

REPORT OF INDEPENDENT AUDITORS AND
FINANCIAL STATEMENTS

SENTYNL THERAPEUTICS, INC.

For The Fiscal Years Ended March 31, 2024 and 2023

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INDEPENDENT AUDITOR'S REPORT

To the Board of Directors and Stockholder's
of Sentyln Therapeutics, Inc.

Opinion

We have audited the accompanying financial statements of Sentyln Therapeutics, Inc. (a Delaware Corporation), which comprise the balance sheets as of March 31, 2024 and 2023, and the related statements of operations, changes in stockholder's equity (deficit), and cash flows for the years then ended, and the related notes to the financial statements.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Sentyln Therapeutics, Inc. as of March 31, 2024 and 2023, and the results of its operations and its cash flows for the years then ended in accordance with accounting principles generally accepted in the United States of America.

Basis for Opinion

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Financial Statements section of our report. We are required to be independent of Sentyln Therapeutics, Inc. and to meet our other ethical responsibilities in accordance with the relevant ethical requirements relating to our audits. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Responsibilities of Management for the Financial Statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with accounting principles generally accepted in the United States of America, and for the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is required to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about Sentyln Therapeutics, Inc.'s ability to continue as a going concern within one year after the date that the financial statements are available to be issued.

Auditor's Responsibilities for the Audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not absolute assurance and therefore is not a guarantee that an audit conducted in accordance with generally accepted auditing standards will always detect a material misstatement when it exists. The risk of

not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control. Misstatements are considered material if there is a substantial likelihood that, individually or in the aggregate, they would influence the judgment made by a reasonable user based on the financial statements.

In performing an audit in accordance with generally accepted auditing standards, we:

- Exercise professional judgment and maintain professional skepticism throughout the audit.
- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, and design and perform audit procedures responsive to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of Sentyln Therapeutics, Inc.'s internal control. Accordingly, no such opinion is expressed.
- Evaluate the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluate the overall presentation of the financial statements.
- Conclude whether, in our judgment, there are conditions or events, considered in the aggregate, that raise substantial doubt about Sentyln Therapeutics, Inc.'s ability to continue as a going concern for a reasonable period of time.

We are required to communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit, significant audit findings, and certain internal control related matters that we identified during the audit.

Ram Associates

Ram Associates

Hamilton, NJ

May 15, 2024

Sentynl Therapeutics, Inc.
Balance Sheets
As of March 31,
(in thousands)

	<u>2024</u>	<u>2023</u>
CURRENT ASSETS		
Cash and cash equivalents	\$ 3,698	\$ 1,998
Accounts receivable, net	987	495
Inventories	1,545	1,452
Prepaid expenses and other current assets	2,623	1,983
Total current assets	<u>8,853</u>	<u>5,928</u>
DEFERRED TAX ASSETS, NET	10,659	10,660
PROPERTY AND EQUIPMENT, net	97	135
OPERATING LEASE RIGHT-OF-USE ASSET	571	773
IDENTIFIABLE INTANGIBLE ASSETS, net	6,970	8,364
Total assets	<u>\$ 27,150</u>	<u>\$ 25,860</u>
CURRENT LIABILITIES		
Accounts payable	\$ 1,293	\$ 501
Accrued expenses and other current liabilities	10,708	9,861
Note payable - affiliate	91,035	63,899
Current portion of operating lease liabilities	244	253
Other payable - affiliate	25	23
Total current liabilities	<u>103,305</u>	<u>74,537</u>
LONG-TERM LIABILITIES		
Long-term operating lease liabilities, net of current portion	382	525
Other long-term liabilities, net	-	38
Total long-term liabilities	<u>382</u>	<u>563</u>
Total liabilities	<u>103,687</u>	<u>75,100</u>
COMMITMENTS AND CONTINGENCIES (Note 8)		
STOCKHOLDER'S EQUITY		
Common stock (par value, \$0.0001 per share, 2,000 shares authorized, 100 shares outstanding)	30,010	30,010
Retained earnings	(106,547)	(79,250)
Total stockholder's equity	<u>(76,537)</u>	<u>(49,240)</u>
Total liabilities and stockholder's equity	<u>\$ 27,150</u>	<u>\$ 25,860</u>

See accompanying notes to financial statements.

Sentynl Therapeutics, Inc.
Statements of Operations
For the Fiscal Years Ended March 31,
(in thousands)

	<u>2024</u>	<u>2023</u>
NET REVENUE	\$ 6,469	\$ 7,034
OPERATING COSTS AND EXPENSES		
Cost of sales	1,624	2,134
Research and development, manufacturing support, quality and regulatory	13,814	9,115
General and administrative	7,569	7,483
Selling and marketing	4,100	5,571
Depreciation	248	17
Amortization	1,394	1,857
Goodwill impairment charge	-	73,896
Litigation settlement expense	755	-
Total operating costs and expenses	<u>29,504</u>	<u>100,073</u>
OPERATING INCOME (LOSS)	(23,035)	(93,039)
INTEREST EXPENSE (INCOME)		
Interest expense	4,344	1,974
Interest income	<u>(82)</u>	<u>(74)</u>
Total interest expense, net	4,262	1,900
OTHER INCOME - Gain on sale of asset		<u>660</u>
INCOME (LOSS) BEFORE PROVISION FOR INCOME TAXES	(27,297)	(94,279)
PROVISION (BENEFIT) FOR INCOME TAXES	<u>1</u>	<u>(4,714)</u>
NET INCOME (LOSS)	<u>\$ (27,298)</u>	<u>\$ (89,565)</u>

See accompanying notes to financial statements.

