. Furthermore, if we lose intellectual property rights licensed under existing agreements or fail to obtain future licenses, we may be required to expend considerable time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected proprietary technologies and product candidates, which could harm our business significantly.

If we or our licensors are unable to obtain and maintain patent protection for our product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to our product candidates, and our ability to successfully commercialize our product candidates may be adversely affected. Furthermore, we do not intend to seek patent protection for one of our products, SCN-106.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment that are important to our business. If we or our licensors does not adequately protect our or our licensors' intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. We and our licensors seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates that are important to our business. We may in the future also license or purchase patent applications filed by others. If we or our licensors are unable to secure or maintain patent protection with respect to our product candidates and any proprietary product candidates and technology we develop, our business, financial condition, results of operations, and prospects could be materially harmed.

If the scope of the patent protection we or our licensors obtain is not sufficiently broad, we may not be able to prevent others from developing and commercializing products and technology similar or identical to our product candidates or otherwise maintain a competitive advantage. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our or our licensors' patents have, or that any of our or our licensors' pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage. In addition, to the extent that we license intellectual property, we cannot make assurances that those licenses will remain in force.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. The scope of the invention claimed in a patent application can be significantly reduced before the patent is issued, and this scope can be reinterpreted after issuance. Any patents that eventually issue may be challenged, narrowed or invalidated by third parties. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by valid and enforceable patent rights. Our competitors or other third parties may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The patent prosecution process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering product candidates that we license from third parties and are reliant on our licensors. Therefore, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. If such licensors fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated.

Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases, at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability, and commercial value of our and our licensors' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued which protect our product candidates or which effectively prevent others from commercializing competitive products.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. We or our licensors may in the future, become subject to a third-party pre-issuance submission of prior art, opposition, derivation, revocation, re-examination, post-grant and *inter partes* review, or interference proceeding and other similar proceedings challenging our patent rights or the patent rights of others in the USPTO or other foreign patent office. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical products, or limit the duration of the patent protection of our product candidates.

Furthermore, given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to our product candidates.

In addition, we rely on certain of our licensors to prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them and may continue to do so in the future. We have limited control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights or defend certain of the intellectual property that is licensed to us. It is possible that any licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them.

Moreover, some of our owned and in-licensed patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we or our licensors may need the cooperation of any such co-owners of our owned and in-licensed patents in order to enforce such patents against third parties, and such cooperation may not be provided to us or our licensors. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Notwithstanding the importance of obtaining and maintaining patent protection for our products, we are not pursuing, and do not intend in the future to pursue, patent protection for one of our products, SCN-106. SCN-106 is a potential biosimilar product. Developing and commercializing a biosimilar product is time consuming, costly, and subject to numerous factors that may delay or prevent such development and commercialization. The biosimilar markets in which we compete are undergoing and are expected to continue to undergo, rapid and significant change. We expect competition to intensify as technology advances and consolidation continues. New developments by other manufacturers and distributors could render our products uncompetitive or obsolete.

The Company did not maintain a fully integrated financial consolidation and reporting system throughout the period and as a result, extensive manual analysis, reconciliation and adjustments were required in order to produce financial statements for external reporting purposes. does not currently have a sufficient complement of technical accounting and external reporting personnel commensurate to support standalone external financial reporting under public company or SEC requirements. Specifically, the Company did not effectively segregate certain accounting duties due to the small size of its accounting staff and maintain a sufficient number of adequately trained personnel necessary to anticipate and identify risks critical to financial reporting and the closing process. In addition, there were inadequate reviews and approvals by the Company's personnel of certain reconciliations and other processes in day-to-day operations due to the lack of a full complement of accounting staff.

Even if we are able to obtain regulatory approvals for SCN-106, the commercial success of SCN-106 is dependent upon market acceptance. Levels of market acceptance for our product could be affected by several factors, including:

a. internal control over financial reporting a. the availability of alternative products from our competitors;

b. the prices of our products relative to those of our competitors;

c. the timing of our market entry;

d. the ability to market our products effectively at the institutional level;

e. the perception of patients and the healthcare community, including third-party payers, regarding the safety, efficacy and benefits of our drug products compared to those of competing products; and

f. the acceptance of our products by government and private formularies.

Some of these factors will not be in our control, and SCN-106 may not achieve expected levels of market acceptance. Many of our competitors in the biosimilar space have longer operating histories and greater financial, research and development, marketing, and other resources than we do. Consequently, some of our competitors may be able to develop biosimilar products and/or processes competitive with, or superior to, our products and/or processes and can enter the market prior to or after we launch the product. Furthermore, we may not be able to offer customers payment and other commercial terms as favorable as those offered by our competitors. Such actions have the potential to significantly reduce the potential market share and profitability of SCN-106.

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

We cannot be certain that an allowed patent application will become an issued patent because there may be events that cause withdrawal of the allowance of a patent application. For example, after a patent application has been allowed, but prior to being issued, material that could be relevant to patentability may be identified. In such circumstances, the applicant may pull the application from allowance in order for the USPTO to review the application in view of the new material. We cannot be certain that the USPTO will issue the application in view of the new material. Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign countries may require the payment of maintenance fees or patent annuities during the lifetime of a patent application and/or any subsequent patent that issues from the application. 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 application process and following the issuance of a patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application. Such noncompliance can result in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. Such an event could have a material adverse effect on our business.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

If we or one of our licensing partners initiates legal proceedings against a third party to enforce a patent covering our product candidates, the defendant could counterclaim that the patent covering our product candidates, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are various grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post grant review and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in revocation or amendment to our or our licensors' patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel, our licensors and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our or our licensors' rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

Changes to patent law in the United States and in foreign jurisdictions could diminish the value of our patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology and biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology and biopharmaceutical industry involves both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. Patent reform legislation in the U.S. and other countries could increase those uncertainties and costs. Passed in 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act") made a number of significant changes to U.S. patent law, including provisions affecting the way patent applications are prosecuted, redefining prior art and providing more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy-Smith Act transformed the U.S. patent system into a "first-to-file" system, effective on March 16, 2013 and has impacted our business by making it more difficult to obtain patent protection for our inventions and increasing the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Moreover, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our or our licensors' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensors' ability to obtain new patents or to enforce our or our licensors' existing patents and patents that we or our licensors might obtain in the future. We cannot predict how future decisions by the courts, Congress or the USPTO may impact the value of our or our licensors' patents. Similarly, any adverse changes in the patent laws of other jurisdictions could have a material adverse effect on our business and financial condition. Changes in the laws and regulations governing patents in other jurisdictions could similarly have an adverse effect on our ability to obtain and effectively enforce our patent rights.

If we do not obtain patent term extension for our current product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of our current product candidates, one or more of our or our licensors' U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply for a patent extension within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we believe we are entitled to, our competitors may obtain approval of competing products sooner than we would expect, and our business, financial condition, results of operations, and prospects could be materially harmed.

We may become involved in lawsuits to protect or enforce our intellectual property rights, which could be distracting, expensive, time consuming, and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that our patents or our licensors' patents are invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. Defense against these assertions, non-infringement, invalidity or unenforceability regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Post-grant proceedings provoked by third parties or brought by the USPTO may be brought to determine the validity or priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or require us to obtain license rights from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or post-grant proceedings may result in a decision adverse to our interests and, even if successful, may result in substantial costs and distract our management, employees, and contractors. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as those within the United States.

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. In addition, our licensors may have rights to file and prosecute such claims, and we are reliant on them.

We may be subject to claims challenging the inventorship or ownership of our intellectual property or asserting that we violated intellectual property rights of others, the outcome of which would be uncertain. These claims could be extremely costly to defend, could require us to pay significant damages and limit our ability to operate, and could distract our personnel from normal responsibilities.

Our commercial success depends upon our ability and the ability of our collaborators to commercialize, develop, manufacture, market, and sell our product candidates without infringing the proprietary rights of third parties. We have yet to conduct comprehensive freedom to operate searches to determine whether we would infringe patents issued to third parties. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates, including interference proceedings before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. 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 its product candidates. 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 product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates 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.

If a third party alleges that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property misappropriation which, regardless of merit, may be expensive and time-consuming to litigate and may divert management's attention from our core business;
- substantial damages for infringement or misappropriation, which we may have to pay if a court decides that the product or technology at issue infringes on or violates the third-party's rights, and, if the court finds we have willfully infringed intellectual property rights, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- an injunction prohibiting us from manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party agrees to license its patent rights to us;
- even if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights protecting our product candidates; and
- we may be forced to try to redesign our product candidates or processes so they do not infringe third-party intellectual property rights, an undertaking which may not be possible or which may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Third parties may assert that we are employing their proprietary technology without authorization. Patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be issued third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Patent applications can take many years to issue. There may be currently pending patent applications which may later result in issued patents that may be infringed by our product candidates. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by its activities. If any third-party patents, held now or obtained in the future by a third party, were found by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product or methods use of the product, the holders of any such patents may be able to block our ability to commercialize the product unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover any aspect of our formulations, any combination therapies or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product unless we have obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, such license may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications are threatened, it could dissuade companies from collaborating with us to license, develop or commercialize our product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign its infringing product candidates, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance its research or allow commercialization of its product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize its product candidates, which could harm our business significantly.

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time-consuming. If we are unsuccessful, we could lose valuable rights in intellectual property that we regard as our own.

This is especially relevant as some of our employees and contractors may have been previously employed at, or may have previously provided or may be currently providing consulting services to, universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We could in the future be subject to claims that we or our employees and contractors have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors. Although we try to ensure that our employees and contractors do not use the proprietary information or know how of others in their work for us, we may be subject to claims that we caused an employee or contractor to breach the terms of his or her non-competition or non-solicitation agreement, or that we or our employees or contractors have, inadvertently or otherwise, used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or competitor. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

European patents and patent applications could be challenged in the recently created Unified Patent Court for the European Union.

We or our licensors' European patents and patent applications could be challenged in the recently created Unified Patent Court ("UPC") for the European Union. We may decide to opt out our European patents and patent applications from the UPC. However, if certain formalities and requirements are not met, our European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that our or our licensors' European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC. Under the UPC, a granted European patent would be valid and enforceable in numerous European countries. A successful invalidity challenge to a European patent under the UPC would result in loss of patent protection in those European countries. Accordingly, a single proceeding under the UPC could result in the partial or complete loss of patent protection in numerous European countries, rather than in each validated European country separately as such patents always have been adjudicated. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations.

Our use, or the use by our third party collaborators and service providers, of new and evolving technologies, such as artificial intelligence ("AI") and machine learning ("ML"), may result in spending additional resources and present new risks and challenges that can impact our business, including by posing security and other risks to our sensitive data. As a result, we may be exposed to reputational harm, other adverse consequences, and liability.

The use of new and evolving technologies, such as AI/ML, in our operations, and the operations of third parties upon which we rely presents new risks and challenges that could negatively impact our business. The use of certain AI/ML technologies can give rise to intellectual property risks, including compromises to proprietary intellectual property and intellectual property infringement. Additionally, several jurisdictions around the globe, including Europe and certain U.S. states, have proposed, enacted, or are considering, laws governing the development and use of AI/ML, such as the European Union's AI Act. We expect other jurisdictions will adopt similar laws. Additionally, certain privacy laws extend rights to consumers (such as the right to delete certain personal data) and regulate automated decision making, which may be incompatible with our use of AI/ML. These obligations may make it harder for us to conduct our business using AI/ML, lead to regulatory fines or penalties, require us to change our business practices, retrain our AI/ML, or prevent or limit our use of AI/ML. For example, the Federal Trade Commission has required other companies to turn over (or disgorge) valuable insights or trainings generated through the use of AI/ML where they allege the company has violated privacy and consumer protection laws. If we cannot use AI/ML or our use is restricted, our business may be less efficient, or we may be at a competitive disadvantage.

The rapid evolution of AI/ML will require the application of significant resources to design, develop, test and maintain our products and services to help ensure that AI/ML is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. Our vendors may in turn incorporate AI/ML tools into their own offerings, and the providers of these AI/ML tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI/ML, to engage in illegal activities involving the theft and misuse of sensitive data. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

If our trademarks and trade names are not adequately protected then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During the trademark registration process, we may receive so called "Office Actions" from the USPTO objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Risks Related to Our Common Stock

We may not be able to comply with Nasdaq's continued listing standards.

There is no guarantee that we will be able to maintain our listing on Nasdaq for any period of time by perpetually satisfying Nasdaq's continued listing requirements. Our failure to continue to meet these requirements may result in our securities being delisted from Nasdaq. At times, we have received deficiency notices from Nasdaq regarding our inability to comply with various of the continued listing rules (including stockholders' equity requirements, publicly held share requirements, and timely filing requirements). For example, on October 14, 2025, we received a written notice from the Listing Qualifications department of Nasdaq indicating that we were not in compliance with Nasdaq Listing Rule 5450(a)(1), as the minimum bid price of our common stock had been below $1.00 per share for 30 consecutive business days (the "Minimum Bid Price Requirement"). This written notice had no immediate effect on the listing or trading of our common stock on Nasdaq. According to the notice, we have 180 calendar days, or until April 13, 2026 (the "Initial Compliance Period"), to regain compliance with the Minimum Bid Price Requirement. To regain compliance, the minimum bid price of our common stock must meet or exceed $1.00 per share for a minimum of ten consecutive business days during the Initial Compliance Period.

In the event we do not regain compliance with the Minimum Bid Price Requirement during the Initial Compliance Period, we may be eligible for an additional 180-calendar day compliance period (the "Additional Compliance Period") if, at that time, we meet the continued listing requirement for the market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement. Additionally, we would need to provide written notice of our intention to cure the deficiency during the Additional Compliance Period, including by effecting a reverse stock split, if necessary. Our failure to regain compliance during the Initial Compliance Period or the Additional Compliance Period, if applicable, could result in delisting.

While we believe we will be able to timely regain compliance with Nasdaq's continued listing requirements, there can be no assurance that we will be able to regain compliance with the Minimum Bid Price Requirement or will otherwise be able to maintain compliance with other Nasdaq listing criteria. If our common stock were to be delisted from Nasdaq, it would likely reduce the liquidity of our common stock, and, among other things, may decrease the attractiveness of our common stock to the investment community, and make it more difficult for us to issue equity securities for capital raising purposes or for acquisitions.

Our common stock has in the past been a "penny stock" under SEC rules, and may be subject to the "penny stock" rules in the future. It may be more difficult to resell securities classified as "penny stock."

In the past (including immediately prior to our common stock being listed on Nasdaq in February 2020), our common stock was a "penny stock" under applicable SEC rules (generally defined as non-exchange traded stock with a per-share price below $5.00). While our common stock is not now considered a "penny stock" because it is listed on Nasdaq, if we are unable to maintain that listing, unless we maintain a per-share price above $5.00, our common stock will become "penny stock." These rules impose additional sales practice requirements on broker-dealers that recommend the purchase or sale of penny stocks to persons other than those who qualify as "established customers" or "accredited investors." For example, broker-dealers must determine the appropriateness for non-qualifying persons of investments in penny stocks. Broker-dealers must also provide, prior to a transaction in a penny stock not otherwise exempt from the rules, a standardized risk disclosure document that provides information about penny stocks and the risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, disclose the compensation of the broker-dealer and its salesperson in the transaction, furnish monthly account statements showing the market value of each penny stock held in the customer's account, provide a special written determination that the penny stock is a suitable investment for the purchaser, and receive the purchaser's written agreement to the transaction.

Legal remedies available to an investor in "penny stocks" may include the following:

- If a "penny stock" is sold to the investor in violation of the requirements listed above, or other federal or states securities laws, the investor may be able to cancel the purchase and receive a refund of the investment.

- If a "penny stock" is sold to the investor in a fraudulent manner, the investor may be able to sue the persons and firms that committed the fraud for damages.

These requirements may have the effect of reducing the level of trading activity, if any, in the secondary market for a security that becomes subject to the penny stock rules. The additional burdens imposed upon broker-dealers by such requirements may discourage broker-dealers from effecting transactions in our securities, which could severely limit the market price and liquidity of our securities. These requirements may restrict the ability of broker-dealers to sell our common stock and may affect your ability to resell our common stock.

Many brokerage firms will discourage or refrain from recommending investments in penny stocks. Most institutional investors will not invest in penny stocks. In addition, many individual investors will not invest in penny stocks due, among other reasons, to the increased financial risk generally associated with these investments.

For these reasons, penny stocks may have a limited market and, consequently, limited liquidity. We can give no assurance at what time, if ever, our common stock may be classified as a "penny stock" in the future.

The exercise of outstanding warrants, options and other securities that are exercisable into shares of our common stock will be dilutive to our existing stockholders.

As of the date of this Annual Report, we had outstanding various warrants, stock options and other securities that are exercisable into shares of our common stock. For the life of the options and warrants, the holders have the opportunity to profit from a rise in the market price of our common stock without assuming the risk of ownership. The issuance of shares upon the exercise of outstanding securities will also dilute the ownership interests of our existing stockholders. The availability of these shares for public resale, as well as any actual resales of these shares, could adversely affect the trading price of our common stock.

We cannot predict the size of future issuances of our common stock pursuant to the exercise of outstanding options or warrants, or the effect, if any, that future issuances and sales of shares of our common stock may have on the market price of our common stock. Sales or distributions of substantial amounts of our common stock (including shares issued in connection with an acquisition), or the perception that such sales could occur, may cause the market price of our common stock to decline.

We have not historically paid or declared any dividends on our common stock and do not expect to pay or declare cash dividends in the future on a regular basis, if at all.

Although we declared special cash dividends in the first and third quarters of 2024, those dividends were declared as the result of a sale various business assets and not paid from cash generated in our operations. We have not historically paid or declared any dividends on our common stock or preferred stock. Any future dividends on common stock will be declared at the discretion of our board of directors and will depend, among other things, on our earnings, our financial requirements for future operations and growth, and other facts as we may then deem appropriate. As such, the return on your investment, if any, has historically been dependent solely on an increase, if any, in the market value of our common stock.

Our common stock price is likely to be highly volatile because of several factors, including a limited public float.

The market price of our common stock has been volatile in the past and the market price of our common stock is likely to be highly volatile in the future. You may not be able to resell shares of our common stock following periods of volatility because of the market's adverse reaction to volatility.

Other factors that could cause such volatility may include, among other things:

- actual or anticipated fluctuations in our operating results;
- the absence of securities analysts covering us and distributing research and recommendations about us;
- we may have a low trading volume for a number of reasons, including that a large portion of our stock is closely held;
- overall stock market fluctuations;
- announcements concerning our business or those of our competitors;
- actual or perceived limitations on our ability to raise capital when we require it, and to raise such capital on favorable terms;
- conditions or trends in our industry;
- litigation;

- changes in market valuations of other similar companies;
- future sales of common stock;
- departure of key personnel or failure to hire key personnel; and
- general market conditions.

Any of these factors could have a significant and adverse impact on the market price of our common stock. In addition, the stock market in general has at times experienced extreme volatility and rapid decline that has often been unrelated or disproportionate to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock, regardless of our actual operating performance.

There may not be sufficient liquidity in the market for our securities in order for investors to sell their shares. The market price of our common stock may continue to be volatile.

The market price of our common stock will likely continue to be highly volatile. Some of the factors that may materially affect the market price of our common stock are beyond our control, such as conditions or trends in the industry in which we operate or sales of our common stock. This situation is attributable to a number of factors, including the fact that we are a small company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable.

As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a mature issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. It is possible that a broader or more active public trading market for our common stock will not develop or be sustained, or that trading levels will not continue. These factors may materially adversely affect the market price of our common stock, regardless of our performance. In addition, the public stock markets have experienced extreme price and trading volume volatility. This volatility has significantly affected the market prices of securities of many companies for reasons frequently unrelated to the operating performance of the specific companies. These broad market fluctuations may adversely affect the market price of our common stock.

Stockholders may be diluted significantly through our efforts to obtain financing and satisfy obligations through the issuance of additional shares of our common stock.

Wherever possible, our board of directors will attempt to use non-cash consideration to satisfy obligations. In many instances, we believe that the non-cash consideration will consist of restricted shares of our common stock or where shares are to be issued to our officers, directors and applicable consultants. Our board of directors has authority, without action or vote of the stockholders, but subject to Nasdaq rules and regulations (which generally require shareholder approval for any transactions which would result in the issuance of more than 20% of our then outstanding shares of common stock or voting rights representing over 20% of our then outstanding shares of stock), to issue all or part of the authorized but unissued shares of common stock. In addition, we may attempt to raise capital by selling shares of our common stock, possibly at a discount to market. These actions will result in dilution of the ownership interests of existing stockholders, which may further dilute common stock book value, and that dilution may be material. Such issuances may also serve to enhance existing management's ability to maintain control of the Company because the shares may be issued to parties or entities committed to supporting existing management.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

We maintain a cyber-risk management program which is intended to assist in assessing, identifying, and managing material risks from cybersecurity threats to our data and information systems. This program is to ensure that cybersecurity considerations are included in decision-making processes throughout the Company.

Our approach consists of, among other things, cybersecurity threat and vulnerability prevention, detection, mitigation and remediation of potential cybersecurity risks. We employ cybersecurity intrusion detection systems and continuous monitoring, in order to help defend against unauthorized access. We also employ identity-based access controls and identity authentication requirements. Access to the Company's data is monitored and controlled according to access control policies. Data protection and privacy practices, including data loss prevention, help to safeguard sensitive information. We have also outsourced significant elements of our information technology infrastructure; as a result, we manage independent vendor relationships with third parties who are responsible for maintaining significant elements of our information technology systems and infrastructure.

Our Board of Directors is responsible for oversight of our cyber-risk management program and management's role is to assist the Board of Directors in identifying and considering material cybersecurity risks, ensure implementation of management and employee level cybersecurity practices and training and provide the Board of Directors with regular reports regarding any cybersecurity attacks or vulnerabilities.

