

REPORT OF INDEPENDENT AUDITORS AND  
FINANCIAL STATEMENTS

**SENTYNL THERAPEUTICS, INC.**

For The Fiscal Years Ended March 31, 2023 and 2022

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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, 2023 and 2022, and the related statements of operations, statements of 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, 2023 and 2022, 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

Hamilton, NJ

May 15, 2023

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

	<u>2023</u>	<u>2022</u>
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 1,998	\$ 1,204
Accounts receivable, net	495	306
Inventories	1,452	1,874
Prepaid expenses and other current assets	1,983	3,478
Note and interest receivable – affiliates	-	30,068
Other receivable – affiliates	-	506
Total current assets	<u>5,928</u>	<u>37,436</u>
DEFERRED TAX ASSETS, NET	10,660	5,945
PROPERTY AND EQUIPMENT, net	135	8
OPERATING LEASE RIGHT-OF-USE ASSET	773	173
IDENTIFIABLE INTANGIBLE ASSETS, net	8,364	10,873
GOODWILL	-	73,896
Total assets	<u>\$ 25,860</u>	<u>\$ 128,331</u>
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 501	\$ 202
Accrued expenses and other current liabilities	9,861	14,340
Note payable - affiliate	63,899	73,151
Current portion of operating lease liabilities	253	142
Other payable - affiliate	23	-
Total current liabilities	<u>74,537</u>	<u>87,835</u>
<b>LONG-TERM LIABILITIES</b>		
Long-term operating lease liabilities, net of current portion	525	48
Other long-term liabilities, net	38	124
Total long-term liabilities	<u>563</u>	<u>172</u>
Total liabilities	<u>75,100</u>	<u>88,007</u>
<b>COMMITMENTS AND CONTINGENCIES (Note 8)</b>		
<b>STOCKHOLDER'S EQUITY / (DEFICIT)</b>		
Common stock (par value, \$0.0001 per share, 2,000 shares authorized, 100 shares outstanding)	30,010	30,010
Retained earnings	(79,250)	10,314
Total stockholder's equity / (deficit)	<u>(49,240)</u>	<u>40,324</u>
Total liabilities and stockholder's equity / (deficit)	<u>\$ 25,860</u>	<u>\$ 128,331</u>

See accompanying notes to financial statements.

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

	<u>2023</u>	<u>2022</u>
NET REVENUE	\$ 7,034	\$ 7,720
OPERATING COSTS AND EXPENSES		
Cost of sales	2,134	2,096
Research and development, manufacturing support, quality and regulatory	9,115	9,203
General and administrative	7,483	7,192
Selling and marketing	5,571	2,369
Depreciation	17	12
Amortization	1,857	6,878
Goodwill impairment charge	73,896	-
Total operating costs and expenses	<u>100,073</u>	<u>27,748</u>
OPERATING INCOME (LOSS)	<b>(93,039)</b>	<b>(20,028)</b>
INTEREST EXPENSE (INCOME)		
Interest expense	1,974	828
Interest income	<u>(74)</u>	<u>(285)</u>
Total interest expense, net	<b>1,900</b>	<b>543</b>
OTHER INCOME - Gain on sale of asset	<u>660</u>	<u>-</u>
INCOME (LOSS) BEFORE PROVISION FOR INCOME TAXES	<b>(94,279)</b>	<b>(20,571)</b>
PROVISION (BENEFIT) FOR INCOME TAXES	<u>(4,714)</u>	<u>(3,739)</u>
NET INCOME (LOSS)	<u><b>\$ (89,565)</b></u>	<u><b>\$ (16,832)</b></u>

See accompanying notes to financial statements.

**Sentynl Therapeutics, Inc.**  
**Statements of Stockholder's Equity / (Deficit)**  
**For the Fiscal Years Ended March 31,**  
**(in thousands)**

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	Common Stock		Retained Earnings	Total
	Units	Amount		Stockholder's Equity/(Deficit)
BALANCE, April 1, 2021	100	\$ 30,010	\$ 27,146	\$ 57,156
Net loss	-	-	(16,832)	(16,832)
BALANCE, March 31, 2022	100	30,010	10,314	40,324
Net loss	-	-	(89,565)	(89,565)
BALANCE, March 31, 2023	<b>100</b>	<b>\$ 30,010</b>	<b>\$ (79,250)</b>	<b>\$ (49,240)</b>