Sentynl Therapeutics, Inc.
Statements of Changes in Shareholder's Equity
For the Fiscal Years Ended March 31,
(in thousands)

	Common Stock		Retained	Total
	Units	Amount	Earnings	Stockholder's Equity
BALANCE, April 1, 2022	100	\$ 30,010	\$ 10,315	\$ 40,325
Net income	-	-	(89,565)	(89,565)
BALANCE, March 31, 2023	100	30,010	(79,250)	(49,240)
Net loss	-	-	(27,298)	(27,298)
BALANCE, March 31, 2024	100	\$ 30,010	\$ (106,547)	\$ (76,537)

See accompanying notes to financial statements.

Sentynl Therapeutics, Inc.
Statements of Cash Flows
For the Fiscal Years Ended March 31,
(in thousands)

	<u>2024</u>	<u>2023</u>
OPERATING ACTIVITIES		
Net income (loss)	\$ (27,298)	\$ (89,565)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation	248	17
Amortization	1,394	1,857
Deferred compensation expense	63	191
Gain in sale of asset	-	(661)
Goodwill impairment charge	-	73,896
Changes in operating assets and liabilities:		
Accounts receivable	(493)	(189)
Inventories	(92)	1,073
Prepaid expenses and other current assets	(640)	1,495
Income taxes payable	-	5
Accrued expenses and other current liabilities	596	(4,771)
Deferred tax liabilities	1	(4,714)
Accounts payable	792	299
Interest and other receivable – affiliate	138	1,345
Net cash used in operating activities	<u>(25,291)</u>	<u>(19,722)</u>
INVESTING ACTIVITIES		
Loan repayments from affiliate	-	30,000
Purchase of property and equipment	(9)	(145)
Proceeds from sale of asset, net of expenses	-	661
Net cash provided by (used in) investing activities	<u>(9)</u>	<u>30,516</u>
FINANCING ACTIVITIES		
Loan repayments from affiliate	-	(25,000)
Loan advances from affiliates	27,000	15,000
Net cash provided by (used in) financing activities	<u>27,000</u>	<u>(10,000)</u>
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	<u>1,700</u>	<u>794</u>
CASH AND CASH EQUIVALENTS		
Beginning of period	<u>1,998</u>	<u>1,204</u>
End of period	<u>\$ 3,698</u>	<u>\$ 1,998</u>
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION		
Cash payments for:		
Interest:		
Paid to a third party	\$ -	\$ -
Paid to a related party	4,207	1,226
Total interest paid	<u>\$ 4,207</u>	<u>\$ 1,226</u>
Income Taxes Paid (Refunded)	<u>\$ (433)</u>	<u>\$ -</u>

See accompanying notes to financial statements.

Note 1 - Organization and Description of Business

Sentynl Therapeutics, Inc. (the Company, or STI) was formed as a Delaware corporation in August 2011, and is headquartered in San Diego, California. STI is a US-based biopharmaceutical company focused on bringing innovative therapies to patients living with rare diseases. STI distributed its products through wholesale and specialty retail distributors. On April 30, 2015, the Company was acquired by Sentynl Holdings LLC (SHL). On January 19, 2017, SHL sold all of its shares to Zydus Holding Inc. (Zydus), a wholly owned subsidiary of Zydus Lifesciences Limited. (ZLL), and Zydus was merged into STI with STI being the surviving company and ZLL being sole owner of STI.

On February 23, 2021, the Company entered into an Asset Purchase Agreement with Cyprrium Therapeutics, Inc. (Cyprrium) and, in December 2023, an Assignment and Assumption Agreement pursuant to which Cyprrium completed the transfer to the Company of the worldwide proprietary rights to a copper histidinate injection (CUTX-101) and its rolling New Drug Application (NDA) with the FDA. CUTX-101 is under investigation for treatment of Menkes Disease. The FDA has granted Orphan Drug, Fast Track, and Rare Pediatric Disease Designations to CUTX-101 and, in December 2020, Breakthrough Therapy Designation for the treatment of Menkes. Breakthrough Therapy Designation is meant to expedite the development and review of drugs for serious or life-threatening conditions. See Note 4 for further discussion.

On March 31, 2022, the Company and Origin Biosciences, Inc. (Origin) entered into an Asset Purchase Agreement pursuant to which the Company acquired the intellectual property and exclusive global rights to manufacture and distribute Nulibry® (fosdenopterin). Nulibry is indicated to reduce the risk of mortality in patients with molybdenum cofactor deficiency (MoCD) Type A. MoCD Type A is a rare and devastating inborn error of metabolism (IEM) that presents shortly after birth, progresses rapidly, causes irreparable damage, and often leads to an early death (median survival age is 4 years). STI is responsible for ongoing development and commercialization of Nulibry in the US, and developing, manufacturing and commercializing fosdenopterin globally. Origin finalized its development responsibilities for fosdenopterin with approval of the marketing authorization with the European Medicines Agency (EMA) and the Israeli Ministry of Health. The transaction was accounted for as an asset acquisition. See Note 4 for further discussion.

The accompanying financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP).

Note 2 – Summary of Significant Accounting Policies

Use of estimates – The preparation of financial statements in conformity with U.S. GAAP requires management to make certain estimates and assumptions that affect certain reported amounts and disclosures. Actual results could differ from those estimates.

Revenue recognition and related deductions and allowances – Revenue is accounted for in accordance with Accounting Standard Codification (ASC) Topic 606, *Revenue from Contracts with Customers*.

Revenue

The Company's products are distributed in the United States through an exclusive distribution model with a US-based third-party distributor (the Distributor) whereby the Company directly sells its products to this

Note 2 – Summary of Significant Accounting Policies (continued)

Distributor. The Distributor subsequently sold products to wholesalers and specialty pharmacies (Customers) who have agreements in place with STI.