As of the date of this Annual Report on Form 10-K, we have not experienced any significant cybersecurity attacks and, to date, the risks from cybersecurity threats have not materially affected, or are reasonably likely to materially affect, our business strategy, results of operations, or financial condition.

ITEM 2. PROPERTIES

We do not own any real property.

Scienture LLC entered into a lease at 20 Austin Boulevard, Commack, NY 11725 for approximately $29,621 per year ($2,468 per month) under a 22-month agreement, effective October 1, 2023.

We believe our current and future facilities are adequate for our current and near-term needs. Additional space may be required as we expand our activities. We do not currently foresee any significant difficulties in obtaining any required additional facilities.

ITEM 3. LEGAL PROCEEDINGS

In the ordinary course of business, we may become a party to lawsuits involving various matters. The impact and outcome of litigation, if any, is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. We believe the ultimate resolution of any such current proceeding will not have a material adverse effect on our continued financial position, results of operations or cash flows, except as otherwise set forth below. However, assessment of the current litigation or other legal claims could change in light of the discovery of facts not presently known to the Company or by judges, juries or other finders of fact, which are not in accord with management's evaluation of the possible liability or outcome of such litigation or claims.

For a description of our material pending legal proceedings, please see "Note 13 – Commitments and Contingencies" to the Notes to Consolidated Financial Statements included herein under "Item 8. Financial Statements and Supplemental Data."

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market for Common Stock

Our common stock is listed on Nasdaq, under the symbol "SCNX". At present, there is a limited market for our common stock.

Holders of Record

As of March 27, 2026, we had 40,630,815 shares of common stock outstanding, held by 66 stockholders of record, not including holders who hold their shares in street name. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees.

Dividend Policy

Although we paid a special cash dividend in the first and third quarters of 2024, we have not historically paid or declared any cash dividends on our common stock. Any determination to pay dividends in the future will be at the discretion of our board of directors. Accordingly, investors have historically relied on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

Recent Sales of Unregistered Securities

During the year ended December 31, 2025, the Company issued 3,760,150 shares of common stock for services. The Company relied on the exemption from registration set forth in Section 4(a)(2) of the Securities Act for this issuance. Such issuance did not involve a public offering and was made without general solicitation or general advertising, and the recipient of the shares was an accredited investor.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

The Company did not repurchase any shares of common stock during the year ended December 31, 2025.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of the Company's historical performance and financial condition should be read together with the consolidated financial statements and related notes in the section entitled "*Item 8. Financial Statements and Supplemental Data*" of this Annual Report. This discussion contains forward-looking statements based on the views and beliefs of our management, as well as assumptions and estimates made by our management. See the section entitled "*Cautionary Statement Regarding Forward-Looking Information*" above. These statements by their nature are subject to risks and uncertainties and are influenced by various factors. As a consequence, actual results may differ materially from those in the forward-looking statements. See "*Item 1A. Risk Factors*" of this Annual Report for the discussion of risk factors. For all periods presented, the consolidated statements of income and consolidated balance sheet data have been adjusted for the reclassification of discontinued operations information, unless otherwise noted. All references to years relate to the calendar year ended December 31 of the particular year.

Summary of The Information Contained in Management's Discussion and Analysis of Financial Condition and Results of Operations

Our Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") is provided in addition to the accompanying consolidated financial statements and notes to assist readers in understanding our results of operations, financial condition, and cash flows. MD&A is organized as follows:

- ***Company Overview***. Discussion of our business and overall analysis of financial and other highlights affecting us, to provide context for the remainder of MD&A.
- ***Recent Events***. Summary of material transactions occurring during year ended December 31, 2025.
- ***Liquidity and Capital Resources***. An analysis of changes in our consolidated balance sheets and cash flows and discussion of our financial condition.
- ***Results of Operations***. An analysis of our financial results comparing the years ended December 31, 2025 and 2024.
- ***Critical Accounting Policies***. Accounting estimates that we believe are important to understanding the assumptions and judgments incorporated in our reported financial results and forecasts.

Company Overview

On July 25, 2024, we acquired a wholly-owned subsidiary, Scienture LLC. Scienture LLC is a specialty pharmaceutical company focused on the commercialization and development of products for the treatment of Cardiovascular (CVS) and Central Nervous System (CNS) diseases. Scienture LLC launched its first commercial product for hypertension and is in the process of commercializing its second product for the treatment of opioid overdose. Its development pipeline consists of a broad range of novel product candidates including new potential treatments for migraine, thrombosis, pain and other related disorders. Scienture LLC's mission is to bring to market innovative technology-based products to address unmet medical needs. Its targeted portfolio consists of short term and long-term opportunities with efficient development, regulatory, and go to market strategies.

Dispositions

SOSRx, LLC

SOSRx, was formed on February 15, 2022. The Company entered into a relationship with Exchange Health, LLC ("Exchange Health"), a technology company providing an online platform for manufacturers and suppliers to sell and purchase pharmaceuticals, pursuant to which SOSRx, a Delaware limited liability company, was formed, which was owned 51% by the Company and 49% by Exchange Health. SOSRx did not generate material revenue and in February 2023 the Company voluntarily withdrew from the joint venture agreement.

Community Specialty Pharmacy, LLC and Alliance Pharma Solutions, LLC

On January 20, 2023, the Company entered into Membership Interest Purchase Agreements to sell 100% of the outstanding membership interests of the Company's former subsidiaries, Community Specialty Pharmacy, LLC and Alliance Pharma Solutions, LLC (d.b.a DelivMeds). The Company also agreed to enter into a Master Service Agreement to operate the businesses prior to closing. The transactions contemplated by the Membership Interest Purchase Agreements closed on August 22, 2023.

Superlatus Inc.

On July 14, 2023, the Company entered into the Superlatus Merger Agreement with Superlatus Inc., a diversified food technology company, and Merger Sub.

On July 31, 2023, the Company completed its acquisition of Superlatus in accordance with the terms and conditions of the Superlatus Merger Agreement, pursuant to which the Company acquired Superlatus by way of a merger of the Merger Sub with and into Superlatus, with Superlatus being a wholly owned subsidiary of the Company and the surviving entity in the Superlatus Merger.

Under the terms of the Superlatus Merger Agreement, at the Closing, shareholders of Superlatus received an aggregate of 136,441 shares of the Company's common stock and 306,855 shares of the Company's Series B Preferred Stock, convertible into 100 shares of the Company's common stock. At Closing, the value of the Company's common stock was $7.30 per share, resulting in a total value of $225,000,169.

On October 13, 2023, the Company announced that Superlatus PD Holding Company, Inc., a purported subsidiary of Superlatus, entered into a supplier agreement with Rainforest, pursuant to which Superlatus allegedly appointed Rainforest as its exclusive distributor for Superlatus' portfolio of consumer packaged goods brands in certain markets. The Company later learned and announced that neither the Company's management nor the Company's Board of Directors authorized or approved the organization of Superlatus PD Holding Company, Inc. or the entry into the supplier agreement. Instead, the Company's management determined that certain representatives of a former subsidiary of the Company likely unilaterally took actions related to the supplier agreement.

On January 8, 2024, the Company entered into the Superlatus Amendment as not all of the closing conditions of the Superlatus Merger Agreement were met. Under the terms of the Superlatus Amendment, the merger consideration to the shareholders of Superlatus was adjusted to the aggregate of 136,441 shares of the Company's common stock and 15,759 shares of the Company's Series B Preferred Stock, resulting in a total value of $12,500,089. Additionally, the shareholders of Superlatus agreed to surrender back to the Company 291,096 shares of the Company's Series B Preferred Stock.

On March 5, 2024, the Company entered into the Superlatus SPA with the Buyer, Superlatus Foods Inc. Pursuant to the Superlatus SPA, the Company sold all of the issued and outstanding stock of Superlatus to the Buyer. A $1.00 purchase price was delivered to the Company at the closing, which occurred simultaneously with the execution of the Superlatus SPA. As a result of the transaction Superlatus is no longer a subsidiary of the Company, and the rights and assets of Superlatus together with various liabilities and obligations that were specific to Superlatus became rights and obligations of the Buyer.

Other Legacy Subsidiaries

The Company also previously owned 100% of Softell, IPS, Bonum Health, Inc., and Bonum Health, LLC.

Softell & IPS Entities

On October 4, 2024, the Company and Softell entered into the IPS Assignment Agreement, pursuant to which the Company transferred, and Softell accepted, 100% of the membership interests of IPS. As a result, IPS became a wholly-owned subsidiary of Softell.

On April 8, 2025, the Company entered into the IPS MIPA with Tollo, pursuant to which Tollo agreed to purchase and the Company agreed to sell all of the Company's membership interests in IPS. Suren Ajjarapu, the Company's former Chief Executive Officer, and Prashant Patel, the Company's former President and Chief Operating Officer, each have a beneficial interest in Tollo.

On April 8, 2025, the Company also entered into the Softell SPA with Tollo, pursuant to which Tollo agreed to purchase and the Company agreed to sell all issued and outstanding shares of common stock of Softell.

Bonum Health Entities

On April 8, 2025, the Company also entered into the Bonum SPA with Tollo, pursuant to which Tollo agreed to purchase and the Company agreed to sell all issued and outstanding shares of common stock of Bonum Health, Inc.

In November 2025, the Company dissolved Bonum Health, LLC.

The divestitures described above are part of a broader strategic realignment at the Company designed to sharpen operational focus and unlock long-term value. It is aligned with the Company's commitment to streamline its core operations, optimize its portfolio, and accelerate growth in the Branded and Specialty Pharma markets. The Company intends to use the proceeds obtained from the divestment to facilitate the high-growth commercial and strategic product development activities at its Scienture LLC subsidiary.

The Company believes that the key benefits of the divestitures include:

- Increased Operational Efficiency**:** Streamlining the Company's structure aimed at strengthening its balance sheet, providing for leaner operations and a more agile decision-making framework.
- Realize Synergies**:** Consolidating overlapping functions and eliminating redundancies intended to cause annualized cost savings.
- Dedicated Focus**:** Affording the full focus and deployment of resources to the commercial products and the high value product pipeline in development at its Scienture subsidiary.

Liquidity Outlook Cash Explanation

Cash Requirements

As of December 31, 2025, the Company's primary source of liquidity consisted of $6,662,008 in cash and cash equivalents and the Tollo promissory note with a principal balance of $5,000,000 (bearing interest at the prime rate and maturing June 30, 2030). The Company has financed its operations primarily through equity issuances under its equity line of credit ("ELOC") and convertible note arrangements. During the year ended December 31, 2025, the Company raised approximately $26.3 million in gross equity proceeds through ELOC and other equity transactions. The Company's principal uses of cash are commercialization of ARBLI™ and REZENOPY™ research and development, general and administrative costs, and debt service. The Company expects to fund its operations for at least the next twelve months from its existing cash balance and revenues generated from ARBLI™ commercialization, which commenced in the third quarter of 2025 and is expected to grow in 2026. The company also expects to generate revenue from REZENOPY™ which is anticipated to commence in the second quarter of 2026. The Company may also raise additional funding through the sale of debt or equity to fund accelerated pipeline development activities; however, there can be no assurance that such funding will be available on favorable terms, or at all.

The Company's ability to continue to fund operations beyond the next twelve months will depend on its ability to grow revenues from the commercialization of ARBLI™ and REZENOPY™ and, if needed, to access additional capital markets. Management continues to evaluate potential strategic transactions and partnerships to accelerate product development and commercialization across the pipeline.

Going Concern

The consolidated financial statements have been prepared on a going concern basis. As of December 31, 2025, the Company had cash and cash equivalents of $6,662,008, positive working capital of approximately $5,181,000, and current liabilities of approximately $2,735,000. Management evaluated conditions and events in accordance with ASC 205-40 and determined that, based on the factors described below, there is no substantial doubt about the Company's ability to continue as a going concern for the twelve-month period following the date these financial statements are issued. See also "Note 2 – Going Concern" in the Notes to Consolidated Financial Statements for further discussion.

As of December 31, 2025, the Company had an accumulated deficit of $80,551,237 and cash and cash equivalents of $6,662,008. The Company had current liabilities of $2,735,351 and working capital of approximately $5,181,000, an improvement of approximately $6,782,000 from the working capital deficit of $(1,601,416) as of December 31, 2024.

Management believes that the Company's existing cash of $6,662,008, combined with growing revenues from ARBLI™ and REZENOPY™ commercialization and its plans to access additional capital as needed, will be sufficient to fund operations and meet its obligations for at least the twelve months following the issuance of these financial statements. Key factors supporting this assessment include: (i) cash on hand of $6.7 million, which management believes is sufficient to cover current operating requirements; (ii) positive working capital of approximately $5.2 million as of December 31, 2025, compared to a working capital deficit of approximately $(1.6) million as of December 31, 2024; (iii) initial revenues from ARBLI™ commencing in the third quarter of 2025, with projected revenue growth in 2026; (iv) initial revenues from REZENOPY™ commencing in the third quarter of 2025, with projected revenue growth in 2026 and (v) the Company's ability to modulate discretionary spending and access equity markets, as demonstrated by raising approximately $26.3 million in gross equity proceeds during 2025.

Cash Flows

The following table summarizes the Company's Consolidated Statements of Cash Flows for the years ended December 31, 2025 and 2024:

	Year Ended December 31, 2025	Year Ended December 31, 2024	Change	% Change
Net cash used in operating activities from continuing operations	$ (13,382,482)	$ (13,286,163)	$ (96,319)	1%
Net cash provided by (used in) operating activities from discontinued operations	2,799	(979,075)	981,874	-100%
Operating Activities	**$ (13,379,683)**	**$ (14,265,238)**	**$ 885,555**	**-6%**
Net cash used in investing activities from continuing operations	—	$ (2,379,024)	$ 2,379,024	-100%
Net cash provided by investing activities from discontinued operations	—	29,931,815	(29,931,815)	-100%
Investing Activities	**$ —**	**$ 27,552,791**	**$ (27,552,791)**	**-100%**
Net cash provided by (used in) financing activities from continuing operations	$ 19,733,595	$ (12,974,770)	$ 32,708,365	-252%
Net cash used in financing activities from discontinued operations	—	(5,000)	5,000	-100%
Financing Activities	**$ 19,733,595**	**$ (12,979,770)**	**$ 32,713,365**	**-252%**
Net change in cash	**$ 6,353,912**	**$ 307,782**	**$ 6,046,130**	**1,964%**

Net cash used in operating activities from continuing operations for the year ended December 31, 2025 was $13,382,482, compared to net cash used in operating activities of approximately $13,286,163 for the year ended December 31, 2024. The net loss of $43,507,142 was the primary driver of cash used in operations in 2025, partially offset by significant non-cash charges including $26,346,050 of impairment losses, $3,161,100 of debt discount amortization, $2,068,892 of stock-based compensation expense, $4,310,090 of common stock issued for services, $453,846 of amortization of intangible assets, and gains on warrant and derivative fair value changes of $3,205,854. Changes in working capital used cash of approximately $3,0,000, primarily driven by increases in accounts receivable and inventory associated with the ARBLI™ commercialization launch.

Net cash provided by (used in) investing activities from continuing operations was $0 for the year ended December 31, 2025 and $2,379,024 net cash used in investing activities from continuing operations for the year ended December 31, 2024. Net cash provided by investing activities from discontinued operations was $0 for 2025, compared to $29,931,815 in 2024, which primarily reflected proceeds from the disposition of Micro Merchant Systems assets and other asset sales completed in the first and second quarters of 2024.

Net cash provided by financing activities from continuing operations for the year ended December 31, 2025 was $19,733,595, compared to net cash used in financing activities of approximately $12,980,000 for the year ended December 31, 2024. Cash provided by financing activities in 2025 was primarily driven by gross proceeds of $26,293,039 from the issuance of common stock through the Company's ELOC and other equity transactions, partially offset by repayment of convertible notes of $9,244,444, net repayment of related party loans of $415,000, and development liability payments of $400,000. The year ended December 31, 2024 reflected cash used in financing activities primarily due to the payment of special cash dividends of approximately $14,858,000 partially offset by proceeds from convertible note issuances.

Results of Operations

The following selected consolidated financial data should be read in conjunction with the audited consolidated financial statements and the notes to these statements included in this Annual Report.

Year Ended December 31, 2025 Compared to Year Ended December 31, 2024

	Year Ended December 31,			Percent
	2025	2024	Change	Change
Revenues	$ 431,609	$ 136,643	294,966	216%
Cost of sales	100,127	130,638	(30,511)	-23%
Gross profit	331,482	6,005	325,477	5420%
Operating expenses:				
Wage and salary expense	2,118,568	2,111,066	7,502	0%
Professional fees	2,407,822	1,458,332	949,490	65%
Accounting and legal expense	2,070,337	1,807,041	263,296	15%
Technology expense	97,261	416,311	(319,050)	-77%
General and administrative (including stock-based compensation expense)	7,926,016	6,677,580	1,248,436	19%
Research and development	1,956,270	2,236,690	(280,420)	-13%
Impairment loss	26,346,050	-	26,346,050	100%
Total operating expenses	42,922,324	14,707,020	28,215,304	192%
Change in fair value of warrant liability	909,020	(182,982)	1,092,002	-597%
Change in fair value of derivative liability	2,296,834	180,383	2,116,451	1173%
Impairment of investment	-	(2,500,000)	2,500,000	-100%
Loss on conversion of note payable	(53,446)	-	(53,446)	-100%
Loss on disposition of subsidiaries	(288,204)	-	(288,204)	-100%
Interest income	302,702	135,337	167,365	124%
Loss on disposal of asset	-	(374,968)	374,968	-100%
Interest expense	(4,083,206)	(1,335,631)	(2,747,575)	206%
Net loss from continuing operations	(43,507,142)	(18,778,876)	(24,728,266)	132%
Benefit / (provision) for income taxes	1,994,878	534,396	1,460,482	273%
Net loss from continuing operations, net of tax	(41,512,264)	(18,244,480)	(23,267,784)	128%
Income from discontinued operations, net of tax	-	27,310,278	(27,310,278)	-100%
Net (loss) income	$ (41,512,264)	$ 9,065,798	$ (50,578,062)	-558%

Revenues and Gross Profit

Revenues for the year ended December 31, 2025 were $431,609, compared to $136,643 for the year ended December 31, 2024, an increase of $294,966, or approximately 216%. The increase reflects initial sales of ARBLI™ (SCN-102, Losartan Potassium Oral Suspension) through wholesale distribution channels, which commenced in the third quarter of 2025 following FDA approval in March 2025. Revenue in 2024 consisted primarily of residual pharmaceutical wholesale activity prior to the IPS disposition. Cost of sales for the year ended December 31, 2025 was $100,127, resulting in gross profit of $331,482 (gross margin: 76.8%), compared to cost of sales of $130,638 and gross profit of $6,005 (gross margin: 4.4%) for the year ended December 31, 2024. The improvement in gross margin reflects the shift to higher-margin branded pharmaceutical sales through ARBLI™ versus the prior-period lower-margin wholesale distribution activity.

Operating Expenses

Total operating expenses were $42,922,324 for the year ended December 31, 2025 compared to $14,707,020 for the year ended December 31, 2024. The increase of $28,215,304 was primarily driven by non-cash impairment charges of $26,346,050 recognized in 2025 (comprising a goodwill impairment of $21,372,960 and IPR&D impairment of $4,973,090), with no comparable charge in 2024. Excluding impairment charges, total operating expenses were $16,576,274 in 2025 compared to $14,707,020 in 2024. Key components of operating expenses were as follows:

Wage and salary expense was $2,118,568 for the year ended December 31, 2025, relatively flat compared to $2,111,066 for 2024. Professional fees increased $949,490 to $2,407,822 in 2025 from $1,458,332 in 2024, primarily due to higher external consulting costs related to commercialization activities, SEC compliance, and corporate actions. Accounting and legal expense was $2,070,337 in 2025 compared to $1,807,041 in 2024, an increase of $263,296, driven by incremental costs associated with the year-end audit, SEC filings, and legal matters. General and administrative expenses (including non-cash stock-based compensation) increased $1,248,436 to $7,926,016 in 2025 from $6,677,580 in 2024, primarily due to higher non-cash stock-based compensation expense and costs associated with ARBLI™ commercialization activities. Technology expense decreased $319,050 to $97,261 in 2025 from $416,311 in 2024, primarily reflecting the wind-down of legacy technology platform expenses following the IPS and Softell dispositions. Research and development expenses were $1,956,270 in 2025 compared to $2,236,690 in 2024, a decrease of $280,420, reflecting shifts in the timing of CRO and regulatory spending across our pipeline programs (SCN-102: $368K; SCN-104: $422K; SCN-106: $298K; SCN-107: $500K in 2025).

Non-Operating Income (Expense)

Non-operating income (expense) for the year ended December 31, 2025 included: a gain on the change in fair value of warrant liability of $909,020 (2024: loss of $182,982), reflecting mark-to-market decreases in warrant fair value; a gain on the change in fair value of the derivative liability of $2,296,834 (2024: gain of $180,383), primarily related to the derecognition of the Arena convertible debenture derivative liability upon full repayment; interest income of $302,702 (2024: $135,337) on the Tollo promissory note; interest expense of $4,083,206 (2024: $1,335,631), reflecting a full year of amortization of debt discount and interest on the Arena debenture and other convertible notes; a loss on conversion of note payable of $53,446; and a loss on disposition of subsidiaries of $288,204, primarily related to the Bonum Health, Inc. and Softell transactions. The Company recognized an income tax benefit of $1,994,878 for the year ended December 31, 2025 (2024: $nil), reflecting changes in deferred tax liabilities attributable to the intangible asset impairment charges recognized during the year.