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

	<u>2023</u>	<u>2022</u>
<b>OPERATING ACTIVITIES</b>		
Net income (loss)	\$ (89,565)	\$ (16,832)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation	17	12
Amortization	1,857	6,878
Amortization of deferred financing costs	-	131
Deferred compensation expense	191	243
Gain in sale of asset	(661)	-
Goodwill impairment charge	73,896	-
Changes in operating assets and liabilities:		
Accounts receivable	(189)	(143)
Inventories	1,073	446
Prepaid expenses and other current assets	1,495	5,615
Income taxes payable	5	(31)
Accrued expenses and other current liabilities	(4,771)	(7,321)
Deferred tax liabilities	(4,714)	(3,710)
Accounts payable	299	(346)
Interest and other receivable – affiliate	1,345	269
Net cash used in operating activities	<u>(19,722)</u>	<u>(14,790)</u>
<b>INVESTING ACTIVITIES</b>		
Loan repayments from affiliate	30,000	-
Cash paid for asset acquisition	-	(11,433)
Purchase of property and equipment	(145)	(8)
Proceeds from sale of asset, net of expenses	661	-
Net cash provided by (used in) investing activities	<u>30,516</u>	<u>(11,441)</u>
<b>FINANCING ACTIVITIES</b>		
Note payable repayments	-	(40,000)
Loan repayments from affiliate	(25,000)	-
Loan advances from affiliates	15,000	61,000
Net cash provided by (used in) financing activities	<u>(10,000)</u>	<u>21,000</u>
<b>INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<u>794</u>	<u>(5,231)</u>
<b>CASH AND CASH EQUIVALENTS</b>		
Beginning of period	<u>1,204</u>	<u>6,435</u>
End of period	<u>\$ 1,998</u>	<u>\$ 1,204</u>
<b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION</b>		
<b>Cash payments for:</b>		
Interest:		
Paid to a third party	\$ -	\$ 303
Paid to a related party	1,226	394
Total interest paid	<u>\$ 1,226</u>	<u>\$ 698</u>
Income Taxes Paid (Refunded)	<u>\$ -</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 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 shares development responsibilities for fosdenopterin through approval of the marketing authorization application already under accelerated assessment with the European Medicines Agency (EMA) and through approval of its regulatory submission with the Israeli Ministry of Health. The transaction was accounted for as an asset acquisition. See Note 4 for further discussion.

On February 23, 2021, the Company entered into an Asset Purchase Agreement with Cyprium Therapeutics, Inc. (Cyprium) pursuant to which the Company committed development funding for and will acquire the rights to a copper histidinate injection (CUTX-101) for treatment of diseases involving copper deficiency or insufficiency, including Menkes Disease, which is currently in a Phase 3 clinical study. 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. Cyprium began a rolling submission of a New Drug Application (NDA) to the FDA. See Note 4 for further discussion.

In 2015, STI acquired the intellectual property and exclusive rights to manufacture and distribute levorphanol tartrate tablets (Levorphanol) in the United States and its territories. The Company sold these rights to Hikma Pharmaceuticals USA Inc. (Hikma) on November 30, 2022 and discontinued its distribution of Levorphanol at that time. 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*.

**Note 2 – Summary of Significant Accounting Policies (continued)**

*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 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, 2023, the first pricing approval for Nulibry in a European Medicines Agency country had not been granted yet. 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 a European-based distributor. The distributor 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.

**Note 2 – Summary of Significant Accounting Policies (continued)**

*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 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)	2023	2022
Invoiced revenue	\$ 8,863	\$ 10,024
Less deductions and allowances:		
Third-party and government rebates / chargebacks	2,794	3,188
Product returns	(1,111)	(1,027)
Distribution fees, trade discounts and other	146	143
Total deductions and allowances	1,829	2,305
Net sales	\$ 7,034	\$ 7,720

**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. As on March 31, 2023, the Company had uninsured cash balances totalling \$2.65 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, 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. During the fiscal year ended on March 31, 2022 three indirect wholesale drug and specialty pharmacy distributors, each of whom individually accounted for more than 10 percent, accounted for 87 percent in aggregate of the Company’s invoiced revenue. The Company extends unsecured credit to a Distributor, and that balance represents the amount classified as accounts receivable. The Distributor and all of the Company’s indirect customers are located in the United States.