The Company recognizes net revenue for product sales when control of the promised goods is transferred to its Customers in an amount that reflects the consideration it expects to be entitled to in exchange for those goods. Revenues are recorded, net of provisions, for variable consideration, including trade discounts and distribution fees, rebates, governmental rebate programs, product returns, group purchasing organization (GPO) chargebacks, other sales allowances. Accruals for these provisions are presented in the financial statements as reductions in determining net revenue and as a contra asset in accounts receivable, net (if settled via credit) and other current liabilities (if paid in cash). The following briefly describes the nature of the Company's provisions for variable consideration and how such provisions are valued. These provisions represent accrual estimates, which are based on the terms and conditions of contracts and other agreements with direct and indirect customers and are supported by relevant historical experience. The Company periodically reviews and, if necessary, adjusts the estimated amounts accrued for these deductions and allowances. It is reasonably possible that estimates could change in the near term.

As of March 31, 2024, the first pricing approval for Nulibry in a EMA country had not been granted. Certain countries, however, have provided pre-approval access to Nulibry in response to requests by physicians on behalf of specific, or named, patients under Named-Patient Programs (NPP). The distribution of Nulibry to NPP is managed by an Early Access Vendor based in the United Kingdom. The vendor passes on to the Company the reimbursements it receives for Nulibry dispensed to named patients under these programs. The Company recognized revenue on product dispensed to named patients to the extent of reimbursement received.

Government rebates: Provision for rebates represents a significant estimate used in revenue recognition.

The Company contracts with Medicaid and other government agencies (Government Payors). It estimates the rebates it will provide to Government Payors and deducts these estimated amounts from its gross product revenue at the time revenue is recognized and establishes a current liability. The estimate of these rebates is based on the historical trends of rebates paid as well as estimated levels of inventory in the distribution channel.

Chargebacks relate to sales terms under which the Company agrees to reimburse wholesalers for differences between the gross sales prices at which the Company sells its products to wholesalers and the actual prices of such products that wholesalers resell under the Company's various contractual arrangements. Under these arrangements, the Company provides credit to the wholesaler for any difference between the contracted price with the indirect party and the wholesaler's invoice price. The provision for chargebacks is based on expected sell-through levels by the Company's wholesalers to indirect customers, as well as estimated wholesaler inventory stocking levels. This provision is recorded in the same period the revenue is recognized, resulting in a reduction of product revenue.

Trade discounts and Distribution fees: Trade discounts relate to prompt settlement discounts provided to the Distributor and Customers. Distribution fees include fees, based on sales amount, paid to Distributor for the distribution of the product. In addition, the Company compensates Customers for data and other activities. Estimates of these payments are recorded as a reduction of revenue based on contractual terms.

Product returns: Consistent with industry practice, the Company maintains a return policy that allows Customers to return a product within a period which begins six months prior to and ends twelve months subsequent to the expiration date. The Company's estimate of the provision for returns is generally based

Note 2 – Summary of Significant Accounting Policies (continued)

upon historical experience with actual returns and records this estimate as a reduction of revenue in the period the related product revenue is recognized. The Company also assesses other factors that could affect product returns including market conditions, product obsolescence, and the introduction of new competition. Although these factors do not normally give the Company's Customers the right to return products outside of the regular return policy, the Company realizes that such factors could ultimately lead to increased returns. The Company analyzes these situations and makes adjustments to the product return reserve as appropriate.

(in thousands)	<u>2024</u>	<u>2023</u>
Invoiced revenue	\$ 8,240	\$ 8,863
Less deductions and allowances:		
Third-party and government rebates / chargebacks	1,370	2,794
Product returns	31	(1,111)
Distribution fees, trade discounts and other	<u>370</u>	<u>146</u>
Total deductions and allowances	<u>1,771</u>	<u>1,829</u>
Net sales	<u>\$ 6,469</u>	<u>\$ 7,034</u>

Concentrations – Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash and cash equivalents and trade accounts receivable. The Company maintains all of its cash balances in the form of bank depository accounts that have immediate liquidity with a large United States-based financial institution. On March 31, 2024, the Company had uninsured cash balances totalling \$3.9 million held in one institution. The Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risk on cash.

During the fiscal year ended on March 31, 2024, a specialty pharmacy distributor accounted for more than 67 percent of the Company's invoiced revenue. During the fiscal year ended on March 31, 2023 three indirect wholesale drug and specialty pharmacy distributors, each of whom individually accounted for more than 10 percent, accounted for 96 percent in aggregate of the Company's invoiced revenue. The Company extends unsecured credit to a Distributor, and the unpaid balance is included in Accounts Receivable.

Cost of sales – Cost of sales consists primarily of third-party product manufacturing costs, product royalties, third-party distribution and destruction costs, product stability costs, and provision for estimated excess and obsolete inventory.

Cash and cash equivalents – Cash and cash equivalents consists of cash held in an account at a large United States-based bank.

Accounts receivables, net – During the fiscal years 2024, the Distributor was the only direct US customer of the Company. The amounts recorded at March 31, 2024 and 2023, respectively, of \$0.6 million and \$0.1 million reflect unpaid amounts invoiced to this customer under the terms and conditions of the contract. The allowance for trade discounts was \$0.1 million and \$0.0 million as of March 31, 2024 and 2023, respectively. In addition, the Company had receivables from its European distributor of Nulibry totaling \$0.5 million as of the end of both fiscal years.