Net Loss and Discontinued Operations

Net loss from continuing operations, net of tax, was $41,512,264 for the year ended December 31, 2025, compared to a net loss from continuing operations of $15,803,908 for the year ended December 31, 2024. The increase in net loss was primarily attributable to the $26,346,050 of non-cash impairment charges recognized in 2025, with no comparable charge in 2024. Excluding impairment, net loss from continuing operations improved by approximately $37,000 year over year. There was no income from discontinued operations in 2025. For the year ended December 31, 2024, income from discontinued operations, net of tax, was $27,310,278, primarily from the gain on the sale of MMS assets and the Softell disposition in the first half of 2024. Net loss for the year ended December 31, 2025 was $41,512,264, compared to net income of $11,506,370 for the year ended December 31, 2024.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of net sales and expenses for each period. The following represents a summary of our critical accounting policies, defined as those policies that we believe are the most important to the portrayal of our financial condition and results of operations and that require management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effects of matters that are inherently uncertain.

Acquisitions

The Company accounts for acquisitions and investments in businesses as business combinations if the target meets the definition of a business and (a) the target is a variable interest entity and the Company is the target's primary beneficiary, and therefore the Company must consolidate its financial statements, or (b) the Company acquires more than 50% of the voting interest of the target and it was not previously consolidated. The Company records business combinations using the acquisition method of accounting, which requires all the assets acquired and liabilities assumed to be recorded at fair value as of the acquisition date. The excess of the purchase price over the estimated fair values of the net tangible and intangible assets acquired is recorded as goodwill.

The application of the acquisition method of accounting for business combinations requires management to make significant estimates and assumptions in the determination of the fair value of assets acquired and liabilities assumed in order to properly

Stock-Based Compensation

The Company accounts for stock-based compensation to employees in accordance with ASC 718, "*Compensation-Stock Compensation*". ASC 718 requires companies to measure the cost of employee services received in exchange for an award of equity instruments, including stock options, based on the grant date fair value of the award and to recognize it as compensation expense over the period the employee is required to provide service in exchange for the award, usually the vesting period. Stock option forfeitures are recognized at the date of employee termination. Effective January 1, 2019, the Company adopted ASU 2018-07 for the accounting of share-based payments granted to non-employees for goods and services.

Revenue Recognition

In general, the Company accounts for revenue recognition in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 606, "Revenue from Contracts with Customers."

IPS is a licensed wholesaler of brand, generic and non-drug products to Customers. IPS takes orders for products, creates invoices for each order and recognizes revenue at the time the product is shipped to the Customer. IPS was divested on April 30, 2025, and its operations are presented as discontinued operations for all periods presented. Following the IPS disposition, the Company's revenue is derived solely from the sale of pharmaceutical products through wholesale distribution channels. ARBLI™ (SCN-102, Losartan Potassium Oral Suspension) is the Company's first commercially available product, with sales commencing in the third quarter of 2025. The Company sells its products to wholesale distributors, who in turn sell to retail pharmacies, hospitals, and other healthcare providers. Revenue is recognized at the point in time when control of the product transfers to the customer, which generally occurs upon delivery to the customer's designated facility. Revenue is measured at the net transaction price, which reflects the gross invoice price reduced by estimated variable consideration, as described below.

Gross-to-Net Sales Adjustments. The Company records product revenue net of estimated variable consideration. Gross-to-net adjustments include: (i) chargebacks, representing the difference between the price charged to wholesale distributors and the lower contract price that distributors extend to their end-customers (including retail pharmacies, hospitals, and clinics under contracted pricing arrangements), estimated based on expected sell-through to qualifying end-customers and contractual terms; (ii) wholesaler rebates and distribution service fees, representing fees and rebates paid to wholesale distributors and, where applicable, group purchasing organizations ("GPOs") under contractual arrangements, estimated based on contracted rates, expected sales volumes, and historical payment patterns; (iii) prompt pay discounts, representing discounts offered to wholesale distributors for timely payment, estimated based on contractual terms and expected payment timing; and (iv) product returns, estimated based on contractual return rights and available market data, which have not been material to date given the early stage of commercialization of ARBLI™. Estimates of variable consideration are updated each reporting period based on available historical data, contractual terms, and management's judgment regarding current market conditions. Accrued liabilities related to gross-to-net adjustments are classified within accrued liabilities on the consolidated balance sheets. The Company does not disclose the value of unsatisfied performance obligations as all contracts have an expected duration of one year or less.

Acquisitions, Goodwill and Other Intangible Assets

The Company allocates the cost of an acquired business to the assets acquired and liabilities assumed based on their estimated fair values at the date of acquisition. The excess value of the cost of an acquired business over the estimated fair value of the assets acquired and liabilities assumed is recognized as goodwill. The Company uses a variety of information sources to determine the value of acquired assets and liabilities, including: identifiable intangibles.

Goodwill and indefinite-lived intangibles are not amortized but are instead evaluated annually for impairment as part of the Company's annual financial review, or when indicators of a potential impairment are present. The annual test for impairment performed for goodwill can be qualitative or quantitative, taking into consideration certain factors surrounding the fair value of the goodwill including, level by which fair value exceeded carrying value in the prior valuation, as well as macroeconomic factors, industry conditions and actual results at the test date.

Non-GAAP Financial Measures

In addition to our financial results determined in accordance with the generally accepted accounting principles in the United States ("GAAP"), our management uses earnings before interest, taxes, depreciation, and amortization expenses to net income ("EBITDA"), a non-GAAP measure, as a key measure in operating our business. We use EBITDA to make strategic decisions, establish business plans and forecasts, identify trends affecting our business, and evaluate performance. For example, we use adjusted EBITDA as a measure of our operating performance. Adjusted EBITDA is presented for supplemental informational purposes only, should not be considered a substitute for, or a more meaningful measure than, financial information presented in accordance with GAAP, and may be different from similarly titled non-GAAP measures used by other companies. A reconciliation is provided below for adjusted EBITDA to the most directly comparable financial measure presented in accordance with GAAP. Investors are encouraged to review the related GAAP financial measure and the reconciliation of adjusted EBITDA to its most directly comparable GAAP financial measure.

For the year ended December 31, 2025, adjusted EBITDA was $(5,384,274), compared to adjusted EBITDA of $17,820,898 for the year ended December 31, 2024. The decrease reflects the transition from a diversified operating business (which included higher-revenue wholesale and asset-sale activities in 2024) to a focused specialty pharmaceutical company in 2025, with initial ARBLI™ revenues only commencing in Q3 2025 and higher operating costs associated with the build-out of commercialization infrastructure. Excluding the non-cash impairment charges of $26,346,050 recognized in 2025, adjusted EBITDA was $(5,384,274), reflecting the early-stage commercial nature of the business. The following table reconciles net loss from continuing operations to adjusted EBITDA for the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	**2024**
Net (loss) income	$ (41,512,264)	$ 9,065,798
Depreciation and amortization	491,781	53,361
Benefit for income taxes	1,994,878	
Interest expense	4,083,206	1,335,631
Other non-operating expenses (income)	(3,166,906)	2,742,230
Stock based compensation (non-cash)	6,378,981	4,623,878
Impairment loss	26,346,050	-
Adjusted EBITDA	$ (5,384,274)	$ 17,820,898

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

Recently Issued Accounting Standards

For more information on recently issued accounting standards, see "Note 1 – Organization and Basis of Presentation" to the Notes to Consolidated Financial Statements included herein under "*Item 8. Financial Statements and Supplemental Data*.".

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Pursuant to Item 305(e) of Regulation S-K (§ 229.305(e)), the Company is not required to provide the information required by this Item as it is a "smaller reporting company," as defined by Rule 229.10(f)(1).

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTAL DATA

Scienture Holdings, Inc.
FORM 10-K
For the Year Ended December 31, 2025

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PART II: FINANCIAL INFORMATION

ITEM 8. FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Scienture Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Scienture Holdings, Inc. (the Company) as of December 31, 2025 and 2024, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Emphasis of a matter – Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Critical Audit Matter — Impairment assessment of goodwill and indefinite-lived intangible assets

We identified the impairment assessment of goodwill and indefinite-lived intangible assets as a critical audit matter. Auditing management's judgments regarding forecasts of future revenue and operating margin, and the discount rate to be applied involved a high degree of subjectivity and significant judgment.

How the Critical Audit Matter Was Addressed in Our Audit:

- Obtaining an understanding of management's process for determining goodwill and intangible asset impairment
- Reviewing management's impairment analysis, including the determination of fair value
- Comparing actual sales to prior forecasts to assess forecasting accuracy
- Utilizing valuation specialists to evaluate methodologies used by management

/s/ CM3 Advisory

We have served as the Company's auditor since 2023

San Diego, California

March 30, 2026

Scienture Holdings, Inc.
Consolidated Balance Sheets
December 31, 2025 and 2024

	December 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,662,008	$ 308,096
Accounts receivable, net	731,328	11,106
Inventory	213,408	-
Prepaid expenses	262,278	4,560
Notes receivable - related party	-	1,300,000
Other receivables	-	4,138,770
Deferred offering costs	47,384	534,800
Current assets of discontinued operations	-	8,145
Total current assets	7,916,406	6,305,477
Property, plant and equipment, net	15,500	17,500
Deposits	-	22,039
Notes receivable	5,000,000	-
Interest receivable	250,000	-
Intangible assets, net	70,973,064	76,400,000
Goodwill	-	21,372,960
Operating lease right-of-use assets	23,360	201,433
Deferred tax asset	-	534,396
Total assets	$ 84,178,330	$ 104,853,805
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,443,266	$ 2,898,683
Accrued liabilities	657,034	1,313,731
Other current liabilities	-	5,441
Loan payable, related party	-	415,000
Convertible note, net of debt discount - current portion	-	2,285,423
Operating lease liability - current	24,137	63,334
Warrant liability	10,914	919,935
Development agreement liability - current portion	600,000	-
Current liabilities of discontinued operations	-	5,346
Total current liabilities	2,735,351	7,906,893
Convertible notes, net of debt discount	-	612,275
Derivative liability	-	2,296,834
Operating lease liability - net of current portion	-	156,469
Development agreement liability	285,000	1,285,000
Deferred tax liability	11,037,595	13,524,213
Total liabilities	14,057,946	25,781,684
Commitments and contingencies (Note 15)		
Stockholders' equity (deficit):		
Series A preferred stock, $0.00001 par value; 0 and 9,211,246 shares authorized; 0 shares issued and outstanding as of both December 31, 2025 and 2024	-	-
Series B preferred stock, $0.00001 par value; 787,754 shares authorized; 15,759 shares issued and outstanding as of both December 31, 2025 and 2024	-	-
Series C preferred stock, $0.00001 par value; 1,000 shares authorized; 0 shares issued and outstanding as of both December 31, 2025 and 2024	-	-
Series X preferred stock, $0.00001 par value; 9,211,246 shares authorized; 0 shares issued and outstanding as of both December 31, 2025 and 2024	-	-
Common stock, $0.00001 par value; 100,000,000 shares authorized; 40,630,815 and 8,750,582 shares issued and outstanding as of December 31, 2025 and 2024, respectively 1,015,000 and 0 shares unvested as of December 31, 2025 and 2024, respectively	406	87
Additional paid-in capital	150,671,215	118,111,007
Accumulated deficit	(80,551,237)	(39,038,973)
Total stockholders' equity	70,120,384	79,072,121
Total liabilities and stockholders' equity	$ 84,178,330	$ 104,853,805

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

Scienture Holdings, Inc.
Consolidated Statements Of Operations
Years Ended December 31, 2025 and 2024

	Year Ended December 31,	
	2025	**2024**
Revenues	$ 431,609	$ 136,643
Cost of sales	100,127	130,638
Gross profit	331,482	6,005
Operating expenses:		
Wage and salary expense	2,118,568	2,111,066
Professional fees	2,407,822	1,458,332
Accounting and legal expense	2,070,337	1,807,041
Technology expense	97,261	416,311
General and administrative	7,926,016	6,677,580
Research and development	1,956,270	2,236,690
Impairment loss	26,346,050	-
Total operating expenses	42,922,324	14,707,020
Operating loss	(42,590,842)	(14,701,015)
Non-operating income (expense):		
Change in fair value of warrant liability	909,020	(182,982)
Change in fair value of derivative liability	2,296,834	180,383
Impairment of investment	-	(2,500,000)
Loss on conversion of note payable	(53,446)	-
Loss on disposition of subsidiaries	(288,204)	-
Interest income	302,702	135,337
Loss on disposal of asset	-	(374,968)
Interest expense	(4,083,206)	(1,335,631)
Total non-operating expense	(916,300)	(4,077,861)
Net loss from continuing operations	(43,507,142)	(18,778,876)
Benefit / (provision) for income taxes	1,994,878	534,396
Net loss from continuing operations, net of tax	(41,512,264)	(18,244,480)
Net income from discontinued operations, net of tax	-	27,310,278
Net (loss) income	$ (41,512,264)	$ 9,065,798
Net loss per common share from continuing operations		
Basic	$ (2.70)	$ (5.41)
Diluted	$ (2.70)	$ (5.41)
Net income per common share from discontinued operations		
Basic	$ -	$ 8.09
Diluted	$ -	$ 7.47
Net (loss) income per common share		
Basic	$ (2.70)	$ 2.69
Diluted	$ (2.70)	$ 2.48
Weighted average common shares outstanding		
Basic	15,347,312	3,375,325
Diluted	15,347,312	3,653,609

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

Scienture Holdings, Inc.
Consolidated Statements of Changes in Stockholders' Equity

	Series A Preferred Stock		Series B Preferred Stock		Series C Preferred Stock		Series X Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balances at December 31, 2023	-	$ -	15,759	$ -	290	$ -	-	$ -	905,008	$ 9	$ 33,788,284	$ (33,245,940)	$ 542,353
Common stock issued for services	-	-	-	-	-	-	-	-	490,698	5	4,598,289	-	4,598,294
Conversion of Series C preferred stock into common stock	-	-	-	-	(290)	-	-	-	52,158	1	(1)	-	-
Issuance of shares pursuant to Merger	-	-	-	-	-	-	6,826,753	68	291,536	3	78,646,113	-	78,646,184
Conversion of Series X preferred stock into common stock	-	-	-	-	-	-	(6,826,753)	(68)	6,826,753	68	-	-	-
Equity line of commitment shares issued	-	-	-	-	-	-	-	-	70,000	1	534,799	-	534,800
Issuance of common shares in connection with convertible note	-	-	-	-	-	-	-	-	55,000	1	420,199	-	420,200
Warrants issued with convertible note	-	-	-	-	-	-	-	-	-	-	71,332	-	71,332
Options exercised for common shares	-	-	-	-	-	-	-	-	2,371	-	9,840	-	9,840
Warrants exercised for cash	-	-	-	-	-	-	-	-	57,058	-	16,567	-	16,567
Options expense	-	-	-	-	-	-	-	-	-	-	25,584	-	25,584
Cash dividends paid ($8 per share)	-	-	-	-	-	-	-	-	-	-	-	(12,671,072)	(12,671,072)
Cash dividends paid ($1.50 per share)	-	-	-	-	-	-	-	-	-	-	-	(2,187,759)	(2,187,759)
Net income	-	-	-	-	-	-	-	-	-	-	-	9,065,798	9,065,798
Balances at December 31, 2024	-	-	15,759	-	-	-	-	-	8,750,582	87	118,111,007	(39,038,973)	79,072,121
Common stock issued for services	-	-	-	-	-	-	-	-	3,760,150	38	4,310,052	-	4,310,090
Common stock issued for cash, net of offering costs	-	-	-	-	-	-	-	-	22,826,273	228	23,879,077	-	23,879,305
Cancellation of stock options and issuance of common stock	-	-	-	-	-	-	-	-	2,000,000	20	1,512,974	-	1,512,994
Equity line of commitment shares issued	-	-	-	-	-	-	-	-	1,064,512	11	1,526,307	-	1,526,318
Conversion of note payable into common stock	-	-	-	-	-	-	-	-	274,000	3	410,997	-	411,000
Common stock issued for convertible note settlement	-	-	-	-	-	-	-	-	224,998	2	189,671	-	189,673
Common stock issued for convertible note extension	-	-	-	-	-	-	-	-	250,000	3	175,248	-	175,250
Warrants exercised for shares	-	-	-	-	-	-	-	-	279,402	3	(3)	-	-
Restricted shares issued for services	-	-	-	-	-	-	-	-	1,200,898	12	(12)	-	-
Stock-based compensation expense	-	-	-	-	-	-	-	-	-	-	555,898	-	555,898
Net loss	-	-	-	-	-	-	-	-	-	-	-	(41,512,264)	(41,512,264)
Balances at December 31, 2025	-	$ -	15,759	$ -	-	$ -	-	$ -	40,630,815	$ 406	$150,671,215	$ (80,551,237)	$ 70,120,384

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

Scienture Holdings, Inc.
Consolidated Statements of Cash Flows
Years Ended December 31, 2025 and 2024

	Year Ended December 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss from continuing operations	$ (43,507,142)	$ (18,778,876)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	2,000	2,000
Amortization of intangible assets	453,846	-
Change in fair value of warrant liability	(909,020)	182,982
Change in fair value of derivative liability	(2,296,834)	(180,383)
Loss on conversion of note payable	53,446	-
Loss on disposition of subsidiaries	214,486	-
Stock-based compensation	2,068,892	25,584
Common stock issued for services	4,310,090	4,598,294
Goodwill impairment	26,346,050	-
Impairment of investment	-	2,500,000
Amortization of debt discount	3,161,100	912,447
Amortization of right-of-use assets	35,935	51,361
Interest income	(250,000)	-
Changes in operating assets and liabilities:		
Accounts receivable, net	(720,222)	(11,106)
Prepaid expenses and deposits	(193,023)	34,656
Inventory	(213,408)	968
Other receivables	(80,469)	(2,914,068)
Lease liability	(36,979)	(51,587)
Accounts payable	(1,567,215)	448,572
Accrued liabilities	(248,574)	(44,616)
Current liabilities	(5,441)	(62,390)
Net cash used in operating activities from continuing operations	(13,382,482)	(13,286,163)
Net cash provided by (used in) operating activities from discontinued operations	2,799	(979,075)
Net cash used in operating activities	(13,379,683)	(14,265,239)
Cash flows from investing activities:		
Cash received in acquisition	-	132,976
Acquisition of property and equipment	-	(12,000)
Investment in securities	-	(2,500,000)
Net cash used in investing activities from continuing operations	-	(2,379,024)
Net cash provided by investing activities from discontinued operations	-	29,931,815
Net cash provided by investing activities	-	27,552,791
Cash flows from financing activities:		
Repayment of contingent liability	-	(1,246,346)
Proceeds from loan payable, related party	116,000	150,000
Repayment of loan payable, related party	(531,000)	-
Proceeds from issuance of convertible notes, net of issuance costs	-	2,954,000
Proceeds from convertible notes	3,500,000	-
Repayment of convertible notes	(9,244,444)	-
Gross proceeds from issuance of common stock	26,293,039	-
Repayment of development liability	(400,000)	-
Cash dividends paid	-	(14,858,831)
Proceeds from exercise of warrants	-	16,567
Proceeds from exercise of options	-	9,840
Net cash provided by (used in) financing activities from continuing operations	19,733,595	(12,974,770)
Net cash used in financing activities from discontinued operations	-	(5,000)
Net cash provided by (used in) financing activities	19,733,595	(12,979,770)
Net change in cash	6,353,912	307,782
Cash at beginning of period	308,096	314
Cash at end of period	$ 6,662,008	$ 308,096
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ -	$ -
Cash paid for taxes	$ -	$ -
Supplemental disclosure of non-cash investing and financing activities:		
Conversion of note payable into common stock	$ 411,000	$ -
Equity line of commitment shares issued as offering costs	$ 1,526,318	$ 534,800
Issuance of note receivable in exchange for other receivables	$ 5,000,000	$ -
Issuance of shares pursuant to Merger	$ -	$ 78,646,184
Assets acquired in connection with Merger	$ -	$ 194,554
Liabilities assumed in connection with Merger	$ -	$ 5,797,117
Insurance premium financed	$ -	$ 198,245
Issuance of common shares in connection with converible debenture	$ -	$ 420,200
Deferred offering costs	$ -	$ 69,444
Derivative liability recognized in connection with issuance of convertible note	$ -	$ 2,477,217
Warrants issued with convertible note	$ -	$ 71,332
Common stock issued for convertible note settlement	$ 189,673	$ -
Common stock issued for convertible note extension	$ 175,250	$ -
Accretion of original issue discount on Treasury Bills	$ 20,625	$ -

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

NOTE 1 – ORGANIZATION AND BASIS OF PRESENTATION

Overview

On September 20, 2024, changed its legal name from "TRxADE HEALTH, Inc." to "Scienture Holdings, Inc." As of the date of these financial statements, the Company's primary operating subsidiary is Scienture, LLC (f/k/a Scienture, Inc.) ("***Scienture***"). Scienture was acquired in July 2024.

Scienture is a New York based branded, specialty pharmaceutical research company focused on the commercialization and development of products for the treatment of Cardiovascular (CVS) and Central Nervous System (CNS) diseases. Scienture launched its first commercial product for hypertension and is in the process of commercializing its second product for the treatment of opioid overdose. Its development pipeline consists of a broad range of novel product candidates including new potential treatments for migraine, thrombosis, pain and other related disorders. Scienture's mission is to bring to market innovative technology-based products to address unmet medical needs. Its targeted portfolio consists of short term and long-term opportunities with efficient development, regulatory, and go to market strategies.

Dispositions

SOSRx, LLC

SOSRx, LLC ("SOSRx") was formed on February 15, 2022. The Company entered into a relationship with Exchange Health, LLC ("Exchange Health"), a technology company providing an online platform for manufacturers and suppliers to sell and purchase pharmaceuticals, pursuant to which SOSRx, a Delaware limited liability company, was formed, which was owned 51% by the Company and 49% by Exchange Health. SOSRx did not generate material revenue and in February 2023 the Company voluntarily withdrew from the joint venture agreement.

Community Specialty Pharmacy, LLC and Alliance Pharma Solutions, LLC

On January 20, 2023, the Company entered into Membership Interest Purchase Agreements to sell 100% of the outstanding membership interests of the Company's former subsidiaries, Community Specialty Pharmacy, LLC and Alliance Pharma Solutions, LLC (d.b.a DelivMeds). The Company also agreed to enter into a Master Service Agreement to operate the businesses prior to closing. The transactions contemplated by the Membership Interest Purchase Agreements closed on August 22, 2023.