**Cost of sales** – Cost of sales consist 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 2023 and 2022, the Distributor was the only direct US customer of the Company. The amounts recorded at March 31, 2023 and 2022, respectively, of \$0.1 million and \$0.5million reflects unpaid amounts invoiced to this customer under the terms and conditions of the contract. The allowance for trade discounts was \$0.0 million and \$0.2 million as of March 31, 2023 and 2022, respectively. In addition, the Company had receivables from its European distributor of Nulibry totaling \$0.5 million as of March 31, 2023.

**Note 2 – Summary of Significant Accounting Policies (continued)**

**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.

**Note receivable – affiliates** – The Company had loan agreements with its affiliates, Zydus Pharmaceuticals (USA) Inc. (ZPUI) and Zydus Worldwide DMCC (ZWWD). These were fully repaid to the Company in the fiscal year ended March 31, 2023. See Note 11 for further discussion.

**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 makes adjustments 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 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

**Note 2 – Summary of Significant Accounting Policies (continued)**

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.

As of 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 other expense in the statement of operations. As of March 31, 2023 and 2022, 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.

**New accounting pronouncements**

**In March 2020, the FASB issued ASU 2020-04**, Facilitation of the Effects of Reference Rate Reform on Financial Reporting which provides optional expedients and exceptions for applying GAAP to contracts, hedging relationships, and other transactions affected by the discontinuation of the London Interbank Offered Rate (“LIBOR”) or by another reference rate expected to be discontinued. This guidance is effective for all entities upon issuance on March 12, 2020 and may be applied through December 31, 2023. The expedients and exceptions in this guidance are optional, and the Company is evaluating the potential future financial statement impact of any such expedient or exception that it may elect to apply as the Company evaluates the effects of adopting this guidance on its financial statements.

**Note 2 – Summary of Significant Accounting Policies (continued)**

**In October 2022, the FASB released ASU 2022-08—Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers.** For public business entities, the amendments in this Update are effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption of the amendments is permitted, including adoption in an interim period. The Company is currently evaluating the impact that the adoption of ASU 2016-02 will have on its financial statements.

**In November 2022, the FASB issued ASU 2022-10—Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance.** The amendments in this Update are effective for all entities within their scope for financial statements issued for annual periods beginning after December 15, 2022. Early application of the amendments is permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-02 will have on its financial statements.

**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, 2022, including interim periods within those fiscal years. Early application continues to be allowed. The Company is currently evaluating the effect that implementation of this ASU will have on its financial statements.

**Note 3 – Balance Sheet Details**

Balance sheet details as of March 31, 2023 and 2022, are as follows:

(in thousands)	2023	2022
Accounts receivable, net		
Trade accounts receivable	\$ 596	\$ 471
Trade discounts	(101)	(165)
Accounts receivable, net	\$ 495	\$ 306
Inventories		
Raw materials	\$ 897	\$ 105
Work-in progress	448	-
Finished goods	107	1,769
Inventories	\$ 1,452	\$ 1,874
Note Receivable – Affiliate		
Note receivable (principal)	\$ -	\$ 30,000
Interest receivable, affiliate	-	68
Note receivable and interest receivable – affiliate	\$ -	\$ 30,068

# Sentynl Therapeutics, Inc.

## Notes to Financial Statements

### Note 3 – Balance Sheet Details (continued)

	2023	2022
Prepaid expenses and other current assets		
Prepaid market data	\$ 555	\$ 670
Prepaid commercial insurance	517	412
Income tax receivable	433	433
Prepaid subscription fees	243	152
Prepaid PDUFA fees	197	-
Capitalized R&D costs	-	1,551
Employer Retention Tax Credit receivable	-	215
Other	38	45
Prepaid expenses and other current assets	<u>\$ 1,983</u>	<u>\$ 3,478</u>
Property and equipment, net		
Computer hardware and software	\$ 357	\$ 324
Furniture and fixtures	265	153
	<u>622</u>	<u>477</u>
Accumulated depreciation	<u>(487)</u>	<u>(469)</u>
Property and equipment, net	<u>\$ 135</u>	<u>\$ 8</u>
	2023	2022
Accrued expenses and other current liabilities		
Accrued product returns	\$ 3,875	\$ 7,433
Accrued regulatory and medical affairs costs	1,080	389
Accrued marketing costs	846	453
Accrued incentive compensation	769	1,292
Accrued rebates and wholesaler fees	563	1,800
Deferred revenue	530	566
Accrued contract manufacturing costs	424	1,022
Accrued market data costs	385	614
Accrued consulting and professional fees	289	79
Accrued legal fees	174	192
Accrued product royalties	171	22
Other	755	478
Accrued expenses and other current liabilities	<u>\$ 9,861</u>	<u>\$ 14,340</u>
Other long-term liabilities, net		
Deferred compensation liability, net	\$ 38	\$ 124
Other long-term liabilities, net	<u>\$ 38</u>	<u>\$ 124</u>

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

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.