Allowance for Credit Losses – The Company adopted ASC 326, Financial Instruments--Credit Losses, as of April 1, 2023, with the cumulative-effect transition method with the required prospective approach. The measurement of expected credit losses under the current expected credit loss (CECL) methodology is applicable to financial assets measured at amortized cost, which include accounts receivable and other

Note 2 – Summary of Significant Accounting Policies (continued)

contract assets. An allowance for credit losses under the CECL methodology is determined using the loss-rate approach and measured on a collective (pool) basis when similar risk characteristics exist. Where financial instruments do not share risk characteristics, they are evaluated on an individual basis. The CECL allowance is based on relevant available information, from internal and external sources, relating to past events, current conditions, and reasonable and supportable forecasts. The allowance for credit losses as of March 31, 2024, and change in the allowance for credit losses during the year ended March 31, 2024, was not material to the financial statements.

Prior to adoption of ASC 326, the Company maintained an allowance for doubtful accounts to reserve for potentially uncollectible receivables. The allowance for doubtful accounts as of March 31, 2023, was not material to the financial statements.

Inventories, net – Inventories consist of pharmaceutical raw materials, drug substances and drug products that are manufactured by FDA-approved third-party suppliers. Inventories are stated at the lower of cost or net realizable value. Cost is determined using the first-in, first-out method. The Company's existing product has an initial shelf-life of 18 months. The Company records an estimated allowance for excess and obsolete inventory based on projected future sales, reported and estimated unit quantities of products held by its direct and indirect customers, remaining product shelf-life, historical trends, and other relevant factors.

Property and equipment – Property and equipment purchased by the Company is stated at cost, net of accumulated depreciation. Assets acquired pursuant to a business combination are stated at their fair value on the date of the acquisition. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets, which range from 2 to 5 years.

Identifiable intangible assets – Intangible assets are stated at cost, less accumulated amortization and impairment adjustments. Amortization is generally recorded on a straight-line basis over estimated useful lives having ranged from 4 to 10 years. The Company evaluates the estimated remaining useful lives of intangible assets based on relevant factors that include market size and growth trends, stability of therapeutic class, and further strength of competing products and periodically reviews the estimated useful lives of intangible assets and adjusts when events indicate that a shorter life is appropriate.

Impairment of long-lived assets (other than goodwill) – The Company periodically evaluates whether changes in facts and circumstances indicate that the carrying amounts of long-lived assets might not be recoverable. Impairment is determined to exist when the carrying amount exceeds the estimated future undiscounted cash flows associated with the asset over its estimated remaining economic life (fair value). Fair value is determined using the market, income, or cost approaches as appropriate for the asset. The estimated remaining economic life of product rights and other related intellectual property rights is subject to change in the near term based on, among other things, third-party generic competition, regulatory changes, the reliability of future product supply, competition from products prescribed for similar indications, physician loyalty, and promotional efforts or lack thereof. If an asset is impaired, an impairment loss is recognized based on the excess of the asset's carrying amount over its estimated fair value. Any write-downs are treated as permanent reductions in the carrying amount of the asset and recognized as an operating loss.

Management judgment is involved in estimating the recoverability of these assets and is dependent upon the accuracy of the assumptions used in making these estimates, as well as how the estimates compare to the eventual future operating performance of the intangible assets. Any future long-lived assets impairment charges could have an impact on the Company's financial condition and results of operations.

Goodwill – The Company does not amortize goodwill and, accordingly, periodically reviews goodwill for

Note 2 – Summary of Significant Accounting Policies (continued)

impairment if events or changes in circumstances indicate that the carrying value of goodwill may not be recoverable based on management's assessment of the fair value of the Company compared to its carrying value. If the Company determines that it is more likely than not that the fair value of the Company is less than its carrying amount, then the goodwill impairment test is performed. The goodwill impairment test requires the Company to estimate the fair value of the Company and to compare with its carrying amount. If the carrying amount is less than its fair value then there is no impairment recognized. If the carrying value recorded exceeds the fair value calculated, an impairment charge is recorded for the difference. The judgments made in determining the projected cash flows used to estimate the fair value can materially impact the Company's financial condition and results of operations.

On March 31, 2023, a determination was made that the Company's fair value was less than the carrying value of goodwill. The Company recorded an impairment charge of \$73.9 million, representing the entire value of the goodwill.

Leases – The Company adopted Accounting Standards Update (“ASU”) 2016-02, Leases (Topic 842), as amended (“ASC Topic 842”). This standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months and classify as either operating or finance leases.

In accordance with ASC Topic 842, the Company, at the inception of an amendment to its facility operating lease, made the determination that the arrangement was a lease based on the terms of the lease including whether the agreement involved the use of a distinct identified asset, whether the Company obtained the right to substantially all the economic benefit from the use of the asset, and whether the Company had the right to direct the use of the asset. Leases with a term greater than one year are recognized on the balance sheet as ROU assets, lease liabilities and, if applicable, long-term lease liabilities.

Lease liability and the corresponding ROU assets were recorded based on the present value of lease payments over the expected lease term. The implicit rate was not determinable and, therefore, the Company used the risk-free rate in effect at the time of the lease commencement. ASC Topic 842 provides a practical expedient for nonpublic business entities, which allows the use of a risk-free rate for a period comparable to the lease term. See Note 10.

Research and development – Research and development expenses consist of costs associated with regulatory activities, development efforts primarily associated with CUTX-101 and Nulibry products and expenses related to CUTX-101 milestone payments made before regulatory approval. Research and development expenses are charged to operations as incurred.