Superlatus Inc.

On July 14, 2023, the Company entered into an Amended and Restated Agreement and Plan of Merger (the "Superlatus Merger Agreement") with Superlatus Inc., a diversified food technology company, and Foods Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of the Company ("Merger Sub").

On July 31, 2023, the Company completed its acquisition of Superlatus in accordance with the terms and conditions of the Superlatus Merger Agreement (the "Superlatus Merger"), pursuant to which the Company acquired Superlatus by way of a merger of the Merger Sub with and into Superlatus, with Superlatus being a wholly owned subsidiary of the Company and the surviving entity in the Superlatus Merger.

Under the terms of the Superlatus Merger Agreement, at the closing of the Superlatus Merger (the "Closing"), shareholders of Superlatus received an aggregate of 136,441 shares of the Company's common stock and 306,855 shares of the Company's Series B Preferred Stock, par value $0.00001 per share (the "Series B Preferred Stock"), convertible into 100 shares of the Company's common stock. At Closing, the value of the Company's common stock was $7.30 per share, resulting in a total value of $225,000,169.

On October 13, 2023, the Company announced that Superlatus PD Holding Company, Inc., a purported subsidiary of Superlatus, entered into a supplier agreement with Rainforest Distribution Corp, a New York corporation ("Rainforest"), pursuant to which Superlatus allegedly appointed Rainforest as its exclusive distributor for Superlatus' portfolio of consumer packaged goods brands in certain markets. The Company later learned and announced that neither the Company's management nor the Company's Board of Directors authorized or approved the organization of Superlatus PD Holding Company, Inc. or the entry into the supplier agreement. Instead, the Company's management determined that certain representatives of a former subsidiary of the Company likely unilaterally took actions related to the supplier agreement.

On January 8, 2024, the Company entered into Amendment No. 1 to the Amended and Restated Agreement and Plan of Merger (the "Superlatus Amendment") as not all of the closing conditions of the Superlatus Merger Agreement were met. Under the terms of the Superlatus Amendment, the merger consideration to the shareholders of Superlatus was adjusted to the aggregate of 136,441 shares of the Company's common stock and 15,759 shares of the Company's Series B Preferred Stock, resulting in a total value of $12,500,089. Additionally, the shareholders of Superlatus agreed to surrender back to the Company 291,096 shares of the Company's Series B Preferred Stock.

On March 5, 2024, the Company entered in a Stock Purchase Agreement ("Superlatus SPA") with Superlatus Foods Inc. (the "Buyer"). Pursuant to the Superlatus SPA, the Company sold all of the issued and outstanding stock of Superlatus to the Buyer. A $1.00 purchase price was delivered to the Company at the closing, which occurred simultaneously with the execution of the Superlatus SPA. As a result of the transaction Superlatus is no longer a subsidiary of the Company, and the rights and assets of Superlatus together with various liabilities and obligations that were specific to Superlatus became rights and obligations of the Buyer.

Other Legacy Subsidiaries

The Company also previously owned 100% of Softell Inc. (f/k/a Trxade Inc.) ("Softell"), Integra Pharma Solutions, LLC ("IPS"), Bonum Health, Inc., and Bonum Health, LLC.

Softell & IPS Entities

On October 4, 2024, the Company and Softell entered into an Assignment and Assumption of Membership Interests (the "IPS Assignment Agreement"), pursuant to which the Company transferred, and Softell accepted, 100% of the membership interests of IPS. As a result, IPS became a wholly-owned subsidiary of Softell.

On April 8, 2025, the Company entered into a Membership Interest Purchase Agreement (the "IPS MIPA") with Tollo Health, Inc. ("Tollo"), pursuant to which Tollo agreed to purchase and the Company agreed to sell all of the Company's membership interests in IPS. Suren Ajjarapu, the Company's former Chief Executive Officer, and Prashant Patel, the Company's former President and Chief Operating Officer, each have a beneficial interest in Tollo.

On April 8, 2025, the Company also entered into a Stock Purchase Agreement (the "Softell SPA") with Tollo, pursuant to which Tollo agreed to purchase and the Company agreed to sell all issued and outstanding shares of common stock of Softell.

Bonum Health Entities

On April 8, 2025, the Company also entered into a Stock Purchase Agreement (the "Bonum SPA") with Tollo, pursuant to which Tollo agreed to purchase and the Company agreed to sell all issued and outstanding shares of common stock of Bonum Health, Inc.

In November 2025, the Company dissolved Bonum Health, LLC.

The divestitures described above are part of a broader strategic realignment at the Company designed to sharpen operational focus and unlock long-term value. It is aligned with the Company's commitment to streamline its core operations, optimize its portfolio, and accelerate growth in the Branded and Specialty Pharma markets. The Company intends to use the proceeds obtained from the divestment to facilitate the high-growth commercial and strategic product development activities at its Scienture subsidiary.

See Note 3 for further detail on the dispositions.

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America ("***U.S. GAAP***") and the rules of the SEC. All significant intercompany accounts and transactions have been eliminated.

Use of Estimates

The preparation of condensed consolidated financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses in the reporting period. The Company bases its estimates and assumptions on current facts, historical experience and various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the accrual of costs and expenses that are not readily apparent from other sources. The actual results experienced by the Company may differ materially and adversely from its estimates. Significant estimates for the years ended December 31, 2025 and 2024 include the valuation of intangible assets, including goodwill, and gain (losses) on dispositions.

Revision of Previously Issued Financial Statements for Correction of Immaterial Errors

During the three months ended September 30, 2025, the Company identified and corrected an error impacting additional paid-in capital, debt, and related other expense originally recorded in the first and second quarters of 2025. Specifically, $1.6 million of debt repayment proceeds were incorrectly netted against equity in the first quarter of 2025, resulting in an understatement of stockholders' equity and an overstatement of liabilities. The related income statement impact included a $0.2 million understatement of net loss in the first quarter and a $0.4 million overstatement of net loss in YTD Q2. The cumulative correction to both the condensed consolidated balance sheets and statements of operations was recorded in the third quarter of 2025. As of December 31, 2025, the related debt was fully repaid.

Management assessed the materiality of the error on both a quantitative and qualitative basis, in accordance with SEC Staff Accounting Bulletin No. 99, *Materiality*, codified in ASC Topic 250, *Accounting Changes and Error Corrections*. Management concluded that the error and related impacts did not result in a material misstatement of the Company's previously issued interim financial statements for the three months ended March 31, 2025, or the three and six months ended June 30, 2025.

Fair Value of Financial Instruments

Certain assets and liabilities of the Company are carried at fair value under GAAP. 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 on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The carrying amounts for cash, accounts receivable, accounts payable, accrued liabilities, and other current liabilities approximate their fair value because of their short-term maturity. The Company's notes payables approximate the fair value of such instruments as the notes bear interest rates that are consistent with current market rates.

See Note 9 for further detail.

Cash and Cash Equivalents

The Company's cash equivalents include U.S. Treasury Bills with original maturities of three months or less from the date of purchase. These instruments are classified as held-to-maturity and are recorded at amortized cost, which includes the initial investment cost and the accretion of any purchase discounts. The Company recognizes interest income over the life of the Treasury Bills using the effective interest method. Due to the short-term nature of these investments, the carrying internal value approximates fair value, and no unrealized gains or losses are recognized in the consolidated statements of operations or within accumulated other comprehensive income.

As of December 31, 2025, the Company held U.S. Treasury Bills classified as cash equivalents with a total amortized cost of approximately $6,662,008, consisting of two active positions: a $1,500,000 face value T-Bill maturing January 15, 2026 and a $4,000,000 face value T-Bill maturing February 12, 2026. together with cash on deposit of approximately $1,182,000. These instruments were purchased at a discount and are being accreted to face value over their respective holding periods using the effective interest method. The weighted-average maturity of the T-Bill portfolio as of December 31, 2025 was approximately 40 days. Interest income accreted on these instruments is reported within interest income in the consolidated statements of operations.

Concentration of Credit Risks and Major Customers

Financial instruments that potentially subject the Company to credit risk consist principally of cash and cash equivalents and receivables. The Company places its cash and cash equivalents with financial institutions. Deposits are insured to Federal Deposit Insurance Corporation limits. During the years ended December 31, 2025 and 2024, two customers accounted for 89.97% of revenue.

Accounts Receivable, net

Accounts receivable represent amounts due from wholesale distributors for the sale of pharmaceutical products. These receivables are recorded at the invoiced amount, net of estimated variable consideration including rebates, chargebacks, discounts, and other gross-to-net sales adjustments, consistent with the Company's revenue recognition policy.

Payment terms are generally net 90 days from the date of invoice. The Company monitors the creditworthiness of its customers and evaluates the collectability of outstanding receivables on an ongoing basis. The Company estimates expected credit losses on trade receivables in accordance with ASC 326 using an allowance for credit losses ("ACL"). The ACL reflects management's estimate of lifetime expected credit losses based on historical loss experience, current conditions, and reasonable and supportable forecasts. Trade receivables are pooled by similar risk characteristics. Balances are written off when deemed uncollectible, and recoveries are recorded when received. The Company monitors credit risk primarily through aging and customer-specific evaluations.

Inventory

Inventory is stated at the lower of cost or net realizable value. Cost is determined using the first-in, first-out method and includes the purchase price, inbound freight, and other costs directly attributable to the acquisition of finished goods.

Inventories primarily consist of finished pharmaceutical products held for sale. The Company regularly evaluates inventory for obsolescence and slow-moving items and records a reserve, if necessary, to write down inventories to their estimated net realizable value. Factors considered in the valuation include current market conditions, historical sales trends, product expiration dates, and projected demand.

Inventory write-downs are recorded as a component of cost of goods sold and are not reversed if the market value of the inventory subsequently increases.

Deferred Offering Costs

The Company complies with the requirements of Accounting Standards Codification ("***ASC***") 340-10-S99-1 with regards to offering costs. Prior to the completion of an offering, offering costs are capitalized. The deferred offering costs are charged to additional paid-in capital or as a discount to debt, as applicable, upon the completion of an offering or to expense if the offering is not completed. As of December 31, 2025, the Company has capitalized $47,384 in deferred offering costs. During the year ended December 31, 2025, $1,089,386 of deferred offering costs, including $534,800 capitalized as of December 31, 2024, were charged to additional paid-in capital upon the Company's equity offering.

Acquisitions

The Company accounts for acquisitions and investments in businesses as business combinations if the target meets the definition of a business and (a) the target is a variable interest entity and the Company is the target's primary beneficiary, and therefore the Company must consolidate its financial statements, or (b) the Company acquires more than 50% of the voting interest of the target and it was not previously consolidated. The Company records business combinations using the acquisition method of accounting, which requires all the assets acquired and liabilities assumed to be recorded at fair value as of the acquisition date. The excess of the purchase price over the estimated fair values of the net tangible and intangible assets acquired is recorded as goodwill.

The application of the acquisition method of accounting for business combinations requires management to make significant estimates and assumptions in the determination of the fair value of assets acquired and liabilities assumed in order to properly allocate purchase price consideration between assets that are depreciated and amortized from goodwill. The fair value assigned to tangible and intangible assets acquired and liabilities assumed are based on management's estimates and assumptions, as well as other information compiled by management, including valuations that utilize customary valuation procedures and techniques. Significant assumptions and estimates include, but are not limited to, the cash flows that an asset is expected to generate in the future, the appropriate weighted-average cost of capital, and the cost savings expected to be derived from acquiring an asset, if applicable.

If the actual results differ from the estimates and judgments used in these estimates, the amounts recorded in the Company's financial statements may be exposed to potential impairment of the intangible assets and goodwill.

If the Company's investment involves the acquisition of an asset or group of assets that does not meet the definition of a business, the transaction is accounted for as an asset acquisition. An asset acquisition is recorded at cost, which includes capitalizing transaction costs, and does not result in the recognition of goodwill.

On July 25, 2024, the Company acquired intangible assets of $76,400,000 and recognized goodwill of $21,372,960 pursuant to the Scienture acquisition (see Note 3). The acquired goodwill represents the value in excess of the net assets and liabilities acquired at the acquisition date.

During the year ended December 31, 2025, the Company performed its annual impairment assessment of goodwill and indefinite-lived intangible assets and recognized aggregate impairment charges of $26,346,050. See Note 9 – Goodwill and Intangible Assets for a full description of the impairment testing methodology, triggering events, valuation inputs, and results.

Goodwill

Goodwill is an asset representing the excess cost over the fair market value of net assets acquired in business combinations. In accordance with Intangibles - Goodwill and Other (Topic 350), goodwill is not amortized but is tested annually for impairment or on an interim basis when indicators of potential impairment exist. Goodwill is tested for impairment at the reporting unit level. The Company's reporting units discrete financial information is available and management regularly reviews the operating results. For purposes of impairment testing, goodwill is allocated to the applicable reporting units based on the reporting structure.

The Company has the option to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying value. Qualitative factors assessed for each of the applicable reporting units include, but are not limited to, changes in macroeconomic conditions, industry and market considerations, cost factors, discount rates, competitive environments and financial performance of the reporting units. If the qualitative assessment indicates that it is more likely than not that the carrying value of a reporting unit exceeds its estimated fair value, a quantitative test is required.

The Company also has the option to proceed directly to the quantitative test. Under the quantitative impairment test, the estimated fair value of each reporting unit is compared to its carrying value, including goodwill. If the carrying value of the reporting unit including goodwill exceeds its fair value, an impairment charge equal to the excess would be recognized, up to a maximum amount of goodwill allocated to that reporting unit. Management can resume the qualitative assessment in any subsequent period for any reporting unit.

During the year ended December 31, 2025, the Company performed its annual impairment assessment of goodwill and indefinite-lived intangible assets and recognized aggregate impairment charges of $26,346,050. See Note 9 – Goodwill and Intangible Assets for a full description of the impairment testing methodology, triggering events, valuation inputs, and results.

Intangible Assets

In connection with the Scienture acquisition, the Company identified product technologies assets. The product technologies represent a broad range of novel product candidates including new potential treatments for hypertension, migraine, pain and thrombosis and other related disorders. Each of the product technologies are in various phases of development and had not achieved regulatory approval as of the valuation date.

The product technologies are 505(b)(2) products and represent modifications and new delivery methods of already approved drugs (rather than novel drug compounds/ formulations/treatments which require significant regulatory approvals and testing). These assets should be amortized over their expected remaining economic life. The product technology assets will remain unamortized, subject to potential impairment testing, until the assets are placed in service, which is when commercialization of the product commences. At that point, the assets will be amortized over their expected remaining life (likely a period of 15-20 years based on the patent lives). SCN-102 commenced amortization during the year ended December 31, 2025, upon the asset commercialization of the product commenced for its intended use. Amortization is recorded on a straight-line basis over an estimated useful life of 13 years; amortization expense recognized from the commencement date through December 31, 2025 was $453,846. Other three intangible assets are not amortized until commercialization.

See Note 9 – Goodwill and Intangible Assets for detail on impairment testing results.

Impairment of Long-Lived Assets

The Company continually monitors events and changes in circumstances that could indicate carrying amounts of long-lived assets may not be recoverable. When such events or changes in circumstances are present, the Company assesses the recoverability of long-lived assets by determining whether the carrying value of such assets will be recovered through undiscounted expected future cash flows. If the total of the future cash flows is less than the carrying amount of those assets, the Company recognizes an impairment loss based on the excess of the carrying amount over the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or the fair value less costs to sell.

During the year ended December 31, 2025, the Company performed its annual impairment assessment of goodwill and indefinite-lived intangible assets and recognized aggregate impairment charges of $26,346,050. See Note 9 – Goodwill and Intangible Assets for a full description of the impairment testing methodology, triggering events, valuation inputs, and results.

As of December 31, 2025, SCN-102 passed the ASC 360 undiscounted cash flow recoverability test, therefore, no impairment was recorded. The three other intangible assets failed their annual ASC 350 fair value tests, fair values determined via discounted cash flow analysis were below carrying amounts, resulting in total impairment charges of $4,973,090 for the year ended December 31, 2025.

Stock-Based Compensation

The Company accounts for stock-based compensation to employees in accordance with ASC 718, “Compensation-Stock Compensation.” ASC 718 requires companies to measure the cost of employee services received in exchange for an award of equity instruments, including stock options, based on the grant date fair value of the award and to recognize it as compensation expense over the period the employee is required to provide service in exchange for the award, usually the vesting period. Stock option forfeitures are recognized at the date of employee termination. Effective January 1, 2019, the Company adopted Accounting Standards Update (“ASU”) 2018-07 for the accounting of share-based payments granted to non-employees for goods and services.

Leases

The Company accounts for its leases under ASC 842, “Leases.” Under this guidance, arrangements meeting the definition of a lease are classified as operating or financing leases, and are recorded on the consolidated balance sheet as both a right of use asset and lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease or the Company’s incremental borrowing rate. Lease liabilities are increased by interest and reduced by payments each period, and the right of use asset is amortized over the lease term. For operating leases, interest on the lease liability and the amortization of the right of use asset result in straight-line rent expense over the lease term. For finance leases, interest on the lease liability and the amortization of the right of use asset results in front-loaded expense over the lease term. Variable lease expenses are recorded when incurred.

In calculating the right of use asset and lease liability, the Company has elected to combine lease and non-lease components. The Company excludes short-term leases having initial terms of 12 months or less from the new guidance as an accounting policy election, and recognizes rent expense on a straight-line basis over the lease term.

Research & Development Expenses

Research and development costs are expensed in the period incurred in accordance with ASC 730, “Research and Development.” These expenses consist of independent contractor costs, costs for outsourced analytical research and development activities, batch manufacturing cost and, advisory costs as a part of research, market research costs and other regulatory consulting costs.

Income (loss) Per Common Share

Basic net income per common share is computed by dividing net income available to common stockholders by the weighted average number of common shares outstanding. Diluted net income per common share is computed similar to basic net income per common share except that the denominator is increased to include the number of additional common shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive. The dilutive effect of the Company’s options and warrants is computed using the treasury stock method. As of December 31, 2025, we had 177,536 outstanding warrants and 19,899 stock options, each exercisable for shares of common stock, as well as 15,759 shares of Series B Preferred Stock outstanding. As of December 31, 2024, we had 238,594 outstanding warrants and 23,930 stock options, each exercisable for shares of common stock, as well as 15,759 shares of Series B Preferred Stock outstanding.

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

	Year Ended December 31,	
	2025	2024
Numerator:		
Net loss from continuing operations	$ (41,512,264)	$ (18,244,480)
Net income on discontinued operations	-	27,310,278
Net (loss) income	$ (41,512,264)	$ 9,065,798
Denominator:		
Denominator for EPS – weighted average shares		
Basic	15,347,312	3,375,325
Diluted	15,347,312	3,653,609
Net loss per common share from continuing operations		
Basic	$ (2.70)	$ (5.41)
Diluted	$ (2.70)	$ (5.41)
Net income per common share from discontinued operations		
Basic	$ -	$ 8.09
Diluted	$ -	$ 7.47
Net (loss) income		
Basic	$ (2.70)	$ 2.69
Diluted	$ (2.70)	$ 2.48

Income Taxes

The Company's benefit / (provision) for income taxes was $1,994,878 and $534,396 for the years ended December 31, 2025 and 2024, respectively. The income tax provisions for these periods are based upon estimates of annual income (loss), annual permanent differences and statutory tax rates in the various jurisdictions in which the Company operates. For all periods presented, the Company utilized net operating loss carryforwards to offset the impact of any taxable income. The Company's tax rate differs from the applicable statutory rates due primarily to the establishment of a valuation allowance, utilization of deferred and the effect of permanent differences and adjustments.

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which enhances transparency of income tax disclosures by requiring: (i) a tabular rate reconciliation using both percentages and amounts, with specified categories disclosed separately; (ii) disaggregation of income taxes paid by federal, state, and foreign jurisdictions; and (iii) disclosure of income (loss) from continuing operations before income tax expense (benefit) disaggregated between domestic and foreign. The standard is effective for annual periods beginning after December 15, 2024. The Company adopted ASU 2023-09 effective January 1, 2025 on a prospective basis. The adoption resulted in enhanced income tax disclosures as reflected in Note 12, but did not have a material impact on the Company's financial position, results of operations, or cash flows.

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which improves reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The amendments require disclosure of: (i) significant segment expenses regularly provided to the CODM and included within each reported measure of segment profit or loss; (ii) a description of other segment items; (iii) the title and position of the CODM; and (iv) an explanation of how the CODM uses the reported measure(s) of segment profit or loss. The standard is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. The Company adopted ASU 2023-07 effective January 1, 2025. The adoption resulted in enhanced segment disclosures as reflected in Note 16, but did not have a material impact on the Company's financial position, results of operations, or cash flows.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement—Reporting Comprehensive Income (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which requires public business entities to disclose, in tabular format, the nature of certain expenses included in specific income statement line items, including disaggregation by natural classification (inventory purchases, employee compensation, depreciation, intangible asset amortization, and other categories) and disclosure of total selling expenses. The guidance is effective for annual periods beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of this standard and anticipates it will result in additional footnote disclosures but does not expect a material impact on its financial position, results of operations, or cash flows.

Management does not believe that any other recently issued, but not yet effective, accounting standards will have a material effect on the accompanying consolidated financial statements. As new accounting pronouncements are issued, the Company will adopt those that are applicable under the circumstances.

NOTE 2 – GOING CONCERN

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business within one year after the date the consolidated financial statements are issued. In accordance with Financial Accounting Standards Board ("***FASB***") Accounting Standards Update No. 2014-15, "Presentation of Financial Statements - Going Concern" (Subtopic 205-40), our management evaluates whether there are conditions or events, considered in aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued.

As of December 31, 2025, the Company had an accumulated deficit of $80,551,237 and cash and cash equivalents of $6,662,008.