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

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 shares development responsibilities for fosdenopterin through approval of the marketing authorization application already under accelerated assessment with the European Medicines Agency (EMA) and through approval of its regulatory submission with the Israeli Ministry of Health. Origin will be eligible to receive commercial milestone payments as well as tiered royalties on adjusted net sales of Nulibry.

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, 2023. Accordingly, no contingent consideration was recognized as of the reporting date.

Other liabilities associated with contracts assigned to the Company were limited to those arising and accruing after the Closing Date.

This transaction was accounted for as an asset acquisition. STI paid \$10.0 million in cash at closing and incurred \$1.4 million 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.

In February 2021, the Company entered into an Asset Purchase Agreement with Cyprium (Cyprium APA) pursuant to which the Company committed development funding for and will acquire the rights to a copper histidinate injection (CUTX-101) for treatment of diseases involving copper deficiency or insufficiency, including Menkes Disease.

Up-front payments, as well as other milestone payments to be made before regulatory approval (pre-approval), are considered as acquired IPR&D. In the fiscal year ended March 31, 2021, the Company paid Cyprium an upfront payment of \$8.0 million in connection with this agreement 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 was performing development services amounting to \$1.6 million and \$6.3 million in the fiscal years ended March 31, 2023 and 2022, respectively. This expense is included within research and development expenses on the Company's statements of operations.

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. As of March 31, 2023, if all pre-commercialization milestones are timely achieved, the Company would pay an additional \$12.0 million. 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 pay royalties at a wide range of rates as a percentage of net sales of the product as defined in the Cyprium APA.

Effective November 30 2022, the closing date, 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



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

of operations. The Company discontinued its distribution of Levorphanol at that time.

**Note 5 – Identifiable Intangible Assets and Goodwill**

In connection with the sale of Levorphanol in November 2022, the fully-depreciated identifiable intangible asset associated with Levorphanol was derecognized in the fiscal year ended 2023. At March 31, 2022, the intangible asset was valued at \$0.5 million.

In the year ended March 31, 2023 and March 31, 2022, the identifiable intangible assets related to Nulibry are valued at \$9.8 million and \$10.4 million, respectively, and are being amortized over a useful life of 7 years.

The carrying amounts of intangible assets were as follows:

(in thousands)	2023	2022
Gross carrying amount, net of impairment		
License and product rights - Levorphanol	\$ -	\$ 7,340
License and product rights - Nulibry	9,758	10,411
	9,758	17,751
Less accumulated amortization	(1,394)	(6,878)
Intangible assets, net	\$ 8,364	\$ 10,873
Goodwill	\$ -	\$ 73,896

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 \$1.9 million and \$6.9 for the fiscal years 2023 and 2022, respectively. Future expected amortization expense for identifiable intangible assets held as of March 31, 2023, is as follows:

Year ended March 31 (in thousands).

2024	\$ 1,394
2025	1,394
2026	1,394
2027	1,394
2028	1,394
Thereafter	1,394
Total	\$ 8,364

**Note 6 – Debt**

In connection with the January 19, 2017, acquisition and resulting merger, the Company assumed a loan and outstanding indebtedness with the Bank of Tokyo – Mitsubishi (BTMU) dated January 12, 2017 (effective date), totaling \$120.0 million with an initial term of five years. Principal repayment was made in three equal installment payments of \$40.0 million each. The Company made the final payment associated with this loan in January 2022. The Company incurred deferred financing costs of \$0.8 million in connection with this agreement, which was fully amortized on a straight-line basis over the term of the loan which ended in January 2022.

During the fiscal year 2022, the interest rates ranged from 0.94 percent to 0.96 percent. For the fiscal year 2023 and 2022, the Company recognized interest expense associated with this loan of \$0 and \$0.4 million, respectively, which includes \$0 and \$0.1 million, respectively, of expense related to amortization of deferred financing costs.