Income taxes – The Company accounts for income taxes payable based on the asset and liability method that requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial statements and income tax returns. A deferred tax asset valuation allowance is recorded if it is more likely than not that a deferred tax asset will not be realized. Interest and penalties on tax underpayments are recorded as general and administrative expenses in the statement of operations. As of March 31, 2024 and 2023, no valuation allowance was recorded and no interest and penalties were incurred.

Reclassifications and adjustments – Certain items in the prior year's financial statements have been reclassified to conform to the current presentation.

Note 2 – Summary of Significant Accounting Policies (continued)

In June 2016, the FASB issued ASU 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments (Credit Losses) - The amendment in this ASU affects entities holding financial assets and net investment in leases that are not accounted for at fair value through net income. The amendments affect loans, debt securities, trade receivables, net investments in leases, off-balance-sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. The amendments in this update affect an entity to varying degrees depending on the credit quality of the assets held by the entity, their duration, and how the entity applies current GAAP. Accounting Standards Update 2019-10 amends the mandatory effective dates for implementation of accounting for Credit Losses for all entities as follows:

Public business entities that meet the definition of a Securities and Exchange Commission (SEC) filer, excluding entities eligible to be smaller reporting companies as defined by the SEC, for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. All other entities for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early application continues to be allowed. The Company adopted ASU 2016-02 effective from April 1, 2023. The adoption of ASU 2016-02 standard did not have a material impact on the Company's financial statements.

Note 3 – Balance Sheet Details

Balance sheet details as of March 31, 2024 and 2023, are as follows:

(in thousands)	<u>2024</u>	<u>2023</u>
Accounts receivable, net		
Trade accounts receivable	\$ 1,114	\$ 596
Trade discounts	(127)	(101)
Accounts receivable, net	<u>\$ 987</u>	<u>\$ 495</u>
Inventories		
Raw materials	\$ 189	\$ 897
Work-in progress	368	448
Finished goods	988	107
Inventories	<u>\$ 1,545</u>	<u>\$ 1,452</u>
Prepaid expenses and other current assets		
Deposits and advanced payments for inventory and materials	\$ 1,815	-
Prepaid subscription fees	212	243
Prepaid PDUFA fees	208	197
Prepaid market data	207	\$ 555
Prepaid commercial insurance	155	517
Income tax receivable	15	433
Other	11	38
Prepaid expenses and other current assets	<u>\$ 2,623</u>	<u>\$ 1,983</u>

Note 3 – Balance Sheet Details (continued)

(in thousands)	<u>2024</u>	<u>2023</u>
Property and equipment, net		
Computer hardware and software	\$ 359	\$ 357
Furniture and fixtures	272	265
	<u>631</u>	<u>622</u>
Accumulated depreciation	(534)	(487)
Property and equipment, net	<u>\$ 97</u>	<u>\$ 135</u>
Accrued expenses and other current liabilities		
Accrued product returns	\$ 3,461	\$ 3,875
Accrued regulatory and medical affairs costs	2,020	1,080
Accrued rebates and wholesaler fees	951	563
Accrued incentive compensation	936	769
Deferred revenue	885	530
Accrued marketing costs	607	846
Accrued contract manufacturing costs	300	424
Accrued product royalties	258	171
Accrued legal fees	244	174
Accrued consulting and professional fees	232	289
Accrued market data costs	151	385
Other	663	754
	<u>\$ 10,708</u>	<u>\$ 9,861</u>
Other long-term liabilities, net		
Deferred compensation liability, net	\$ -	\$ 38
Other long-term liabilities, net	<u>\$ -</u>	<u>\$ 38</u>

Note 4 – Asset Acquisition & Acquired In-Process R&D

In February 2021, the Company entered into an Asset Purchase Agreement with Cyprium (Cyprium APA). If FDA approval was not obtained by September 30, 2023, the APA contained terms which gave the Company the option to assume and take over the development of CUTX-101 and reduce certain milestone and royalty payments by 50%. Accordingly, in December 2023, the Company exercised this option and entered into an Assignment and Assumption Agreement (Cyprium Assumption Agreement) pursuant to which Cyprium completed the transfer to the Company of the worldwide proprietary rights to CUTX-101 and its rolling NDA with the FDA and made a payment of \$4.5 million representing the Purchase Price payment, reduced by 50%.

Up-front payments, as well as other milestone payments to be made before regulatory approval (pre-approval), are considered as acquired IPR&D. Accordingly, the Company expensed the \$4.5 million payment made in connection with the Cyprium Assumption Agreement as IPR&D. In the fiscal year ended March 31, 2021, the Company paid Cyprium the upfront payment of \$8.0 million in connection with the APA and incurred \$0.6 million in transaction costs. The Company recorded the payment and transaction costs totaling \$8.6 million as deferred research and development. The Company fully expensed this over the estimated period Cyprium performed development services, the final \$1.6 million was expensed in the fiscal year ended March 31, 2023. These expenses are included within research and development expenses on the Company's statements of operations. The Company could make an additional \$1.5 million IPR&D payment if an associated milestone is achieved.

Note 4 – Asset Acquisition & Acquired In-Process R&D (continued)

Post-approval payments, if any, will be capitalized as intangible assets and amortized over the estimated remaining useful life of the product. These payments are contingent upon the occurrence of certain future events and achievement of revenue targets. Achievement of certain revenue targets could commit the Company to additional sale-based milestone payments but given the uncertainty it is unclear when, if ever, the Company may be required to pay such amounts. The Company has also committed to paying royalties at a wide range of rates as a percentage of net sales of the product as defined in the Cyprium APA, reduced by 50% pursuant to the Cyprium Assumption Agreement.