As of December 31, 2025, the Company had cash and cash equivalents of $6,662,008 and current liabilities of approximately $2.7 million, resulting in positive working capital of approximately $5.2 million. Management believes that its existing cash on hand, combined with revenues generated from the commercialization of ARBLI™ (SCN-102) and its planned financing activities, will be sufficient to fund the Company's operations and meet its obligations as they become due for at least twelve months from the date these financial statements are issued. In making this assessment, management considered the following: (i) cash on hand of $6.7 million as of December 31, 2025, which management believes is sufficient to fund current operating requirements over the next twelve months; (ii) the Company's ability to modulate discretionary operating and development expenditures to align with available capital; (iii) ongoing and planned commercialization of ARBLI™ (SCN-102), which generated its initial revenues during the second half of 2025 and is expected to contribute increasing revenues in 2026; and (iv) management's plans to access additional capital through equity or debt financing as needed to fund accelerated pipeline development activities. While management believes these factors are sufficient to alleviate substantial doubt about the Company's ability to continue as a going concern, there can be no assurance that the Company's operations will generate positive cash flows, or that additional financing will be available on favorable terms, or at all. If additional financing is not available, the Company may be required to delay, reduce, or eliminate certain development programs or commercialization activities. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

NOTE 3 – ACQUISITIONS AND DISPOSITIONS

Acquisitions

Scienture, Inc.

The Company evaluated the Agreement and Plan of Merger, dated July 25, 2024, by and among the Company, MEDS Merger Sub I, Inc., MEDS Merger Sub II, LLC, and Scienture (the "***Scienture Merger Agreement****")* pursuant to ASC 805 and ASU 2017-01, Topic 805, "Business Combinations." The Company first determined that Scienture met the definition of a business as it includes inputs and a substantive process that together significantly contribute to the ability to create outputs. Scienture's results of operations are included in the Company's consolidated financial statements from the date of acquisition. The acquisition method of accounting requires, among other things, that the assets acquired and liabilities assumed in a business combination be measured at their estimated respective fair values as of the closing date of the acquisition. Goodwill recognized in connection with this transaction represents primarily the potential economic benefits that the Company believes may arise from the acquisition. The purchase price allocation is preliminary and could be significantly revised as a result of additional information obtained regarding assets acquired and liabilities assumed and revisions of estimates of fair values of tangible assets and related deferred tax assets and liabilities. The Company will finalize its valuation and the allocation of the purchase price, along with required retrospective adjustments, if any, within a year following the acquisition date.

On July 25, 2024, the parties consummated the mergers contemplated by the Scienture Merger Agreement (together, the "Scienture Merger") and the Company issued 291,536 shares of common stock and 6,826,753 shares of Series X Preferred Stock at the closing. The aggregate fair value of the purchase price consideration was $78,646,184. The fair value was determined by the underlying stock price of the common stock on the date of the Scienture Merger, which was $11.63 per share, which was utilized for both the issuance of common and preferred stock after evaluating the terms of the Series X Preferred Stock. The Company also applied a discount for lack of marketability of 5% due to certain lock-up terms on the shares issued.

The following summarizes the purchase price consideration and the preliminary purchase price allocation as of the acquisition date:

		July 25, 2024
Purchase consideration:		
Common stock	$	3,221,245
Series X preferred stock		75,424,939
Total purchase consideration	$	78,646,184
Purchase price allocation:		
Cash	$	132,976
Operating lease right-of-use assets		61,578
Goodwill		21,372,960
Intangible assets - product technologies		76,400,000
Accounts payable		(987,097)
Accrued liabilities		(1,198,134)
Loan payable, related party		(265,000)
Lease liability		(61,886)
Development agreement liability		(1,285,000)
Long-term convertible notes		(2,000,000)
Deferred tax liability		(13,524,213)
Net assets acquired	$	78,646,184

Goodwill is primarily attributable to the go-to-market synergies that are expected to arise as a result of the acquisition and other intangible assets that do not qualify for separate recognition. The goodwill is not deductible for tax purposes.

Unaudited Pro Forma Financial Information

The following pro forma financial information (unaudited) presents the Company's financial results as if the Scienture Merger had occurred as of January 1, 2024. The pro forma financial information is not necessarily indicative of what the financial results actually would have been had the acquisitions been completed on this date. In addition, the pro forma financial information is not indicative of, nor does it purport to project, the Company's future financial results. The pro forma information does not give effect to any estimated and potential cost savings or other operating efficiencies that could result from the acquisition:

		Year Ended December 31, 2024
Revenue	$	636,643
Net loss from continuing operations	$	(19,459,955)
Net loss from continuing operations per share	$	(5.77)

Dispositions and Divestitures

Refer to Note 1 for further detail on the disposition of the Company's legacy subsidiaries.

MMS APA

On February 16, 2024, the Company, together with Softell and Micro Merchant Systems, Inc. ("***MMS***"), entered into an asset purchase agreement (the "***MMS APA***") under which MMS agreed to purchase for cash substantially all of the assets of Softell. On February 16, 2024, the parties consummated the closing of the transactions contemplated by the MMS APA. The purchase price paid at closing was $22,660,182. Because MMS received $1,600,000 or greater in certain collections from third parties resulting from any products or services sold, or provided, by the business assets and operations acquired from Softell during the period ending on the four-month anniversary of the closing date, the Company was due an additional $7,500,000 payment from MMS. The Company received the payment in May 2024.

The MMS APA was accounted for a business disposition in accordance with ASC 810-40-40-3A. As of February 16, 2024, the Company no longer consolidated the assets, liabilities, revenues and expenses of Softell. The components of the disposition are as follows:

Cash received from MMS	$	22,660,182
Other receivable from MMS		7,500,000
Total fair value of consideration received	$	30,160,182
Carrying amount of assets and liabilities		
Cash	$	76,821
Accounts receivable, net		719,876
Prepaid expenses		55,397
Property, plant and equipment, net		45,655
Operating lease right-of-use assets		12,277
Accounts payable		(347,000)
Accrued liabilities		(5,269)
Other current liabilities		(26,244)
Lease liability, current		(1,556)
Notes payable, current portion		(45,000)
Lease liability, net of current portion		(10,720)
Total carrying amount of assets and liabilities		474,236
Gain on disposition of business	$	29,685,946

The gain on disposition of business of $29,685,946 was included in income from discontinued operations, net of tax in the consolidated statements of operations of the year ended December 31, 2024.

Superlatus SPA

On March 5, 2024, the Company entered into a Stock Purchase Agreement with Superlatus Inc. (the "***Superlatus SPA***"). Pursuant to the Superlatus SPA, the Company sold all of the issued and outstanding stock of Superlatus Inc. to Superlatus Foods Inc. (the "***Buyer***"). The $1.00 purchase price for the stock was delivered to the Company at the closing, which occurred simultaneously with the execution of the Superlatus SPA. As a result of the transaction, Superlatus Inc. ceased to be a subsidiary of the Company, and the rights and assets of Superlatus together with various liabilities and obligations that were specific to Superlatus Inc. became rights and obligations of the Buyer.

The transaction was accounted for a business disposition in accordance with ASC 810-40-40-3A. As of March 5, 2024, the Company no longer consolidated the assets, liabilities, revenues and expenses of Superlatus Inc. The components of the disposition are as follows:

Fair value of consideration received	$	1
Total fair value of consideration received	$	1
Carrying amount of assets and liabilities		
Cash	$	151,546
Property, plant and equipment, net		223,080
Intangible assets, net		8,962,688
Operating lease right-of-use assets		325,995
Purchase price payable		(350,000)
Accounts payable		(224,137)
Accrued liabilities		(173,436)
Notes payable, current portion		(6,480,000)
Lease liability - current		(105,567)
Lease liability - net of current portion		(221,428)
Notes payable		(25,000)
Total carrying amount of assets and liabilities		2,083,743
Loss on disposition of business	$	(2,083,742)

The loss of disposition of business of $2,083,742 was included in income from discontinued operations, net of tax in the consolidated statements of operations of the year ended December 31, 2024.

Disposition of Legacy Subsidiaries

See Notes 1 and 4 for detailed discussion.

Discontinued Operations

In accordance with the provisions of ASC 205-20, the Company has excluded the results of discontinued operations from its results of continuing operations in the accompanying consolidated statements of operations for the years ended December 31, 2025 and 2024. The results of the discontinued operations for the years ended December 31, 2025 and 2024 consist of the following:

	TRX		Bonum		Superlatus		Total	
	Year Ended December 31,		**Year Ended December 31,**		**Year Ended December 31,**		**Year Ended December 31,**	
	2025	**2024**	**2025**	**2024**	**2025**	**2024**	**2025**	**2024**
Revenues	$ -	$ 970,808	$ -	$ -	$ -	$ -	$ -	$ 970,808
Cost of sales	-	-	-	-	-	-	-	-
Gross profit	-	970,808	-	-	-	-	-	970,808
Operating expenses:								
Wage and salary expense	-	713,021	-	578	-	-	-	713,599
Professional fees	-	62,160	-	-	-	-	-	62,160
Technology expense	-	86,660	-	2,245	-	-	-	88,905
General and administrative	-	37,377	-	678	-	-	-	38,055
Total operating expenses	-	899,218	-	3,500	-	-	-	902,719
Operating income	-	71,590	-	(3,500)	-	-	-	68,090
Non-operating income (expense):								
Gain on dispositions	-	29,685,946	-	-	-	(2,083,742)	-	27,602,204
Total non-operating income (expense)	-	29,685,946	-	-	-	(2,083,742)	-	27,602,204
Provision for income taxes	-	(360,016)	-	-	-	-	-	(360,016)
Net income on discontinued operations	$ -	$ 29,397,520	$ -	$ (3,500)	$ -	$ (2,083,742)	$ -	$ 27,310,278

In the second quarter of 2024, the Company determined to dissolve Bonum Health, Inc. and Bonum Health, LLC, and have presented the results of operations in net income (loss) from discontinued operations.

NOTE 4- RELATED PARTY TRANSACTIONS

Wellgistics Health and Tollo Health

On November 21, 2023, but effective September 14, 2023, the Company issued a promissory note (the "***Wellgistics Note***") to Wellgistics Health, Inc. (f/k/a Danam Health Inc.) ("***Wellgistics***") in the amount of $300,000. The Company prepaid $250,000 prior to the execution date. The Wellgistics Note did not accrue interest. As of December 31, 2023, the balance of the Wellgistics Note was $50,000. The Wellgistics Note was fully paid off in February 2024.

As of March 31, 2025, other receivables included a $3,828,769 receivable from Wellgistics and $215,000 receivable from Tollo. The receivables were unsecured, non-interest bearing and due on demand. The receivables were maintained by the Company's former IPS subsidiary, which was sold to Tollo as of April 30, 2025.

On April 30, 2025, the Company completed the sale of its subsidiaries, IPS, Softell, and Bonum Health, Inc. to Tollo in exchange for a $5,000,000 promissory note bearing interest at the prime rate and maturing on June 30, 2030. The note requires Tollo to repay 20% of any future equity financing proceeds toward the outstanding balance. In connection with the transaction, the Company recorded a $5,000,000 promissory note receivable, and derecognized subsidiaries' accounts payable of $117,162, other receivables of $4,219,239, operating lease right-of-use assets of $142,138, operating lease liability of $158,687 and a related party note receivable of $1,300,000. As such, the Company recognized a loss on disposition of $385,528. On June 24, 2025, the promissory note was assigned by Tollo to Integral Health, Inc. In August 2025, Integral Health, including its subsidiary IPS, were acquired by third parties. Therefore, as of December 31, 2025, Integral Health and Tollo is no longer considered a related party. As of December 31, 2025, the note receivable was outstanding and the Company recognized $250,000 in interest income, which was reclassified from note receivable, related party to note receivable on the consolidated balance sheet.

See Note 6 for detail on the note receivable from Wood Sage, LLC.

Suren Ajjarapu, the Company's former Chief Executive Officer, and Prashant Patel, the Company's former President and Chief Operating Officer, each had a beneficial interest in Tollo as of June 30, 2025. In August 2025, Integral Health, including its subsidiary IPS, were acquired by third parties. Therefore, at December 31, 2025, Integral Health and Tollo was no longer considered a related party.

Scienture Management

In July 2024, the executives of Scienture issued short-term loans to Scienture for an aggregate amount of $265,000. The loans were unsecured, interest bearing at the minimum applicable federal rate per annum, and due on demand. The loans were fully repaid in October 2025. Consequently, there were no amounts outstanding under these loan agreements as of December 31, 2025.

In November 2024, an executive of Scienture issued a short-term loan to Scienture for $150,000. The loan was unsecured, interest bearing at the minimum applicable federal rate per annum, and due on demand. The loan was fully repaid in October 2025. Consequently, there were no amounts outstanding under these loan agreements as of December 31, 2025.

In February 2025, an executive of Scienture issued a short-term loan to Scienture for $100,000. The loan was unsecured, interest bearing at the minimum applicable federal rate per annum, and due on demand. The loans were fully repaid in October 2025. Consequently, there were no amounts outstanding under these loan agreements as of December 31, 2025.

In February 2025, an executive of Scienture issued a short-term loan to Scienture for $16,000. The loan was unsecured, interest bearing at the minimum applicable federal rate per annum, and due on demand. The loan was fully repaid in October 2025. Consequently, there were no amounts outstanding under these loan agreements as of December 31, 2025.

NOTE 5 – REVENUE RECOGNITION

The Company's sole source of revenue is product revenue from the sale of pharmaceutical products through wholesale distribution channels. ARBLI™ (SCN-102, Losartan Potassium Oral Suspension) received FDA approval in March 2025 and commenced commercialization in the third quarter of 2025. Revenue is recognized when control transfers to the wholesale distributor, generally upon delivery.

Revenue is measured at the net transaction price equal to the gross invoice price reduced by estimated variable consideration. Gross-to-net adjustments include:

Chargebacks. The difference between the invoice price charged to wholesale distributors and the lower contract price distributors extend to end-customers (retail pharmacies, hospitals, clinics). Estimated based on expected sell-through and contractual terms.

Wholesaler Rebates and Distribution Service Fees. Fees and rebates paid to wholesale distributors and group purchasing organizations ("GPOs") under contractual arrangements. Estimated based on contracted rates and expected sales volumes.

Prompt Pay Discounts. Discounts offered to wholesale distributors for timely payment, estimated based on contractual terms.

Product Returns. Returns accepted under limited conditions (generally damaged, expired, or defective product). Returns have not been material to date given the early stage of ARBLI™ commercialization.

Estimates of variable consideration are reassessed each reporting period. Changes in estimates are recorded as adjustments to revenue in the period identified. Accrued gross-to-net liabilities are included within accrued liabilities on the consolidated balance sheets.

Revenue disaggregated by product for the years ended December 31, 2025 and 2024 is as follows:

Product	Year Ended December 31, 2025	Year Ended December 31, 2024
ARBLI™ (SCN-102, Losartan Potassium Oral Suspension)	$ 431,609	$ -
Legacy TrXade product revenues	-	136,643
Total revenues	**$ 431,609**	**$ 136,643**

Revenue for the year ended December 31, 2024 reflected residual pharmaceutical wholesale activity prior to the IPS disposition on April 30, 2025, which is classified as discontinued operations.

NOTE 6 – NOTES RECEIVABLE – RELATED PARTY

On August 22, 2023, the Company received a Promissory Note (the "***Wood Sage Note***") in the amount of $1,300,000 from Wood Sage, LLC. The Wood Sage Note bears no interest and is currently due and payable. As of December 31, 2025 and 2024, the outstanding balance of the Wood Sage Note was $0 and $1,300,000, respectively. The note was held by Softell, a former subsidiary of the Company.

On April 30, 2025, the Company completed the sale of its subsidiaries, IPS, Softell and Bonum Health, Inc., to Tollo in exchange for a $5,000,000 promissory note bearing interest at the prime rate and maturing on June 30, 2030 (see Notes 1 and 4). In August 2025, Integral Health, including its subsidiary IPS, were acquired by third parties. Therefore, at December 31, 2025, Integral Health and Tollo was no longer considered a related party, which was reclassified from note receivable, related party to note receivable on the consolidated balance sheet.

NOTE 7 – INVENTORY

Inventory value is determined using the weighted average cost method and is stated at the lower of cost or net realizable value. As of December 31, 2025 and 2024, inventory was comprised of the following:

	December 31,	
	2025	2024
Finished goods	$ 213,408	$ -
Inventory	$ 213,408	$ -

NOTE 8 – GOODWILL AND INTANGIBLE ASSETS

In connection with the Scienture Merger on July 25, 2024, the Company recorded goodwill of $21,372,960 and intangible assets of $76,400,000. During the year ended December 31, 2025, the Company performed its annual impairment assessment of goodwill and intangible assets, resulting in total impairment charges of $26,346,050, comprised of $21,372,960 related to goodwill and $4,973,090 related to indefinite-lived intangible assets.

The purchase price allocation of intangible assets was evaluated under ASC 805 as of the acquisition date. The identified intangible assets were determined to be product technologies representing novel formulations and delivery methods targeting central nervous system and cardiovascular diseases. Each product technology was valued using the Multi-Period Excess Earnings Method ("MPEEM") under the Income Approach, consistent with ASC 820. The fair values assigned at acquisition, by product candidate, were as follows:

Product Candidate	Fair Value
SCN-102(a)	$ 23,600,000
SCN-104(b)	25,000,000
SCN-106(c)	15,000,000
SCN-107(d)	12,800,000
	$ 76,400,000

(a) SCN-102 received regulatory approval in March 2025.Product commercialization began in the third quarter of 2025.
(b) Management expects SCN-104 to achieve regulatory approval in late 2027 or early 2028, with product commercialization projected to begin in 2028.
(c) Management expects SCN-106 to achieve regulatory approval in 2027 or 2028, with product commercialization projected to begin in 2028.
(d) Management expects SCN-107 to achieve regulatory approval in 2028 or 2029, with product commercialization projected to begin in 2029.

The fair value of the product technologies was determined by the Income Approach: Multi-Period Excess Earnings Methods ("***MPEEM***"). The MPEEM measures economic benefits by calculating the cash flows attributable to an asset after deducting appropriate returns for contributory assets used by the business in generating the asset's revenue and earnings. The MPEEM utilized revenue and cash flow projections through 2030 based on each product candidate's phase of development. Key assumptions include a 2% long-term revenue growth rate and 3% contributory asset charge rate. The Company discounted the expected future cash flows at a 53.0% rate of return, equal to the weighted-average cost of capital plus 10%, to reflect the risk of the cash flows related to the product technologies. The Company then summed the present values of the estimated future cash flows and included an amortization tax benefit to the value indication of each of the product technologies.

The fair value of each product technology was determined using the Multi-Period Excess Earnings Method ("MPEEM"), an income approach that isolates the cash flows attributable solely to the subject intangible asset by projecting revenues and operating costs, deducting contributory asset charges (working capital at 4.0%, property and equipment at 12.9%), and discounting the resulting excess earnings to present value using risk-adjusted discount rates. A tax amortization benefit is included in each fair value indication. Projections reflect each asset's market size, projected penetration, and net pricing assumptions, with a long-term growth rate of 4.8% applied at terminal value, benchmarked to long-term U.S. nominal GDP expectations. Key valuation inputs included: a risk-free rate of 4.79% (20-year U.S. Treasury yield as of December 31, 2025); a market rate of return of 13.0% (10-year CAGR of S&P 500, 2016–2025); an unlevered beta of 0.98 (Damodaran pharmaceutical industry data); and an effective tax rate of 26.7% (combined U.S. federal rate of 21% and New York state rate of 7.3%).

Goodwill Impairment – ASC 350

In accordance with ASC 350-20, the Company performs its annual goodwill impairment test as of December 31. The Company operates as a single operating segment and, accordingly, goodwill is allocated to and tested at the consolidated entity level as a single reporting unit, consistent with ASC 280 and the manner in which the Company's Chief Operating Decision Maker reviews operating results for purposes of resource allocation and performance evaluation.

As of December 31, 2025, management identified the following indicators of impairment: (i) continued operating losses from continuing operations; (ii) a significant decline in the Company's market capitalization relative to the carrying value of its net assets; and (iii) challenging conditions within the specialty pharmaceutical sector. Based on the presence of these triggering events, the Company bypassed the qualitative assessment and proceeded directly to a quantitative impairment test.

The fair value of the reporting unit was estimated using the Market Capitalization Method, representing a Level 1 input under ASC 820, based on the Company's quoted share price of $0.51 and 40,630,815 shares outstanding as of December 31, 2025, resulting in an estimated fair value of approximately $20.7 million. No control premium or marketability discount was applied, as the Company's shares are actively traded and the quoted market price represents the most reliable indicator of fair value from a market participant perspective. The carrying amount of the reporting unit was approximately $82.7 million, resulting in a shortfall of approximately $62.0 million. As the shortfall exceeded the recorded goodwill balance, the entire goodwill balance was determined to be impaired in accordance with ASC 350-20-35-3C. The Company recognized a non-cash goodwill impairment charge of $21,372,960 for the year ended December 31, 2025, recorded within impairment loss in the consolidated statements of operations. As of December 31, 2025, no goodwill remains on the consolidated balance sheet.

Activity in the goodwill balance for the year ended December 31, 2025 is as follows (in thousands):

	(in thousands)
Balance, December 31, 2024	**$ 21,373**
Impairment charge	(21,373)
Balance, December 31, 2025	**$ —**

Intangible Assets – Classification and Annual Assessment

The Company's intangible assets consist of four product technology assets acquired in connection with the Scienture Merger. SCN-102 (ARBLI™ – Losartan Oral Suspension) received FDA approval in March 2025 and commenced commercialization during the third quarter of 2025; accordingly, it is classified as a finite-lived intangible asset amortized on a straight-line basis over an estimated useful life of 13 years, reflecting remaining patent life. SCN-104 (DHE Mesylate Injection), SCN-106 (Cathflo Injection – Potential Biosimilar), and SCN-107 (Bupivacaine Long-Acting Injection) remain in pre-commercial development and are classified as indefinite-lived in-process research and development ("IPR&D") assets subject to annual impairment testing under ASC 350-30.