**Note 7 – 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 8 – 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. At present, management believes that it is more likely than not that the net deferred tax assets will be realized, accordingly, management has determined that no valuation allowance is necessary.

Currently, the Company does not have any uncertain tax positions and does not anticipate any significant changes within twelve months of March 31, 2023 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)	2023	2022
Current:		
Federal	\$ -	\$ -
State	-	1
Total current	-	1
Deferred:		
Federal	(4,714)	(3,740)
State	-	-
Total deferred	(4,714)	(3,740)
Total income tax benefit	\$ (4,714)	\$ (3,739)

**Note 8 – Income Taxes (continued)**

STI's net deferred tax assets are as follows:

(in thousands)	2023	2022
Deferred tax liabilities (assets):		
Net operating loss	\$ 7,778	\$ 2,343
Allowance for returns and rebates	813	1,561
Amortization of R&D expenses	1,461	1,232
Amortization Historical Basis Intangibles	156	195
Amortization Stepped Up Basis	-	163
Allowance for inventory obsolescence	5	290
Deferred revenue, net of expenses	65	58
Deferred compensation	8	26
Depreciation and amortization	(28)	(2)
Interest limitation	477	156
Other	(75)	(77)
	<b>\$ 10,660</b>	<b>\$ 5,945</b>
Total net deferred tax assets / (liabilities)	<b>\$ 10,660</b>	<b>\$ 5,945</b>

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)	2023	
	Amount	Percentage
Tax on Income before Income Tax	\$ (19,799)	21.00%
Effect of permanent differences	15,505	-16.45%
Net operating loss	4,294	-4.55%
	-	-0.00%
Total income tax expense	-	-0.00%
Deferred tax benefit	(4,714)	5.00%
	<b>\$ (4,714)</b>	<b>5.00%</b>

(in thousands)	2022	
	Amount	Percentage
Tax on Income before Income Tax	\$ (4,320)	21.00%
State income tax, net of federal benefit	1	-0.03%
Effect of permanent differences	(13)	0.06%
Net operating loss	4,332	-21.06%
Other	(29)	-0.11%
	(29)	-0.14%
Total income tax expense	(29)	-0.14%
Deferred tax benefit	(3,710)	18.32%
	<b>\$ (3,739)</b>	<b>18.18%</b>

**Note 8 – Income Taxes (continued)**

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, 2023, the Company's tax years for 2019 through 2022 are subject to examination by the taxing authorities.

**Note 9 – 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 2023 and 2022, the Board approved, and the Company paid, matching contributions of \$0.1 million in each of the years related to employee services for the immediately preceding years. At March 31, 2023, the Company accrued a discretionary matching contribution for employee services related to 2023 totaling \$0.1 million, which, subject to Board approval, will be funded in early 2024.

The Company had a deferred compensation plan in which certain key employees were eligible to participate effective January 19, 2017. This plan allowed each participant to accrue deferred compensation equal to their share, as further defined in the plan agreement, of annual net revenue growth measured against the previous year's annual net revenue. At March 31, 2023 and 2022, the Company recorded deferred compensation asset of \$0.1 million and \$0.3 million, respectively, which reflected future amortization over the remaining service period at each date. In addition, the Company accrued a liability of \$0.1 million and \$0.4 million at March 31, 2023 and 2022, respectively, which reflects the amount of future payments, representing a net liability of \$0.0 million and \$0.1 million at March 31, 2023 and 2022, respectively, and classified as other long-term liability.

**Note 10 – 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. At this time, the Company cannot predict or determine the outcome of this matter and is fully cooperating with the Government Investigation.

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. The Company retained legal counsel to assist the Company in responding to the lawsuit. At this time, the Company cannot predict or determine the outcome of this matter.

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 \$0.2million in each of the years ended March 31, 2023 and 2022.

**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.

**Note 10 – Commitments and Contingencies (continued)**

The Company made purchases totaling \$0.6 million and \$1.3 million under such contracts in fiscal years 2023 and 2022, respectively. At March 31, 2023, there were \$1.8 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.

STI's obligation to pay quarterly royalties related to Levorphanol sales ceased as a result of the sale of Levorphanol in November 2022. Prior, the royalties paid were based on a percentage of the gross profit and totaled \$0.1 million for the fiscal year ended March 31, 2023.