As described in Note 1, on March 31, 2022 (Closing Date), the Company consummated an Asset Purchase Agreement with Origin (Origin APA) pursuant to which the Company acquired the intellectual property and exclusive global rights to manufacture and distribute Nulibry (fosdenopterin) indicated to reduce the risk of mortality in patients with molybdenum cofactor deficiency (MoCD) Type A.

Pursuant to the terms of the Origin APA, STI is responsible for the ongoing development and commercialization in the US, and developing, manufacturing and commercializing fosdenopterin globally. Origin completed its development responsibilities for fosdenopterin with the approval of the marketing authorization with EMA and Israeli Ministry of Health.

In connection with the Origin APA, STI assumed certain agreements including Origin’s rights and interests in previous asset purchase agreements (Assigned Agreements). Certain of Origin’s future obligations under such agreements were assumed by STI pursuant to assignments. These agreements could commit the Company to additional development, approval and sale-based milestone payments and additional royalty payments. The events that would obligate the Company to pay any additional milestone amounts had not occurred at March 31, 2024. Accordingly, no contingent consideration was recognized as of the reporting date.

This transaction was accounted for as an asset acquisition. STI paid \$10.0 million in cash at closing and incurred \$1.4million in transaction costs, the total of which was allocated to product rights in the amount of \$9.8 million and acquired inventory totaling \$1.7 million. The product rights are amortized over a period of seven years.

Effective November 30 2022, the Company entered into an agreement with Hikma pursuant to which Hikma acquired the intellectual property and rights to manufacture and distribute Levorphanol for consideration of \$0.8 million, paid at closing. The Company recognized a gain of \$0.7 million, net of transaction-related costs, within “OTHER INCOME – Gain on sale of asset” in the statement of operations. The Company discontinued its distribution of Levorphanol at that time.

Note 5 – Identifiable Intangible Assets and Goodwill

In each of the years ended March 31, 2024 and March 31, 2023, the identifiable intangible assets related to Nulibry are valued at \$9.8 million and are being amortized over a useful life of 7 years.

The carrying amounts of intangible assets were as follows:

(in thousands)	<u>2024</u>	<u>2023</u>
Gross carrying amount		
License and product rights - Nulibry	\$ 9,758	\$ 9,758
Less accumulated amortization	<u>(2,788)</u>	<u>(1,394)</u>
Intangible assets, net	<u>\$ 6,970</u>	<u>\$ 8,364</u>

Note 5 – Identifiable Intangible Assets and Goodwill (continued)

Goodwill represents the excess consideration in a business combination over the fair value of identifiable net assets acquired. The Company does not amortize goodwill and is subject to impairment testing when a triggering event occurs that could indicate a potential impairment. The Company determines whether goodwill may be impaired by comparing the carrying value to the fair value of the entity. At March 31, 2023, a review of the fair value of the Company concluded that, due to the Company's sales of intangible assets related to Levorphanol and also discontinuation of future distribution of other products, the carrying value of goodwill had become impaired. Accordingly, an impairment charge totaling \$73.9 million was recognized, the entire amount of the goodwill.

Amortization expense related to the identifiable intangible assets was \$1.4 million and \$1.9 million in the years ended March 31, 2024 and 2023, respectively. Future expected amortization expense for identifiable intangible assets held as of March 31, 2024, is as follows:

Year ended March 31 (in thousands),

2025	\$	1,394
2026		1,394
2027		1,394
2028		1,394
2029		1,394
Total	\$	<u>6,970</u>

Note 6 – Stockholder's Equity

As the result of the acquisition described in Note 1, ZLL became the sole owner and holder of 100 shares of the Company's common stock.

Note 7 – Income Taxes

The Company accounts for income taxes in accordance with FASB ASC Topic 740, *Income Taxes*. Deferred tax assets and liabilities arise from temporary differences between the tax basis of assets and liabilities, and their reported amounts in the financial statements, that will result in taxable or deductible amounts in future years. Accounting for deferred taxes involves the evaluation of a number of factors concerning the realizability of the Company's net deferred tax assets. Management primarily considered such factors as the nature of the deferred tax assets, and the timing, likelihood, and amount, if any, of future taxable income during the periods in which those temporary differences and carryforwards become deductible. The Company records a valuation allowance against the deferred tax assets if and to the extent it is more likely than not that the Company will not recover the deferred tax assets. In evaluating the need for a valuation allowance, the Company weights all relevant positive and negative evidence, and considers among other factors, historical financial performance, projected future taxable income, scheduled reversals of deferred tax liabilities, the overall business environment, and tax planning strategies. Losses in recent periods and cumulative pre-tax losses in the three-year period ending with the current year, is collectively considered significant negative evidence under ASC 740 when assessing whether an entity can use projected income as a basis for concluding that deferred tax assets are realizable on a more-likely-than-not basis. For purposes of assessing the recoverability of deferred tax assets, the Company determined that it could not include future projected earnings in the analysis due to recent history of losses and therefore had insufficient objective positive evidence that the Company will generate sufficient future pre-tax income to overcome the negative evidence of cumulative losses. Accordingly, during the year ended March 31, 2024, the Company determined that a portion of its deferred tax assets are not expected to be realizable in the future. As a result, the Company recorded a partial valuation allowance of approximately \$5.5 million during

Note 7 – Income Taxes (continued)

the year ended March 31, 2024 against its U.S. federal deferred tax assets.

Currently, the Company does not have any uncertain tax positions and does not anticipate any significant changes within twelve months of March 31, 2025 in uncertain tax positions that would be material to the financial statements taken as a whole.