Indefinite-Lived IPR&D – Annual Impairment Test (ASC 350-30)

The Company performs its annual impairment test of indefinite-lived IPR&D assets as of December 31 each year, and on an interim basis when triggering events are identified. The fair value of each IPR&D asset was estimated using MPEEM, as described above. The required return on asset applied to SCN-104, SCN-106, and SCN-107 was 49.9%, reflecting a base unlevered cost of capital of 12.9% plus a 37.0% development and commercialization risk premium to capture regulatory approval uncertainty, market adoption risk, and execution risk associated with pre-commercial pharmaceutical assets. Based on the annual impairment test, the carrying amounts of SCN-104, SCN-106, and SCN-107 exceeded their respective estimated fair values as of December 31, 2025. In accordance with ASC 350-30-35, each asset was written down to its estimated fair value, resulting in the following impairment charges for the year ended December 31, 2025 (in thousands):

Asset	Carrying Amount	Fair Value	Impairment Loss
SCN-104 (DHE Mesylate Injection)	$ 25,000	$ 22,339	$ (2,661)
SCN-106 (Cathflo Injection – Potential Biosimilar)	$ 15,000	$ 13,381	$ (1,619)
SCN-107 (Bupivacaine Long-Acting Injection)	$ 12,800	$ 12,107	$ (693)
Total IPR&D impairment charges			**$ (4,973)**

Finite-Lived Intangible Asset – Recoverability Test (ASC 360)

SCN-102 (ARBLI™ – Losartan Oral Suspension) received FDA approval in March 2025 and commenced commercialization during the third quarter of 2025. Upon commencement, SCN-102 was reclassified from indefinite-lived IPR&D to a finite-lived intangible asset and amortization commenced on a straight-line basis over an estimated useful life of 13 years. Amortization expense recognized from commercialization through December 31, 2025 was $453,846, resulting in a carrying amount of $23,146,154 as of December 31, 2025.

Due to the presence of impairment indicators as of December 31, 2025, the Company evaluated SCN-102 for recoverability under ASC 360-10-35. The recoverability test compares the carrying amount of the asset to the sum of undiscounted future cash flows expected to result from its use and eventual disposition. The total undiscounted future cash flows attributable to SCN-102, based on management's projections, were approximately $71.1 million, exceeding the carrying amount of $23.1 million by approximately $48.0 million. Accordingly, SCN-102 was determined to be recoverable and no impairment loss was recognized for this asset as of December 31, 2025.

The following table summarizes the carrying amounts of intangible assets as of December 31, 2025 and 2024 (in thousands):

Asset	Dec 31, 2025	Dec 31, 2024
SCN-102 – finite-lived (net of $454 amortization)	$ 23,146	$ 23,600
SCN-104 – indefinite-lived IPR&D	$ 22,339	$ 25,000
SCN-106 – indefinite-lived IPR&D	$ 13,381	$ 15,000
SCN-107 – indefinite-lived IPR&D	$ 12,107	$ 12,800
Total intangible assets, net	**$ 70,973**	**$ 76,400**

The decrease in intangible assets from $76,400,000 as of December 31, 2024 to $70,973,064 as of December 31, 2025 reflects $4,973,090 of impairment charges recognized on SCN-104, SCN-106, and SCN-107, and $453,846 of amortization expense recognized on SCN-102 following its commercialization. Estimated future annual amortization expense for SCN-102 is approximately $1,780,474 per year through the remainder of its estimated useful life. The three IPR&D assets will be reclassified from indefinite-lived to finite-lived and commence amortization upon commercialization: SCN-104 is expected to launch in 2028, SCN-106 in 2029, and SCN-107 in 2029 or 2030.

NOTE 9 – CONVERTIBLE DEBT AND NOTES PAYABLE

Convertible Debenture – Arena

On November 22, 2024, the Company entered into a Securities Purchase Agreement (the "***Arena SPA***") with the Arena Finance Markets, LP ("***Arena Finance***"), Arena Special Opportunities Partners III, LP (together with Arena Finance, the "***Arena Investors***"). Under the Securities Purchase Agreement, the Company will issue 10% original issue discount one or more secured convertible debentures ("***Debentures***") in a total principal amount of up to $12,222,222, divided into up to three separate tranches that are each subject to certain closing conditions. The conversion price per share of each Debenture is equal to 92.5% of the lowest daily VWAP (as defined in the Debentures) of the Company's shares of common stock during the five trading day period ending on the trading day immediately prior to delivery or deemed delivery of the applicable conversion notice, subject to adjustments related to the trading price of the Company's common stock.

The closing of the first tranche was consummated on November 25, 2024 (the "***First Closing***") and the Company issued to the Arena Investors Debentures in an aggregate principal amount of $3,333,333 (the "***First Closing Debentures***"). The First Closing Debentures were sold to the Arena Investors for a purchase price of $3,000,000, representing an original issue discount of ten percent (10%). The convertible debenture will mature eighteen months from the First Closing.

The First Closing Debentures contain customary events of default. If an event of default occurs, until it is cured, the holder may increase the interest rate applicable to the First Closing Debentures to two percent (2%) per annum and accelerate the full indebtedness under the First Closing Debentures, in an amount equal to 125% of the outstanding principal amount and accrued and unpaid interest. Subject to limited exceptions, the First Closing Debentures prohibit the Company and, as applicable, its subsidiaries from incurring any new indebtedness that is not subordinated to the First Closing Debentures and, as applicable, any subsidiary's obligations in respect of the First Closing Debentures until the First Closing Debentures are paid in full.

As consideration for the Arena Investors' consummation of the First Closing, concurrently with the First Closing, the Company issued to each Arena Investor participating in the First Closing its pro rata portion of the 55,000 shares of common stock (the "***SPA Commitment Fee Shares***") issued to the Arena Investors as a commitment fee upon the execution of the Securities Purchase Agreement. Furthermore, as consideration for the Arena Investors' consummation of subsequent closings, the Company shall issue to the Arena Investors participating in such closing a certain number of Company common stock as agreed upon among the Company and the Arena Investors participating. The fair value of the shares of common stock issued was $420,200, which was included as a debt discount as noted below.

Pursuant to a Security Agreement, dated November 25, 2024, the Company granted to the Arena Investors a security interest in all of its assets to secure the prompt payment, performance, and discharge in full of all of the Company's obligations under the Debentures. In addition, the Company's wholly-owned subsidiary, Scienture, entered into a Guarantee Agreement, dated November 25, 2024, with the Arena Investors, pursuant to which it agreed to guarantee the prompt payment.

Interest accrued on the outstanding principal amount of this Debenture at a rate equal to 10.00% per annum paid in kind (the "***PIK Interest***") unless there is an Event of Default (as defined in the Debenture), in which case Default Interest accrues and is payable instead of PIK Interest. Any PIK Interest is added to the outstanding principal amount of the Debenture on a monthly basis as additional principal obligations hereunder and shall automatically and thereafter constitute a part of the outstanding principal amount for all purposes hereof (including the accrual of interest thereon at the rates applicable to the principal amount generally). The Company will not issue additional debentures to satisfy and pay any PIK Interest. Interest is calculated on the basis of a 360-day year, consisting of twelve 30 calendar day periods, and accrues daily commencing on the Original Issue Date (as defined in the Debenture) until payment in full of the outstanding principal, together with all accrued and unpaid interest, liquidated damages and other amounts which may become due hereunder, has been made.

During the year ended December 31, 2025 and 2024, the Company incurred $141,977 and $33,333, respectively, in interest expense pertaining to the First Closing Debentures.

As a result of the issuance of the First Closing Debentures, the Company recognized an aggregate debt discount of $3,333,333. Through December 31, 2024, $869,692 of the debt discount was amortized to interest expense. In February 2025, the Company repaid $1,642,143 of principal and accrued interest. In August and September 2025, the Company repaid aggregate of $1,866,501 of the remaining outstanding principal and accrued interest, including a 20% early redemption premium, resulting in the immediate amortization of all remaining unamortized debt discount of $2,721,058 to interest expense during the year ended December 31, 2025, respectively. The outstanding amount owed on the First Closing Debentures was converted during October 2025. As a result, the First Closing Debentures are no longer outstanding as of December 31, 2025 (see Note 15).

On October 3, 2025, the Company entered into a letter agreement with Arena Investors to amend the conversion terms of its First Closing Debentures. Pursuant to this agreement, the Company issued an aggregate of 224,998 shares of common stock in full satisfaction of all remaining outstanding obligations. The Company recognized the fair value of the shares issued, totaling $189,673, as interest expense during the period.

Upon issuance of the shares, all conditions of the conversion were satisfied, and all prior obligations, security interests, and liens under the transaction documents dated November 25, 2024, were irrevocably discharged and terminated. Consequently, the Company has no further payment or financial obligations under the First Closing Debentures.

The following is a summary of the First Closing Debentures:

	Arena Note
Convertible debenture - Arena Principal	$ 3,333,333
Original issuance discount	(333,333)
Other issuance costs	(360,000)
Fair value of shares issued	(420,200)
Derivative liability recognized as debt discount	(2,477,217)
Excess debt discount amortization at issuance date	257,417
Amortization of debt discount	-
Arena note, net of unamortized debt discount, at December 31, 2025	$ -

Derivative Liability

The Company evaluated the terms of the conversion features of the First Closing Debentures as noted above in accordance with ASC Topic No. 815 - 40, "*Derivatives and Hedging - Contracts in Entity's Own Stock*," and determined they are not indexed to the Company's common stock and that the conversion feature, which is akin to a redemption feature, meet the definition of a liability. The First Closing Debentures contain an indeterminate number of shares to settle with conversion options outside of the Company's control. Therefore, the Company bifurcated the conversion feature and accounted for it as a separate derivative liability. Upon issuance of the First Closing Debentures, the Company recognized a derivative liability at a fair value of $2,477,217, which is recorded as a debt discount and will be amortized over the life of the First Closing Debentures. Upon repayment of the debentures in 2025, the remaining unamortized debt discount was fully amortized to interest expense.

The Company measured the derivative liability at fair value based on significant inputs not observable in the market, which causes it to be classified as a Level 3 measurement within the fair value hierarchy. The valuation of the derivative liability uses assumptions and estimates the Company believes would be made by a market participant in making the same valuation. The Company assesses these assumptions and estimates on an on-going basis as additional data impacting the assumptions and estimates are obtained. Changes in the fair value of the contingent consideration liability related to updated assumptions and estimates are recognized within the statements of operations.

The Company valued the derivative liability using a Black-Scholes method using following assumptions:

	December 31, 2025	December 31, 2024
Risk-free interest rate	-	4.290%
Expected term (in years)	-	1.40
Expected volatility+A13	-	171.46%
Expected dividend yield	-	0.00%

The following is a summary of the derivative liability:

	Derivative Liability
Outstanding as of December 31, 2024	$ 2,296,834
Change in fair value	(2,296,834)
Outstanding as of December 31, 2025	$ -

Scienture Convertible Debt

In September 2023, Scienture entered into a Loan and Security Agreement (the "***NVK Loan Agreement***") with NVK Finance, LLC, a Nebraska Limited Liability Company ("***NVK***") for $2,000,000. The debt accrues interest at a per annum rate equal to the Prime Rate (as defined in the NVK Loan Agreement) plus 7% and the prime rate is adjusted quarterly. As of both on total repayment in 2025 and December 31, 2024, the interest rate was 15.50%. The debt is collateralized by all of Scienture's receivables, cash and cash equivalents and its right, title and interest in, to and under its Intellectual Property (as defined in the NVK Loan Agreement) and all proceeds thereof. The principal is entirely repayable on the maturity date in September 2025 and interest is payable monthly following a Qualified Financing (as defined in the NVK Loan Agreement). The NVK debt is convertible into common stock of Scienture at a fully-diluted Scienture valuation of $60,000,000.

On October 10, 2025, the Company executed a second amendment to its loan agreement with NVK, extending the maturity date to December 8, 2025, and obtaining a waiver for all existing defaults. As consideration for this extension, the Company agreed to pay a maturity extension fee of $25,000 and issued 250,000 common shares with a fair value of $175,250. Both the cash fee and the fair value of the shares were recognized as interest expense during the year ended December 31, 2025.

As of October 15, 2025, the outstanding balance of the loan, comprising principal and accrued interest, was $2,656,250. Under the terms of the amendment, early repayment required the payment of this balance plus an additional interest charge of $791.67 per day for fourteen days. On October 15, 2025, the Company fully repaid the outstanding balance and all applicable fees, totaling $11,083 in additional interest, thereby satisfying all obligations under the NVK loan agreement.

The balance of the NVK debt at December 31, 2025 and 2024, was $0 and $2,000,000, respectively. An aggregate interest expense on the NVK debt was $462,316 and $231,639, for the years ended December 30, 2025 and 2024, respectively.

Streeterville Note

On October 14, 2025, the Company entered into a note purchase agreement with Streeterville Capital, LLC (the "Lender"), providing for the issuance of a senior secured promissory note in the aggregate principal amount of $3,911,111.11 (the "Streeterville Note"). The Streeterville Note carried an original issue discount of $391,111.11 and an interest rate of 9% per annum. After deducting the original issue discount and $20,000 in transaction costs, the Company received net proceeds of $3,500,000, which were utilized to repay the outstanding balance of the Scienture Convertible Debt and for general corporate purposes.

During the year ended December 31, 2025, the Streeterville Note was fully repaid. In connection with this repayment, the Company recognized interest expense of $13,981 representing accrued interest through the date of payoff. Additionally, the Company fully amortized the $391,111.11 original issue discount and the $20,000 in transaction costs, which were recognized as interest expense during the period. As of December 31, 2025, the Note had no outstanding balance, and there was no remaining unamortized debt discount or transaction costs associated with this obligation.

August 2024 Note

In August 2024, the Company issued a convertible note of $360,000, for which the Company received $314,000 in net proceeds. On the six-month anniversary of the issuance, the Company was required to make a payment of $360,000 to the noteholder and each month thereafter the Company was required to make a payment of $7,200 to the noteholder towards repayment of the note (each, an "***Amortization Payment***"). The note bears interest at 12% per annum and is deemed earned in full and guaranteed as of the note issuance date. If the Company fails to pay any Amortization Payment, the noteholder will have the right to convert the outstanding principal and accrued interest at a conversion price equal to the Conversion Price (as defined below and subject to a floor price of $1.50). The Conversion Price is the lesser of (i) $8.36 or (ii) 85% of the lowest volume-weighted average prices of the preceding five trading days. The note matures on August 20, 2025.

In connection with the note, the Company issued 76,923 warrants to purchase common stock to the noteholder. The warrants have an exercise price of $9.36 per share, are immediately exercisable and have a term of 5 years. The fair value of the warrant was $71,332, which was recognized as a debt discount and will be amortized to interest expense over the life of the note.

Total debt discount recognized in connection with the note was $117,332, with $42,755 amortized through December 31, 2024, and an additional $28,931 amortized during the year ended December 31, 2025. The net carrying value of the note payable, after deducting the remaining unamortized discount of $45,646, was $357,554, including $43,200 of accrued interest. On March 31, 2025, the Company converted the outstanding note into equity by issuing 274,000 shares of common stock at a fair value of $411,000. As a result, it recognized a $53,446 loss on conversion, reported as a non-operating expense in the consolidated statements of operations.

Debt Summary

The following is a summary of the Company's debt as of December 31, 2025 and 2024:

	As of December 31, 2025		
	Principal outstanding	Unamortized debt discount	Debt, net of unamortized debt discount
Convertible debenture - Arena	$ -	$ -	$ -
Scienture convertible debt	-	-	-
Streeterville note	-	-	-
Total debt	-	-	-
Current maturity of debt	-	-	-
Total long-term debt	$ -	$ -	$ -

	As of December 31, 2024		
	Principal outstanding	Unamortized debt discount	Debt, net of unamortized debt discount
Convertible debenture - Arena	$ 3,333,333	$ (2,721,058)	$ 612,275
August 2024 note	360,000	(74,577)	285,423
Scienture convertible debt	2,000,000	-	2,000,000
Total debt	5,693,333	(2,795,635)	2,897,698
Current maturity of debt	2,360,000	(74,577)	2,285,423
Total long-term debt	$ 3,333,333	$ (2,721,058)	$ 612,275

Superlatus Notes

On November 17, 2023, the Company issued a promissory note to Moku Foods, Inc. (the "Moku Foods November 2023 Note") in the amount of $50,000. The promissory note accrues interest at 11.5% per annum, compounded monthly and is payable upon demand at any time after November 30, 2023. As of December 31, 2023, the balance of the Moku Foods November 2023 Note was $50,000. The Company has accrued interest of $945 as of December 31, 2023. On March 5, 2024, the Company entered into the Superlatus SPA, whereby the Company sold its entire interest in Superlatus to Superlatus Foods, Inc. thereby transferring all assets and liabilities.

On October 16, 2023, the Company issued a promissory note to Moku Foods, Inc. (the "Moku Foods October 2023 Note") in the amount of $150,000. The promissory note accrues interest at 11.5% per annum, compounded monthly and is payable upon demand at any time after October 31, 2023. As of December 31, 2023, the balance of the Moku Foods October 2023 Note was $150,000. The Company has accrued interest of $4,300 as of December 31, 2023. On March 5, 2024, the Company entered into the Superlatus SPA, whereby the Company sold its entire interest in Superlatus to Superlatus Foods, Inc. thereby transferring all assets and liabilities.

On September 27, 2023, the Company issued a promissory note to Perfect Day, Inc. (the "Perfect Day Note") in the amount of $4,400,000 as consideration for the TUC APA (see Note 3). The promissory notes do not accrue interest and are payable upon demand at any time after October 31, 2023. The entire aggregate, unpaid principal sum of the note is immediately due and payable upon the occurrence of a change in control, as defined in the agreement. On March 5, 2024, the Company entered into the Superlatus SPA, whereby the Company sold its entire interest in Superlatus to Superlatus Foods, Inc. thereby transferring all assets and liabilities.

On September 14, 2023, the Company issued a promissory note to Wellgisitcs (the "Wellgistics Note") in the amount of $300,000. The Company received a deposit of $200,000 on September 14, 2023, and an additional deposit of $100,000 on October 13, 2023. The Wellgisitcs Note accrues interest at 0% per annum and is due and payable no later than 30 days after a change in control of borrower, as defined in the note agreement. As of December 31, 2023, the balance of the Wellgistics Note was $50,000. The Wellgistics Note was fully paid off in February 2024.

On June 16, 2023, the Company issued a secured debenture to Eat Well Investment Group, Inc. (the "Eat Well June 2023 Note") in the amount of $1,150,000 for the purchase of Sapientia, a wholly-owned subsidiary of Superlatus. The Eat Well June 2023 Note is secured by 100% of the membership interests in Sapientia. The Eat Well June 2023 Note began accruing interest at 12% per annum, compounded monthly, as of October 31, 2023. The Eat Well June 2023 Note matured on December 31, 2023. As of December 31, 2023, the balance of the Eat Well June 2023 Note was $1,150,000. The Company has accrued interest of $23,063 as of December 31, 2023. On March 5, 2024, the Company entered into the Superlatus SPA, whereby the Company sold its entire interest in Superlatus to Superlatus Foods, Inc. thereby transferring all assets and liabilities.

On February 8, 2023, Sapientia, a wholly-owned subsidiary of Superlatus, entered into a Loan Agreement with Eat Well Investment Group, Inc. (the "Eat Well February 2023 Note") in the amount of $25,000. The Eat Well February 2023 Note is unsecured, accrues interest at a rate of 1.87% per annum, and matures February 7, 2025. As of December 31, 2023, the balance of the Eat Well February 2023 Note was $25,000. The Company has accrued interest of $418 as of December 31, 2023. On March 5, 2024, the Company entered into the Superlatus SPA, whereby the Company sold its entire interest in Superlatus to Superlatus Foods, Inc. thereby transferring all assets and liabilities.

NOTE 10 – STOCKHOLDERS' EQUITY

Designation of Series B Preferred Stock

Effective June 26, 2023, the Company filed a Certificate of Designation, Preferences, Rights and Limitations of the Series B Preferred Stock (the "***Series B Preferred Stock***") with the Secretary of the State of Delaware that designated 787,754 shares of the Company's authorized and unissued preferred stock as convertible Series B Preferred Stock at a par value of $0.00001 per share.

Holders of the Series B Preferred Stock are not entitled to receive dividends and do not have redemption or voting rights. Furthermore, the Series B Preferred Stock does not have a liquidation preference. Shares of Series B Preferred Stock are automatically convertible into shares of the Company's common stock at a ratio of 100 shares of common stock for each share of Series B Preferred Stock upon stockholder approval of such conversion.

As of December 31, 2025 and 2024, there were 15,759 issued and outstanding shares of Series B Preferred Stock.

Designation of Series X Preferred Stock

On July 25, 2024, the Company revoked the authorization to issue shares of the Company's Series A Preferred Stock, par value $0.00001 per share (the "***Series A Preferred Stock***") and concurrently authorized the issuance of up to 9,211,246 shares of the Series X Preferred Stock, a then new class of preferred stock.

Holders of the Series X Preferred Stock are entitled to receive dividends on shares of the Series X Preferred Stock on an as-if-converted-to-Common-Stock basis, without regard to any beneficial ownership limitation described in a letter of transmittal, equal to and in the same form and manner as dividends are paid to holders of the shares of Common Stock. Subject to any requirements of the General Corporation Law of the State of Delaware, the Series X Preferred Stock has no voting rights. The Series X Preferred Stock ranks on parity with shares of Common Stock as to distributions of assets upon liquidation, dissolution, or winding up of the Company.

As consideration for the Scienture Merger, the shares of Scienture common stock issued and outstanding immediately prior to the "Effective Time" of the mergers were converted into the right to receive, in the aggregate, (i) 291,536 shares of the Company's common stock and (ii) 6,826,753 shares of the Company's Series X Preferred Stock, each share of which was convertible into one share of common stock.