Royalty expense in connection with sales of the Company's products totaled \$0.4 million and \$0.1 million for the fiscal years 2023 and 2022, 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, 2023, the unamortized balance of the ROU asset associated with this amendment was \$0.1 million

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.

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 2023 and 2022.

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

	<u>2023</u>
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	\$ 146
ROU assets obtained in exchange for lease liabilities:	\$ 1,014
Leases	
Remaining lease term (in months):	43
Weighted average discount rate:	3.6%

Future minimum payments due and payable under the Company's non-cancelable operating lease, as

**Note 10 – Commitments and Contingencies (continued)**

amended, are as follows:

Years ended March 31, (in thousands)	
2024	154
2025	256
2026	264
2027	157
	<hr/>
Total Lease Payments	831
Less: amount representing interest	(53)
	<hr/>
Total	<u><u>\$ 778</u></u>

**Note 11 – Related Party Transactions**

As of March 31, 2023, the Company had provided cumulative net loan advances of \$30.0 million pursuant to a loan agreement entered into between the Company and Zydus Worldwide DMMC (ZWWD). The loan balance was repaid to the Company in full during the fiscal year ended March 31, 2023. The Company recognized \$0.1 million and \$0.3 million in interest income associated with this loan during the fiscal years 2023 and 2022, respectively. At March 31, 2023, there were no outstanding amounts due to the Company in connection with this loan agreement. The outstanding principal and interest receivable was \$30.1 million at March 31, 2022 and was classified as “Notes and interest receivable – affiliate” in current assets in the balance sheet.

As of March 31, 2023, the Company had received cumulative net loan advances totaling \$48.0 million, net of repayments totaling \$43 million in the year, 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 \$1.5 million and \$0.2 million in interest expense associated with this loan during the fiscal years ended on March 31, 2023 and 2022, respectively. The current outstanding principal and accrued interest payable balance was \$48.5 million at March 31, 2023 and \$73.1 million at March 31, 2022.

The Company received a loan advance totaling \$15.0 million during the fiscal year ended March 31, 2023 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 \$0.5 million of interest expense associated with this loan. The current outstanding principal and accrued interest payable balance was \$15.3 million on March 31, 2023. In addition, the Company had an arrangement with ZLL whereby ZLL provided a guarantee of the Company’s debt obligation with BTMU. This arrangement discontinued upon the final installment payment to BTMU in January 2022. During the fiscal year 2022, the Company recognized expense of \$0.2 million in connection with this arrangement.

As of March 31, 2023 and 2022, the Company classified the outstanding loan payable balances as current liabilities as follows:

(in thousands)	<u>2023</u>	<u>2022</u>
Note and interest Payable - ZPUI	\$ 48,545	\$ 73,101
Note and interest Payable - ZLL	15,354	-
Loan Guarantee Fees - ZPUI	-	50
Note payable and interest payable – affiliate	<u><u>\$ 63,899</u></u>	<u><u>\$ 73,151</u></u>

**Note 11 – Related Party Transactions (continued)**

During fiscal year 2023, 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 \$0.05 million in the fiscal year ended March 31, 2023. As of March 31, 2023, amounts payable to ZPUI associated with such services included in "Other payable - affiliate" in the balance sheets were \$0.02 million.

The Company recognized a loan guarantee fee in connection with ZPUI's guarantee of the Company's debt obligation of \$0.0 million and \$0.1 million in the fiscal years ended March 31, 2023 and 2022, respectively, 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 \$0.4 million and \$0.3 million in fiscal years ended March 31, 2023 and 2022, respectively. As of March 31, 2023 and 2022, amounts payable to ZLL associated with these services included in "Accrued expenses and other current liabilities" in the balance sheets were \$0.2 million and \$0.3 million, respectively.

The Company made no purchases in the fiscal year ended March 31, 2023 in connection with a manufacturing agreement with an affiliate, Neshor Pharmaceuticals (USA) LLC (Neshor), and had no finished goods inventory remaining associated with prior purchases from Neshor. It purchased \$0.8 million under the agreement for the year ended March 31, 2022 and had finished goods inventory associated with product acquired from Neshor of \$0.7 million at March 31, 2022.

**Note 12 – Subsequent Events**

The Company has evaluated subsequent events through May 15, 2023, the date, which the financial statements were available to be issued. No reportable subsequent events have occurred through May 15, 2023, which would have a significant effect on the financial statements as of March 31, 2023, except as otherwise disclosed.