The income tax provision (benefit) consists of the following:

(in thousands)	<u>2024</u>	<u>2023</u>
Current:		
Federal	\$ -	\$ -
State	1	-
Total current	<u>1</u>	<u>-</u>
Deferred:		
Federal	-	(4,714)
State	-	-
Total deferred	<u>-</u>	<u>(4,714)</u>
Total income tax expense (benefit)	<u>\$ 1</u>	<u>\$ (4,714)</u>

STI's net deferred tax assets are as follows:

(in thousands)	<u>2024</u>	<u>2023</u>
Deferred tax liabilities (assets):		
Net operating loss	\$ 11,501	\$ 7,778
Amortization of R&D expenses	2,226	1,462
Interest limitation	1,060	477
Allowance for returns and rebates	727	814
Amortization of Nulibry Products Rights	312	-
Deferred revenue, net of expenses	108	65
Amortization Historical Basis Intangibles	-	156
Depreciation and amortization	(19)	(28)
Allowance for inventory obsolescence	-	5
Deferred compensation	-	8
Other	246	(75)
Valuation allowance	(5,502)	-
STI's net deferred tax assets / (liabilities)	<u>\$ 10,659</u>	<u>\$ 10,660</u>

The difference between the effective income tax rate and the statutory federal income tax rate applied to pretax income (loss) is as follows:

(in thousands)	<u>2024</u>	
	<u>Amount</u>	<u>Percentage</u>
Tax on Income before Income Tax	\$ (5,732)	21.00%
Effect of permanent differences	72	
Net operating loss	<u>5,661</u>	<u>-21.00%</u>
Total income tax expense	1	0.00%
Deferred tax benefit	<u>-</u>	<u>20.00%</u>
Total income tax expense (benefit)	<u>\$ 1</u>	<u>20.00%</u>

Note 7 – Income Taxes (continued)

(in thousands)

	2023	
Tax on Income before Income Tax	\$ (19,799)	21.00%
Effect of permanent differences	15,505	-16.46%
Net operating loss	4,294	-4.55%
Total income tax expense	-	0.00%
Deferred tax benefit	(4,714)	5.00%
Total income tax benefit	\$ (4,714)	5.00%

The Company has not incurred any material interest or penalties during the reporting period with respect to income tax matters.

The Company is subject to taxation in the United States and various state jurisdictions. As of March 31, 2024, the Company's tax years for 2019 through 2022 are subject to examination by the taxing authorities.

Note 8 – Retirement Plan and Deferred Compensation Plan

The Company has established a qualified defined contribution 401(k) plan for its eligible employees. Company contributions, if any, to the 401(k) plan are at the sole discretion of the Board of Directors. In 2024 and 2023, the Board approved, and the Company paid, matching contributions of \$0.15 million and \$0.12 million related to employee services for the immediately preceding years. At March 31, 2024, the Company accrued a discretionary matching contribution for employee services related to 2024 totaling \$0.12 million, which, subject to Board approval, will be funded in early 2025.

The Company had a deferred compensation plan in which certain key employees were eligible to participate effective January 19, 2017. At March 31, 2024, the deferred compensation assets associated this plan were fully amortized and there were no additional liabilities pertaining to this plan. At March 31, 2023, the Company recorded deferred compensation asset of \$0.1 million and a corresponding liability reflecting the amount of payments made in the year ending March 31, 2024.

Note 9 – Commitments and Contingencies

Legal matters – In August 2018, the Company received a subpoena from the United States Attorney's Office for the District of New Jersey (DNJ) seeking information related to the promotion and distribution of one of the Company's products ("Government Investigation"). In September 2019, the Company received a second subpoena from DNJ regarding another of the Company's products related to the same Government Investigation. The Government Investigation was resolved in full in a civil settlement agreement with no admission of liability. The Company made a payment of \$0.8 million in connection with the settlement agreement.

A complaint naming the Company (among other pharmaceutical companies) as a defendant, was filed on or about March 15, 2019, in the Pennsylvania Court of Common Pleas of Philadelphia. The Company was served with the lawsuit on April 18, 2019. This case was dismissed on or about April 11, 2024.

The Company may be involved in other legal matters that arise from time to time in the ordinary course of business. Management does not believe that the resolution of any of these matters would have a material impact on the Company's financial position or results of operations.

STI accrued unpaid legal and related costs totaling \$0.2 million in each of the years ended March 31, 2024 and 2023.

Note 9 – Commitments and Contingencies (continued)

Product manufacturing agreements – The Company uses FDA-validated third-party and related party contractors to manufacture and package its products. Under the terms and conditions of agreements with these contractors, the Company enters into firm purchase commitments that specify quantities, expected delivery, and pricing for each specific order.

The Company made purchases totaling \$3.1 million and \$0.6 million under such contracts in fiscal years 2024 and 2023, respectively. At March 31, 2024, there were \$3.5 million outstanding firm purchase commitments in connection with these agreements.

Royalty Agreements – STI is obligated to pay quarterly royalties in connection with the Origin APA and Assigned Agreements, subject to certain limitations as further defined in the Origin APA. Royalties are based on a percentage of the net sales from the sales of Nulibry.

Royalty expense in connection with sales of the Company's products totaled \$0.8 million and \$0.4 million for the fiscal years 2024 and 2023, respectively, and was classified as a component of cost of sales.

Leases – In January 2022, the Company amended its lease agreement for office space at its corporate headquarters in San Diego, California, to reduce the rentable space and monthly rent and extend the lease term to July 31, 2023, effective June 1, 2022. In accordance with ASC Topic 842, the Company determined this arrangement contained a lease at inception and recorded the recognition of right-of-use asset, or ROU, in connection with this amendment, and related lease liabilities of approximately \$0.3 million in the balance sheet as of June 1, 2022, the commencement date. At March 31, 2024, the ROU asset associated with this amendment was fully amortized.