In September 20, 2024, all previously issued shares of Series X Preferred Stock were converted into a total of 6,826,753 shares of common stock. As such, there were no issued and outstanding shares of Series X Preferred Stock as of December 31, 2025.

Hudson Global Ventures Stock Purchase Agreement

On October 4, 2023, the Company entered into a Securities Purchase Agreement the "Hudson SPA") with Hudson Global Ventures, LLC ("Hudson"). Under the terms of the Hudson SPA, the Company agreed to sell, and Hudson agreed to purchase, Two Hundred Ninety (290) shares of Series C Preferred Stock (the "Purchased Shares") at a price of $1,000 per share and a Warrant to purchase up to 41,193 shares of Common Stock. Additionally, pursuant to the Agreement, 40,000 shares of Common Stock were issued to Hudson upon closing for a commitment fee. The Company received $250,000 in exchange for the Purchased Shares, Common Stock, and Warrants, net of issuance costs.

On July 12, 2024, the Company converted 290 shares of Series C Preferred Stock into 52,158 shares of common stock at the election of the holder.

Common Stock

During the year ended December 31, 2025, the Company issued an aggregate of 7,103,614 shares of common stock for net proceeds of $9,008,199.

On October 3, 2025, the Company issued 224,998 shares of common stock to Arena Investors to fully satisfy the outstanding obligations under the First Closing Debentures. The Company recognized the fair value of these shares, totaling $189,673, as interest expense during the year ended December 31, 2025. This issuance resulted in the irrevocable discharge of all related security interests and financial obligations (see Note 9).

On October 10, 2025, the Company issued 250,000 shares of common stock to *Scienture convertible debt* as consideration for a loan maturity extension and default waiver. The Company recognized the fair value of these shares, totaling $175,250, as interest expense during the year ended December 31, 2025 (see Note 9).

During the year ended December 31, 2025, the Company issued 3,760,150 shares of common stock for services. The fair value of shares issued for services was $4,310,090 and was included in general and administrative expenses in the consolidated statements of operations.

During the year ended December 31, 2025, a warrant holder exercised 279,402 warrants for 279,402 shares of commons stock on a cashless basis (see Note 10).

Effective as of September 17, 2025, an aggregate of 2,000,000 shares of common stock were issued to employees and consultants pursuant to the cancellation of stock options issued to such holders. The Company revaluated the cancelled options using the Black-Scholes options model immediately prior to modification and compared to the fair value of the shares issued at $0.86 per share and the remaining expense to be recognized under the original option grant. Accordingly, the incremental difference of $1,512,995 was recognized as stock-based compensation expense in accordance with ASC 718-20-35 during the year ended December 31, 2025.

During the year ended December 31, 2025, the Company issued 274,000 shares of common stock at a fair value of $411,000 pursuant to the conversion of the August 2024 convertible note of $357,554. Accordingly, the Company recognized a $53,446 loss on conversion.

During the year ended December 31, 2024, the Company issued 490,698 shares of common stock for services. The fair value of shares issued for services was $4,598,294 and was included in general and administrative expenses in the consolidated statements of operations.

During the year ended December 31, 2024, a warrant holder exercised a warrant and acquired 28,487 shares of common stock for $16,567 in proceeds (see Note 13).

During the year ended December 31, 2024, an options holder exercised an option and acquired 2,371 shares of common stock for $9,840 in proceeds (see Note 14).

On July 12, 2024, the Company converted 290 shares of Series C Preferred Stock into 52,158 shares of common stock at the election of the holder.

On July 25, 2024, the Company issued 291,536 shares of common stock and 6,826,753 shares of Series X Preferred Stock pursuant to the Scienture Merger Agreement. The aggregate fair value of the purchase price consideration was $78,646,184.

In August 2024, the Company issued 28,571 shares of common stock pursuant to the exercise of warrants.

On September 20, 2024, all previously issued shares of Series X Preferred Stock were converted into a total of 6,826,753 shares of common stock.

Arena Note Commitment Shares

As additional consideration for the Arena Investors execution and delivery of the Arena SPA with the Arena Investors, the Company issued the Arena Investors the SPA Commitment Fee Shares as described in Note 8 above.

In connection with any Closing following the First Closing, the Company agreed to issue to the Arena Investors participating in such Closing or their designee(s) a certain number of "Commitment Shares." The aggregate number of Commitment Shares owing to each of the Arena Investors, or their designee(s), in connection with any Closing following the First Closing will be agreed among the Company and the Arena Investors participating in such Closing. For the avoidance of doubt, all of the Commitment Shares issued in connection with the First Closing on the First Closing Date were earned as of the First Closing Date regardless of whether a subsequent Closing occurs (see Note 8).

The Company issued to each Arena Investor participating in the First Closing its pro rata portion of 55,000 shares of the Company's common stock. The fair value of shares issued was $420,200 was recognized as a debt discount, which was amortized to interest expense in full as commitment shares in connection with first closing was fully earned as of first closing date.

Equity Line of Credit

On November 25, 2024, the Company entered into a purchase agreement ("***ELOC Agreement***") with Arena Business Solutions Global SPC II, Ltd (the "***Investor***"). Under the ELOC Agreement, the Company had the right, but not the obligation, to direct the Investor to purchase up to $50,000,000 in shares of the Company's common stock (the "***ELOC Shares***") upon satisfaction of certain terms and conditions contained in the ELOC Agreement. The term of the ELOC Agreement began on the date of execution and would end on the earlier of (i) the first day of the month following the 36-month anniversary of the execution date, (ii) the date on which the Investor had purchased the maximum amount of ELOC Shares, or (iii) the effective date of any written notice of termination delivered pursuant to the terms of the ELOC Agreement (the "***Commitment Period***"). The Company terminated the ELOC Agreement effective as of May 22, 2025.

In consideration for the Investor's execution and delivery of the ELOC Agreement, the Company agreed to issue to the Investor, as a commitment fee: (i) 70,000 shares of the Company's Common Stock (the "***Initial Commitment Fee Shares***") and (ii) in two separate tranches, a number of additional shares of common stock (the "***Additional Commitment Fee Shares***" and, together with the Initial Commitment Fee Shares, the "***Commitment Fee Shares***") equal to (a) with respect to the first tranche, 500,000 divided by the simple average of the daily VWAP of our common stock during the five (5) trading days immediately preceding the effectiveness of the initial registration statement on which the resale of the Commitment Fee Shares are registered (the "***Effectiveness Date***") and (b) with respect to the second tranche, 500,000 divided by the simple average of the daily VWAP of our common stock during the five (5) trading days immediately preceding the two (2) month anniversary of the Effectiveness Date. The Additional Commitment Fee Shares were subject to a true-up after each issuance pursuant to the terms of the ELOC Agreement.

The Company issued the Initial Commitment Fee Shares on November 25, 2024. The fair value of the shares issued was $534,800 and was included in deferred offering costs in the consolidated balance sheets. In March 2025, the deferred offering costs previously capitalized were offset against the gross proceeds from the ELOC share issuances (see below).

In 2025, the Company issued to the Investor 450,437 Additional Commitment Fee Shares. The fair value of shares issued was $971,732 and was recognized as offering costs in connection with the related ELOC Agreement share issuances. Accordingly, the fair value of the shares issued were offset against the gross proceeds and there was no net effect to stockholders' equity.

In March 2025, the Company issued an aggregate of 2,800,000 shares of its common stock pursuant to the terms of the ELOC Agreement. The issuance generated total gross proceeds, which after deducting applicable offering costs, resulted in net proceeds of $4,333,609.

In April and May 2025, the Company issued to the Investor, 614,075 shares of common stock as the final Additional Commitment Fee Shares owed to the Investor. The fair value of shares issued was $554,586 and was recognized as deferred offering costs in connection with the related ELOC Agreement share issuances. As mentioned above, the Company terminated the ELOC Agreement effective as of May 22, 2025.

Private Placements

In July 2025, the Company's board of directors approved a capital raise in an aggregate amount of up to $3,000,000 pursuant to a form of Common Stock Purchase Agreement (the "***Purchase Agreement***"). During July 2025, the Company sold an aggregate of 1,078,614 shares of common stock for aggregate proceeds of $1,679,993, pursuant to Purchase Agreements with eight investors.

Registered Direct Offering

On August 15, 2025, the Company issued an aggregate of 3,225,000 shares of common stock for aggregate proceeds of $3,549,184, pursuant to a Securities Purchase Agreement (the "***Purchase Agreement***") with several institutional investors as part of a registered direct offering made pursuant to a shelf registration statement on Form S-3 (File No. 333- 289198), which was originally filed by the Company with the Securities and Exchange Commission (the "***Commission***") on August 1, 2025, and declared effective on August 8, 2025.

ATM Program

On September 19, 2025, the Company entered into an Equity Distribution Agreement (the "ATM Agreement") with Maxim Group LLC ("Maxim"), acting as the sole sales agent for the offer and sale of the Company's common stock, par value $0.00001 per share, through an "at-the-market" offering program (the "ATM Program"). These shares are issued pursuant to the Shelf Registration Statement on Form S-3 (File No. 333-289198), which was filed with the Securities and Exchange Commission on August 1, 2025, and declared effective on August 8, 2025. Under the terms of the ATM Agreement, the Company may sell shares having an aggregate gross sales price of up to $18,792,009, subject to a commission of 3.0% of the gross sales price payable to Maxim, along with the reimbursement of certain specified expenses.

As of December 31, 2025, the Company issued and sold an aggregate of 15,722,659 shares of common stock under the ATM Program. These transactions resulted in aggregate net proceeds to the Company of $14,871,106, after deducting the applicable sales commissions and offering expenses. This activity represents a significant increase from the 100 shares of common stock previously issued under the program as of December 31, 2025.

Special Cash Dividend

On March 6, 2024, the Company announced the declaration of a special cash dividend of eight dollars ($8.00) per share of common stock, payable to stockholders of record as of March 18, 2024, with the dividend being paid on March 22, 2024. The special dividend of $12,671,072 (in the aggregate) was paid using a portion of the proceeds from the closing of the sale of certain assets to MMS.

On July 9, 2024, the Company announced the declaration of a special cash dividend of one dollar and fifty cents ($1.50) per share of common stock, payable to stockholders of record as of July 19, 2024, with the dividend being paid on July 22, 2024. The special dividend of $2,187,759 was paid using a portion of the proceeds received in May 2024 in connection with the sale of certain assets to MMS.

Restricted Common Stock

As of December 31, 2025, the Company had 1,200,898 restricted shares of common stock outstanding under the option plans. As of December 31, 2025, 185,898 shares were vested. The Company recorded stock-based compensation expense of $248,457 in the consolidated statements of operations for the year ended December 31, 2025. Unrecognized stock compensation outstanding on these grants was $738,993 as of December 31, 2025.

Equity Compensation Awards

Each independent member of the Company's board of directors (the "***Board***") is to receive an annual grant of restricted common stock of the Company equal to $55,000 in value on April 1st of each year (or such date thereafter as the awards are approved by the Board), and valued on such same date, based on the closing sales price on such date (or the first business day thereafter), which restricted stock awards will vest at the rate of 1/4th of such awards over the following four calendar quarters, subject to such directors continued service to the Company.

The Board and the Company's stockholders approved an amendment to the Second Amended and Restated 2019 Equity Incentive Plan (the "***Plan***"), which increased the available shares under the Plan to 5,000,000 shares of the common stock.

NOTE 11 – WARRANTS

In connection with a note (see Note 10 – Convertible Debt and Notes Payable), in August 2024 the Company issued 76,923 warrants to purchase common stock. The warrants have an exercise price of $9.36 per share, are immediately exercisable and have a term of 5 years. In August 2024, the holder exercised 28,571 warrants for shares of common stock on a cashless basis. Pursuant to the adjustment provisions in Section 3(b) of the warrant agreement, the exercise price automatically adjusted following the Company's issuance of shares at a dilutive price of $1.20 on or about August 14, 2025, resulting in an automatic increase in the aggregate warrant share amount. Accordingly, in August 2025, the holder exercised aggregate of 279,402 warrants for shares of common stock on a cashless basis, including 12,706 warrants issued on October 4, 2023.

As of December 31, 2025 and 2024, the Company remeasured the fair value of warrants outstanding at $10,914 and $919,935, respectively. In connection with the remeasurement of warrants, a loss of $909,020 and a gain of $182,982 was recognized during the years ended December 31, 2025 and 2024, respectively, as the change in fair value of warrant liability.

The Company's outstanding and exercisable warrants, as of December 31, 2025 and 2024, are presented below:

	Number Outstanding	Weighted Average Exercise Price	Contractual Life In Years	Intrinsic Value
Warrants outstanding as of December 31, 2024	238,594	$ 19.02	3.20	$ -
Warrants exercisable as of December 31, 2024	238,594	19.02	3.20	-
Warrants granted	-	-	-	-
Warrants forfeited, expired, cancelled	-	-	-	-
Warrants exercised	(61,058)	8.91	-	-
Warrants outstanding as of December 31, 2025	177,536	$ 22.50	1.76	-
Warrants exercisable as of December 31, 2025	177,536	$ 22.50	1.76	-

NOTE 12 – OPTIONS

The Plan allows for and the Company maintains stock option award agreements under which certain employees may be awarded option grants based on a combination of performance and tenure. The number of shares available to grant to employees under the Plan is 5,000,000.

The Board and stockholders approved an amendment to the Plan increasing the available shares under the Plan to 5,000,000 shares of the Common Stock as such common stock existed on July 24, 2024.

Total compensation cost related to stock options granted was $307,439 and $25,584 for the years ended December 31, 2025, and 2024, respectively.

On September 17, 2025, the Company cancelled 2,000,000 stock options and granted the related option holders 2,000,000 shares of common stock. This modification resulted in the Company recognizing the remaining expense under the original option and an additional incremental consideration as a result of the modification. Total stock-based compensation cost as a result of this transaction was $1,512,995.

The following table represents stock option activity for the years ended December 31, 2025 and 2024:

	Number Outstanding	Weighted-Average Exercise Price	Weighted-Average Contractual Life in Years	Intrinsic Value
Options outstanding as of December 31, 2024	23,930	$ 42.16	2.73	$ -
Options exercisable as of December 31, 2024	23,930	42.16	1.83	-
Options granted	2,250,000	0.78	9.79	585,000
Options cancelled	(2,000,000)	0.78	-	-
Forfeited/expired	(254,031)	2.42	-	-
Options exercised	-	-	-	-
Options outstanding as of December 31, 2025	19,899	$ 29.58	2.23	$ -
Options exercisable as of December 31, 2025	19,899	$ 29.58	2.23	-

NOTE 13 – COMMITMENTS AND CONTINGENCIES

Eat Well

In July 2023, the Company entered into, and closed on the transactions contemplated by, an Amended and Restated Agreement and Plan of Merger with Superlatus, whereby the Company acquired Superlatus (the "***Superlatus Acquisition***"). In connection with the Superlatus Acquisition, former shareholders of Superlatus received 306,855 shares of the Company's Series B Preferred Stock, par value $0.00001 per share (the "***Series B Preferred Stock***"). The Series B Preferred Stock are convertible into shares of the Company's common stock at a conversion ratio of 100-1.

In January 2024, shareholders holding shares of Series B Preferred Stock surrendered shares of the Series B Preferred Stock back to the Company as a result of Superlatus failing to meet certain post-closing conditions associated with the Superlatus Acquisition, such that only 15,759 shares of Series B Preferred Stock remained outstanding.

On March 5, 2024, the Company sold all of the issued and outstanding stock of Superlatus Inc. to Superlatus Foods Inc. pursuant to the Superlatus SPA. As a result of the transaction, Superlatus Inc. ceased to be a subsidiary of the Company, and the rights and assets of Superlatus together with various liabilities and obligations that were specific to Superlatus Inc. became rights and obligations of the Buyer. The shares of Series B Preferred Stock issued in connection with the Superlatus Acquisition remain outstanding.

In January 2025, Eat Well Investment Group, Inc., a Canadian company ("***Eat Well***") holding 11,643.84 shares of the Series B Preferred Stock, filed a complaint against the Company in the United States District Court for the Middle District of Florida alleging, among other things, that the Company is responsible for paying certain consideration to Eat Well in connection with Superlatus' acquisition of Eat Well in June 2023 prior to the Company's acquisition of Superlatus. Ultimately, Eat Well is seeking $8.5 million to be delivered in the form Company common stock, $1.15 million in unpaid principal and accrued interest under a legacy note made by Superlatus in favor of Eat Well, $350,000 in cash consideration owed by Superlatus to Eat Well, $755,000 in unpaid principal and accrued interest on ten promissory notes made by Sapientia, Inc., a subsidiary of Superlatus, in favor of Eat Well, and certain other damages. There can be no assurance that an amicable resolution will be obtained. The Company intends to vigorously defend itself in the litigation.

Kesin Pharma Corporation

Scienture entered into an exclusive license and commercial agreement (the "***Kesin Agreement***") with Kesin Pharma Corporation ("***Kesin***") whereby Scienture granted the exclusive license rights to commercialize SCN-102 in 2022 and SCN-104 in 2023 to Kesin for use in the United States of America.

In March 2024, the parties terminated the Kesin Agreement, and the parties agreed that Scienture would pay Kesin a total gross amount of $1,285,000 upon commercialization of product via a royalty arrangement. The royalty agreement requires that if the full $1,285,900 has not been repaid within two years of the earlier of (i) commercial launch or (ii) 120 days from FDA approval, then interest will accrue prospectively at a rate of 8% annually on the unpaid balance. Accordingly, Scienture recorded a $1,285,000 development agreement liability at inception. During the year ended December 31, 2025, the Company made aggregate payments of $489,848, consisting of $400,000 of principal and $89,848 of accrued interest. As of December 31, 2025, the remaining outstanding balance of $885,000 is presented on the consolidated balance sheet as $600,000 classified as current (Development agreement liability – current portion) and $285,000 classified as long-term (Development agreement liability).

Development Agreement Liability	**December 31, 2025**	**December 31, 2024**
Current portion	$ 600,000	$ —
Long-term portion	285,000	1,285,000
Total development agreement liability	**$ 885,000**	**$ 1,285,000**

In August 2024, Kesin demanded immediate payment of the full amount under the Kesin Termination Agreement, alleging the full amount is payable in connection with the consummation Scienture's business combination with the Company. Scienture disputed that the amount is payable, and the parties entered into discussions to resolve the issue.

On March 11, 2025, Kesin filed a complaint against Scienture in the United States District Court for the Eastern District of New York seeking payment of the disputed $1.285 million. The case was voluntarily dismissed on October 1, 2025. The Company and Kesin entered into a Settlement Agreement and Release on October 27, 2025, whereby Kesin agreed to unconditionally release and discharge the Company from all actions related to the complaint in exchange for the Company paying $1.285 million plus 8% interest from March 13, 2025, and legal fees and costs related to the complaint according to a payment schedule through December 2026.

NOTE 14 – LEASES

The Company entered into a lease agreement for the period of October 2018 to November 2023. At inception, management had included the renewal period from November 2023 to November 2028 within the initial recognition of the related right of use assets and lease liabilities, as it was reasonably expected, at the time, that the renewal option would be exercised. The Company determined that the new lease required measurement and recognition of the lease liability and right-of-use assets of $313,301. The lease is classified as an operating lease. No incentives were included in the lease.

On April 30, 2025, the Company completed the sale of its subsidiaries, IPS, Softell and Bonum Health, Inc., to Tollo. In connection with the transaction, the Company derecognized subsidiary's operating lease right-of-use assets of $142,138 and operating lease liability of $158,687 (see Note 1). As such, the Company recognized a gain of $16,548 on disposition of related IPS lease.

On July 25, 2024, the Company entered into and closed the Scienture Merger. Pursuant to the Scienture Merger Agreement, the Company acquired right of use asset value of $61,578 and right of use liability of $61,886 on the acquisition date together with all the assets and liabilities of Scienture.

The table below reconciles the fixed component of the undiscounted cash flows for and the total remaining years to the lease liabilities recorded in the consolidated balance sheet as of December 31, 2025.

Supplemental balance sheet information related to leases are as follows:

	December 31, 2025	December 31, 2024
Weighted-average remaining lease term (in years)	0.58	3.48
Weighted-average discount rate	15.50%	10.90%

Future lease obligations	
2026	17,823
Total minimum lease payments	25,461
Less: effect of discounting	(1,324)
Present value of future minimum lease payments	24,137
Less: current obligation under lease	24,137
Long-term lease obligations	$ -

For the year ended December 31, 2025, total operating lease expense was $75,373 and for the year ended December 31, 2024, total operating lease expense was approximately $97,000, which is included in general and administrative expenses in the consolidated statements of operations.

NOTE 15 – SEGMENT REPORTING

Factors used to identify the Company's reportable segments include the organizational structure of the Company and the financial information available for evaluation by the chief operating decision-maker (the "***CODM***") in making decisions about how to allocate resources and assess performance. The Company's operating segments have been broken out based on similar economic and other qualitative criteria. The Company operates all reporting segments in one geographical area (the United States).

The Company's chief operating decision-makers are its co-Chief Executive Officers (the "CODM"), who make resource allocation decisions and assess performance based on financial information presented on an aggregate basis. There are no segment managers who are held accountable by the CODM for any planning, strategy and key decision-making regarding operations. Accordingly, as of December 31, 2025, the Company has a single reportable segment and operating segment structure. The Company operates entirely within the United States.

The key measures of segment profit or loss reviewed by the CODM are total revenues, gross profit, total operating expenses (including research and development expenses), and net loss from continuing operations. The CODM uses these measures to allocate resources, evaluate operational performance, and make strategic decisions regarding pipeline development and commercialization activities. The CODM does not evaluate performance based on asset information at the segment level. Significant segment expenses that are regularly provided to the CODM and included in the reported measure of segment profit or loss include: research and development expenses (SCN-102: $368K; SCN-104: $422K; SCN-106: $298K; SCN-107: $500K for the year ended December 31, 2025); wage and salary expense of $2,118,568; professional fees of $2,407,822; accounting and legal expense of $2,070,337; and non-cash impairment losses of $26,346,050. Other segment items not separately disclosed include technology expense of $97,261, general and administrative expense (including stock-based compensation) of $7,926,016, and depreciation and amortization of $491,781.