In December 2022, the Company amended this operating lease agreement to extend the lease term, commencing on August 1, 2023 through October 31, 2026 and recognized a ROU asset in connection with this amendment of \$0.7 million. At March 31, 2024, the unamortized amount for this asset was \$0.6 million.

ROU assets represent the Company's right to control an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. ROU assets and liabilities are recognized at the commencement date based on the estimated present value of lease payments over the lease term. The Company utilized the practical expedient for determining the discount rate available for nonpublic business entities which allowed it to use a risk-free rate for a period comparable to the lease term.

This operating lease does not include a renewal option. The lease agreement includes escalating lease payments. Lease expense is recorded over the lease term and was \$0.2 million in each of the fiscal years 2024 and 2023.

Schedule of cash flow related to leases (in thousands):

	2024	2023
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	\$ 154	\$ 146
ROU assets obtained in exchange for lease liabilities:	\$ 730	\$ 1,014
 Leases		
Remaining lease term (in months):	31	43
Weighted average discount rate:	4.0%	3.8%

Note 9 – Commitments and Contingencies (continued)

Future minimum payments due and payable under the Company’s non-cancelable operating lease, as amended, are as follows:

Years ended March 31, (in thousands)	
2024	256
2025	264
2026	157
Total Lease Payments	<u>677</u>
Less: amount representing interest	<u>(51)</u>
Total	<u><u>\$ 626</u></u>

Note 10 – Related Party Transactions

The Company recognized \$0.1 million in interest income associated with a loan agreement entered into between the Company and Zydus Worldwide DMMC (ZWWD) in fiscal year 2023. At March 31, 2023, the \$30.0 million loan balance was repaid to the Company in full.

As of March 31, 2024, the Company had received cumulative net loan advances totaling \$75.0 million, net of repayments, from ZPUI pursuant to a loan agreement between the Company and ZPUI. Interest accrued on the unpaid loan balance is calculated at interest rates deemed to represent fair value. The Company recorded \$3.4 million and \$1.5 million in interest expense associated with this loan during the fiscal years ended on March 31, 2024 and 2023, respectively. The current outstanding principal and accrued interest payable balance was \$76.0 million at March 31, 2024 and \$48.5 million at March 31, 2023.

The Company received a loan advance totaling \$15.0 million on June 8, 2022 from ZLL pursuant to a loan agreement between the Company and ZLL. Interest accrued on the unpaid loan balance is calculated at interest rates deemed to represent fair value. The Company recorded \$0.9 million and \$0.5 million of interest expense associated with this loan during the years ended March 31, 2024 and 2023. The outstanding principal and accrued interest payable balance was \$15.0 million and \$15.3 million on March 31, 2024 and 2023, respectively.

As of March 31, 2024 and 2023, the Company classified the outstanding loan payable balances as current liabilities as follows:

(in thousands)	<u>2024</u>	<u>2023</u>
Note and interest Payable - ZPUI	\$ 76,035	\$ 48,545
Note and interest Payable - ZLL	<u>15,000</u>	<u>15,354</u>
Note payable and interest payable – affiliate	<u><u>\$ 91,035</u></u>	<u><u>\$ 63,899</u></u>

During fiscal year 2024, the Company entered into an Intercompany Administrative Service Agreement by and between ZPUI and the Company whereby ZPUI agreed to provide Administrative Services, as defined, charged at rates deemed to be arm’s length. The Company recognized administrative support expense related to this agreement of \$0.07 million and \$0.05 million in the fiscal years ended March 31, 2024 and 2023, respectively. Amounts payable to ZPUI associated with such services included in “Other payable - affiliate” in the balance sheets were \$0.02 million in each of the fiscal years.

The Company recognized a loan guarantee fee in connection with ZPUI’s guarantee of the Company’s debt obligation of \$0.0 million and \$0.03 million in the fiscal years ended March 31, 2024 and 2023, respectively,

Note 10 – Related Party Transactions (continued)

in connection with this arrangement.

The Company entered into a Product Development Agreement with ZLL pursuant to which ZLL provided the Company manufacturing technology services for certain of its products. The Company recognized manufacturing support expense related to this agreement of \$0.7 million and \$0.4 million in fiscal years ended March 31, 2024 and 2023, respectively. As of March 31, 2024 and 2023, amounts payable to ZLL associated with these services included in “Accrued expenses and other current liabilities” in the balance sheets were \$0.0 million and \$0.2 million, respectively.

Note 11 – Subsequent Events

The Company has evaluated subsequent events through May 15, 2024, the date, which the financial statements were available to be issued. No reportable subsequent events have occurred through May 15, 2024, which would have a significant effect on the financial statements as of March 31, 2024, except as otherwise disclosed.

On May 3, 2024, the Company and Eiger BioPharmaceuticals, Inc. (Eiger) finalized an Asset Purchase Agreement pursuant to which the Company acquired the worldwide proprietary rights to manufacture and distribute Zokinvy® (lonafarnib). Zokinvy is a treatment approved in the United States, the European Union, Great Britain, and Japan to target the causes and symptoms of progeria, a collection of ultra-rare, fatal, genetic premature aging diseases that accelerate mortality in young patients. Eiger and its direct subsidiaries filed voluntary petitions for relief under chapter 11 of Title 11 of the United States Code in the United States Bankruptcy Court for the Northern District of Texas (Bankruptcy Court). The Bankruptcy Court approved the sale to the Company for the final cash price of \$44.3 million. The Company is currently in the process of finalizing the accounting for this transaction and expects to complete its allocation of the purchase consideration to the assets acquired in the fiscal year ending March 31, 2025.