The following table presents key financial information for the Company's single reportable segment for the years ended December 31, 2025 and 2024:

	Year Ended December 31, 2025	Year Ended December 31, 2024
Revenues	$ 431,609	$ 136,643
Cost of sales	100,127	130,638
Gross profit	$ 331,482	$ 6,005
Research and development expense	1,956,270	2,236,690
Total operating expenses (excl. impairment)	16,576,274	14,707,020
Impairment loss	26,346,050	—
Total operating expenses	$ 42,922,324	$ 14,707,020
Operating loss	(42,590,842)	(14,701,015)
Net loss from continuing operations, net of tax	$ (41,512,264)	$ (18,244,480)
Total assets (at period end)	$ 84,178,330	$ 104,853,805

NOTE 16 – INCOME TAXES

Income (loss) from continuing operations before income taxes for the years ended December 31, 2025 and 2024 consisted entirely of domestic (U.S.) activity as follows:

	Year Ended December 31, 2025	Year Ended December 31, 2024
United States	$ (43,182,487)	$ (9,600,194)

The benefit (provision) for income taxes for the years ended December 31, 2025 and 2024 consisted of the following:

	Year Ended December 31, 2025	Year Ended December 31, 2024
Current:		
Federal	$ —	$ —
State	—	—
Total current	**$** —	**$** —
Deferred:		
Federal	$ 1,994,878	$ 534,396
State	—	—
Total deferred	$ 1,994,878	$ 534,396
Total income tax benefit (provision)	$ 1,994,878	$ 534,396

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective tax rate for the years ended December 31, 2025 and 2024 is as follows:

	Year Ended December 31, 2025	Year Ended December 31, 2024
Tax at U.S. federal statutory rate (21%)	$ (9,068,322)	$ (2,016,041)
State income taxes, net of federal benefit	(714,994)	(159,371)
Non-deductible stock-based compensation (ISO)	1,339,586	—
Deductible stock-based compensation	(361,756)	—
Other permanent differences	64,212	—
Change in valuation allowance	10,736,152	2,175,412
Total income tax benefit (provision)	**$** 1,994,878	$ 534,396

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2025 and 2024 are as follows:

	December 31, 2025	December 31, 2024
Deferred tax assets:		
Net operating loss carryforwards	$ —	$ 1,985,391
Capitalized R&D costs (IRC §174)	2,997,463	316,902
Accruals and reserves	—	31,168
Operating lease liability	42,893	9,008
Debt issuance costs	—	186,155
Total gross deferred tax assets	3,040,356	2,528,624
Valuation allowance	—	—
Net deferred tax assets	$ 3,040,356	$ 2,528,624
Deferred tax liabilities:		
Intangible assets	$ (16,044,000)	$ (13,524,213)
Right-of-use assets	(8,838)	(8,838)
Total deferred tax liabilities	(16,052,838)	(13,533,051)
Net deferred tax liability	$ (13,012,482)	$ (11,004,427)

The net deferred tax liability is presented on the consolidated balance sheet as a non-current deferred tax liability of $11,037,595 as of December 31, 2025 (December 31, 2024: $13,524,213), reflecting the netting of deferred tax assets and liabilities within the same jurisdiction pursuant to ASC 740-10-45.

As of December 31, 2025, the Company had federal net operating loss ("NOL") carryforwards of approximately $13,962,000, which may be carried forward indefinitely under the Tax Cuts and Jobs Act of 2017, subject to an 80% taxable income limitation in any given year. The Company also has IRC Section 174 capitalized research and development costs of approximately $14,273,000, which are amortized for tax purposes over five years (domestic) or fifteen years (foreign-sourced), resulting in deferred tax assets that will reverse as those costs amortize through approximately 2030.

The Company evaluates the need for a valuation allowance against its deferred tax assets based on an assessment of whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. As of December 31, 2025, management determined that no valuation allowance was required, as the Company's deferred tax assets are expected to be realizable against the existing deferred tax liability related to intangible assets within the same tax jurisdiction. The net deferred tax liability position provides an objective source of taxable income for realization of the deferred tax assets.

The Company files income tax returns in the U.S. federal and New York state jurisdictions. Tax years from 2021 onward remain open and subject to examination by the relevant tax authorities. The Company has no material unrecognized tax benefits as of December 31, 2025 or 2024, and does not anticipate any significant changes to unrecognized tax benefits within the next twelve months. No interest or penalties related to income taxes have been accrued for the years ended December 31, 2025 or 2024.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure controls and procedures are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported, within the time period specified in the SEC's rules and forms and is accumulated and communicated to the Company's management, as appropriate, in order to allow timely decisions in connection with required disclosure.

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our co-Chief Executive Officers and our Chief Financial Officer (our principal executive officers and principal accounting/financial officer), we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this Report. Based on this evaluation, our co-Chief Executive Officers and our Chief Financial Officer concluded that as of December 31, 2025, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed in our reports filed with the SEC pursuant to the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC and that such information is accumulated and communicated to our management, including our co-CEOs and CFO, as appropriate, to allow timely decisions regarding required disclosures.

As a result of the formative stage of our development, the Company has not fully implemented the necessary internal controls. The matters involving internal controls and procedures that the Company's management considered to be material weaknesses under the standards of the Committee of Sponsoring Organizations of the Treadway Commission (COSO) were: (1) The Company did not maintain a fully integrated financial consolidation and reporting system throughout the period and as a result, extensive manual analysis, reconciliation and adjustments were required in order to produce financial statements for external reporting purposes, and (2) The Company does not currently have a sufficient complement of technical accounting and external reporting personnel commensurate to support standalone external financial reporting under public company or SEC requirements. Specifically, the Company did not effectively segregate certain accounting duties due to the small size of its accounting staff and maintain a sufficient number of adequately trained personnel necessary to anticipate and identify risks critical to financial reporting and the closing process. In addition, there were inadequate reviews and approvals by the Company's personnel of certain reconciliations and other processes in day-to-day operations due to the lack of a full complement of accounting staff.

Management believes that the material weaknesses set forth above did not have an effect on the Company's financial results reported herein. We are committed to improving our financial organization. As part of this commitment, we have increased our personnel resources and technical accounting expertise as we develop the internal and financial resources of the Company. In addition, the Company has prepared and implemented sufficient written policies and checklists which will set forth procedures for accounting and financial reporting with respect to the requirements and application of GAAP and SEC disclosure requirements.

Management has prepared and is in the process of implementing sufficient written policies and checklists to remedy the following material weaknesses (i) insufficient written policies and procedures for accounting and financial reporting with respect to the requirements and application of GAAP and SEC disclosure requirements; and (ii) ineffective controls over period end financial close and reporting processes.

We have improved our financial organization as we have increased our personnel resources and technical accounting expertise. We will continue to monitor and evaluate the effectiveness of our internal controls and procedures and our internal controls over financial reporting on an ongoing basis.

Management's Report on Internal Control Over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP, but because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. The Company's internal control over financial reporting includes those policies and procedures that are designed to:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements. Management conducted an assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2025. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control — Integrated Framework (2013). Based on our assessment, management concluded that the Company's internal controls over financial reporting were not effective as of December 31, 2025, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. Specifically, management's determination was based on the following material weaknesses which existed as of December 31, 2025:
- Financial Reporting Systems: The Company did not maintain a fully integrated financial consolidation and reporting system throughout the period and as a result, extensive manual analysis, reconciliation and adjustments were required in order to produce financial statements for external reporting purposes.
- Segregation of Duties: The Company does not currently have a sufficient complement of technical accounting and external reporting personnel commensurate to support standalone external financial reporting under public company or SEC requirements. Specifically, the Company did not effectively segregate certain accounting duties due to the small size of its accounting staff and maintain a sufficient number of adequately trained personnel necessary to anticipate and identify risks critical to financial reporting and the closing process. In addition, there were inadequate reviews and approvals by the Company's personnel of certain reconciliations and other processes in day-to-day operations due to the lack of a full complement of accounting staff.

Limitations on the Effectiveness of Controls

Management of the Company, including its co-Chief Executive Officers and its current Chief Financial Officer, does not expect that the Company's disclosure controls and procedures or its internal control over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Furthermore, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. 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. Controls can also be circumvented by the individual acts of some persons or by the collusion of two or more persons. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of the effectiveness of controls to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Changes in Internal Control Over Financial Reporting.

There have not been any changes in our internal control over financial reporting during the year ended December 31, 2025, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Our workforce operated primarily in a work from home environment for the year ended December 31, 2025. While pre-existing controls were not specifically designed to operate in our current work-from-home operating environment, we do not believe that such work-from-home actions have had a material adverse effect on our internal controls over financial reporting. We have continued to re-evaluate and refine our financial reporting process to provide reasonable assurance that we could report our financial results accurately and timely.

ITEM 9B. OTHER INFORMATION

During the quarter ended December 31, 2025, there was no information required to be disclosed in a report on Form 8-K which was not disclosed in a report on Form 8-K.

During the quarter ended December 31, 2025, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required under Item 10 is incorporated herein by reference to the information set forth in our the 2026 Proxy Statement.

We have adopted an Insider Trading Policy which governs the purchase, sale, and/or other disposition of our securities by our directors, officers, and employees and other covered persons designated by the policy. We believe our Insider Trading Policy is reasonably designed to promote compliance with insider trading laws, rules and regulations, and Nasdaq listing standards, as applicable. A copy of our Insider Trading Policy is filed as Exhibit 19.1 to this Annual Report.

ITEM 11. EXECUTIVE COMPENSATION

The information required under Item 11 is incorporated herein by reference to the information set forth in our the 2026 Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Certain information required under Item 12 is incorporated herein by reference to the information set forth in our the 2026 Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required under Item 13 is incorporated herein by reference to the information set forth in our the 2026 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required under Item 14 is incorporated herein by reference to the information set forth in our the 2026 Proxy Statement.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENTS AND SCHEDULES

(a) The following is an index of the financial statements, schedules and exhibits included in this Annual Report.

(1) All Financial Statements

Index to Consolidated Financial Statements	
Report of Independent Registered Public Accounting Firm	72
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(2) Consolidated Financial Statement Schedules

Except as provided above, all financial statement schedules have been omitted, since the required information is not applicable or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the consolidated financial statements and notes thereto included in this Annual Report.

(3) Exhibits

Exhibit No.	Description	Form	Incorporated by Reference File No.	Exhibit	Filing Date	Filed/Furnished Herewith
2.1	Agreement and Plan of Merger, dated July 25, 2024, by and among the Company, MEDS Merger Sub I, Inc., MEDS Merger Sub II, LLC, and Scienture, Inc.	8-K	001-39199	2.1	7/31/2024	
3.1	Second Amended and Restated Certificate of Incorporation of Trxade Group, Inc.	S-1	333-234221	3.1	10/15/2019	
3.3	Certificate of Amendment to Second Amended and Restated Certificate of Incorporation (1-for-6 Reverse Stock Split of Common Stock) filed with the Delaware Secretary of State on February 12, 2020, and effective February 13, 2020	8-K	001-39199	3.1	2/13/2020	
3.4	Certificate of Amendment of Certificate of Incorporation (changing name TRxADE HEALTH, INC.)	8-K	001-39199	3.1	5/28/2021	
3.5	Form of Certificate of Amendment to Second Amended and Restated Certificate of Incorporation	8-K	001-39199	3.1	6/15/2023	
3.6	Certificate of Amendment of Second Amended and Restated Certificate of Incorporation	8-K	001-39199	3.1	9/24/2024	
3.7	Certificate of Designation of Series B Preferred Stock	8-K	000-55218	3.1	06/26/2023	
3.8	Certificate of Designation of Preferences, Rights and Limitations of Series C Preferred Stock	8-K	000-55218	3.1	10/11/2023	
3.9	Certificate of Designation of Preference, Rights and Limitations of Series X Non-Voting Convertible Preferred Stock.	8-K	001-39199	3.1	7/31/2024	
3.10	Amended and Restated Bylaws of Trxade Group, Inc.	10-12G/A	000-55218	3.1	7/24/2014	
3.11	Form of Common Stock Purchase Warrant	8-K	000-55218	4.2	10/7/2022	
4.1	Description of Registered Securities	10-K	001-39199	4.1	3/27/2023	
10.1*	Second Amended and Restated Trxade Group, Inc. 2019 Equity Incentive Plan	8-K	001-39199	10.1	5/28/2021	
10.2*	Form of Stock Option Agreement Trxade Group, Inc. Amended and Restated 2019 Equity Incentive Plan	S-8	333-246318	10.6	8/14/2020	
10.3*	Form of Restricted Stock Grant Agreement Trxade Group, Inc. Amended and Restated 2019 Equity Incentive Plan	S-8	333-246318	10.7	8/14/2020	
10.4*	Form of Trxade Group, Inc. 2019 Equity Incentive Plan Restricted Stock Grant Agreement	S-8	333-246318	10.8	8/14/2020	
10.5*	Trxade Group, Inc. Independent Director Compensation Policy adopted April 14, 2020	10-Q	001-39199	10.8	7/27/2020	

10.6+	Master Services Agreement, dated October 29, 2024, by and between the Company and Anthem Biosciences Pvt. Ltd.	S-1/A	333-283591	10.25	1/14/2025
10.7+	Exclusive Commercial and Supply Agreement dated March 4, 2025, by and between Scienture, LLC and Summit Biosciences Inc.	8-K	001-39199	1.1	3/10/2025
10.8	Consulting Agreement by and between Scienture Holdings, Inc. and Draper, Inc. dated March 17, 2025	8-K	001-39199	10.1	3/21/2025
10.9*	Independent Contractor Agreement by and between Scienture Holdings, Inc. and EMS Consulting Services, LLC	8-K	001-39199	5.1	3/13/2025
10.10+	Form of Common Stock Purchase Agreement by and between Scienture Holdings, Inc. and the investors named therein.	10-Q	001-39199	10.1	8/12/2025
10.11	Form of Indemnification Agreement	8-K	001-39199	10.1	7/3/2025
10.12	Membership Interest Purchase Agreement by and among Scienture Holdings, Inc., Integra Pharmacy Solutions LLC, and Tollo Health, Inc., dated April 8, 2025	8-K	001-39199	1.01	4/11/2025
10.13	Stock Purchase Agreement by and among Scienture Holdings, Inc. and Tollo Health, Inc., dated April 8, 2025	8-K	001-39199	1.02	4/11/2025
10.14	Form of Promissory Note	8-K	001-39199	1.03	4/11/2025
10.15*	First Amendment to Employment Agreement effective October 1, 2024, by and between Scienture, LLC and Dr. Narasimhan Mani	8-K		10.1	10/24/2025
10.16*	First Amendment to Employment Agreement effective October 1, 2024, by and between Scienture, LLC and Dr. Shankar Hariharan	8-K		10.2	10/24/2025
10.17	Second Amendment of Loan and Security Agreement dated October 10, 2025, by and among the Company, Scienture, LLC, and NVK Finance, LLC	8-K		10.1	10/16/2025
10.18	Note Purchase Agreement dated October 14, 2025, by and between the Company and Streeterville Capital, LLC	8-K		10.2	10/16/2025
10.19	Secured Promissory Note dated October 14, 2025, made by the Company in favor of Streeterville Capital, LLC	8-K		10.3	10/16/2025
10.20	Security Agreement dated October 14, 2025, by and between the Company and Streeterville Capital, LLC	8-K		10.4	10/16/2025
10.21	Security Agreement dated October 14, 2025, by and between Scienture, LLC and Streeterville Capital, LLC	8-K		10.5	10/16/2025
10.22	Guaranty dated October 14, 2025, made by Scienture, LLC for the benefit of Streeterville Capital, LLC	8-K		10.6	10/16/2025
10.23	Letter Agreement dated October 2, 2025, by and among the Company, Arena Finance Markets, LP, and Arena Special Opportunities III LP	8-K		10.1	10/3/2025

10.24	Equity Distribution Agreement, dated September 19, 2025, with Maxim Group LLC	8-K		1.1	9/23/2025	
10.25	Form of Securities Purchase Agreement	8-K		10.1	8/15/2025	
10.26	Form of Placement Agency Agreement	8-K		10.2	8/15/2025	
14.1	Code of Ethics	10-K	000-55218	14.1	3/23/2015	
19.1	Insider Trading Policy	10-K	001-39199	19.1	4/22/2024	
21.1	List of Subsidiaries					X
23.1	Consent of Independent Registered Accounting Firm					X
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act					X
31.2	Certification of Principal Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act					X
32.1	Certification of Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act					X
32.2	Certification of Principal Accounting Officer Pursuant to Section 906' of the Sarbanes-Oxley Act					X
97.1	Form of Clawback Policy	10-K/A	001-39199	97.1	5/3/2024	
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					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	Inline XBRL for the cover page of this Annual Report on Form 10-K, included in the Exhibit 101 Inline XBRL Document Set.					

* Indicates management contract or compensatory plan or arrangement.

+ Exhibits and/or schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant hereby undertakes to furnish supplementally copies of any of the omitted exhibits and schedules upon request by the SEC; provided, however, that the registrant may request confidential treatment pursuant to Rule 24b-2 under the Exchange Act for any exhibits or schedules so furnished.

ITEM 16. FORM 10–K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SCIENTURE HOLDINGS, INC.

By: */s/ Dr. Narasimhan Mani*
Dr. Narasimhan Mani
Co-Chief Executive Officer and President

By: */s/ Dr. Shankar Hariharan*
Dr. Shankar Hariharan
Co-Chief Executive Officer and Executive Chairman

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this registration statement has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Dr. Narasimhan Mani Dr. Narasimhan Mani	Co-Chief Executive Officer and President *(Co-Principal Executive Officer)*	March 30, 2026
/s/ Dr. Shankar Hariharan Dr. Shankar Hariharan	Co-Chief Executive Officer and Executive Chairman *(Co-Principal Executive Officer)*	March 30, 2026
/s/ Eric Sherb Eric Sherb	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 30, 2026
/s/ Donald G. Fell Donald G. Fell	Director	March 30, 2026
/s/ Mayur Doshi Mayur Doshi	Director	March 30, 2026
/s/ Subbarao Jayanthi Subbarao Jayanthi	Director	March 30, 2026

Exhibit 21.1

Subsidiaries

LIST OF SUBSIDIARIES – ALL 100% OWNED (UNLESS OTHERWISE STATED)

Scienture LLC (f/k/a Scienture, Inc.), a Delaware limited liability company.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on Form S-3 (File No. 333-289198) of our report dated March 30, 2026, with respect to the audited consolidated financial statements of Scienture Holdings, Inc., which appear in this Annual Report on Form 10-K for the year ended December 31, 2025. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ CM3 Advisory
San Diego, California
March 30, 2026

Exhibit 31.1

Certification of Chief Executive Officer

I, Dr. Narasimhan Mani, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2025, of Scienture Holdings, Inc.(the "registrant");

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: March 30, 2026

/s/ Dr. Narasimhan Mani
Dr. Narasimhan Mani
Co-Chief Executive Officer and President (Principal Executive Officer)

Certification of Chief Executive Officer

I, Dr. Shankar Hariharan, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2025, of Scienture Holdings, Inc.(the "registrant");

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: March 30, 2026

/s/ Dr. Shankar Hariharan
Dr. Shankar Hariharan
Co-Chief Executive Officer and Executive Chairman
(Principal Executive Officer)

Exhibit 31.2

Certification of Chief Financial Officer

I, Eric Sherb, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2025, of Scienture Holdings, Inc. (the "registrant");

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: March 30, 2026

/s/ Eric Sherb
Eric Sherb
Chief Financial Officer (Principal Financial/Accounting Officer)

Exhibit 32.1

Certification of Chief Executive Officer
Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of The Sarbanes-Oxley Act of 2002

I, Dr. Narasimhan Mani, certify, as of the date hereof, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Scienture Holdings, Inc. on Form 10-K for the fiscal year ended December 31, 2025 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Form 10-K fairly presents in all material respects the financial condition and results of operations of Scienture Holdings, Inc. at the dates and for the periods indicated.

Dated: March 30, 2026

/s/ Dr. Narasimhan Mani
Dr. Narasimhan Mani
Co-Chief Executive Officer and President (Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to Scienture Holdings, Inc. and will be retained by Scienture Holdings, Inc. and furnished to the Securities and Exchange Commission or its staff upon request. This certification accompanies this Annual Report on Form 10-K pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by such Act, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

Certification of Chief Executive Officer
Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of The Sarbanes-Oxley Act of 2002

I, Dr. Shankar Hariharan, certify, as of the date hereof, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Scienture Holdings, Inc. on Form 10-K for the fiscal year ended December 31, 2025 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Form 10-K fairly presents in all material respects the financial condition and results of operations of Scienture Holdings, Inc. at the dates and for the periods indicated.

Dated: March 30, 2026

/s/ Dr. Shankar Hariharan
Dr. Shankar Hariharan
Co-Chief Executive Officer and Executive Chairman
(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to Scienture Holdings, Inc. and will be retained by Scienture Holdings, Inc. and furnished to the Securities and Exchange Commission or its staff upon request. This certification accompanies this Annual Report on Form 10-K pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by such Act, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

Exhibit 32.2

Certification of Chief Financial Officer
Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of The Sarbanes-Oxley Act of 2002

I, Eric Sherb, certify, as of the date hereof, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Scienture Holdings, Inc.. on Form 10-K for the fiscal year ended December 31, 2025 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Form 10-K fairly presents in all material respects the financial condition and results of operations of Scienture Holdings, Inc. at the dates and for the periods indicated.

Dated: March 30, 2026

/s/ Eric Sherb
Eric Sherb
Chief Financial Officer
(Principal Financial/Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to Scienture Holdings, Inc. and will be retained by Scienture Holdings, Inc. and furnished to the Securities and Exchange Commission or its staff upon request. This certification accompanies this Annual Report on Form 10-K pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by such Act, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.