

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

**FORM 8-K/A
(Amendment No. 1)**

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): December 7, 2023

VANDA PHARMACEUTICALS INC.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-34186
(Commission
File No.)

03-0491827
(IRS Employer
Identification No.)

**2200 Pennsylvania Avenue NW
Suite 300E
Washington, DC 20037**
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (202) 734-3400

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	VNDA	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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

Explanatory Note

This Amendment No. 1 on Form 8-K/A (“Amendment No. 1”) amends the Current Report on Form 8-K of Vanda Pharmaceuticals Inc. (“Vanda”), filed on December 7, 2023 (the “Original Report”), in which Vanda reported the acquisition from Actelion Pharmaceuticals Ltd., a Johnson & Johnson Company (“Janssen”), of the U.S. and Canadian rights for PONVORY® (ponesimod) (the “Acquired Business”), pursuant to the terms of that certain Asset Purchase Agreement, dated as of December 7, 2023 by and between Vanda and Janssen.

This Amendment No. 1 is being filed by Vanda to amend the Original Report solely to provide the financial statement and financial information required by Item 9.01 of Form 8-K that were not filed with the Original Report.

Item 9.01. Financial Statements and Exhibits.

(a) Financial Statements of Business Acquired.

The audited special purpose abbreviated financial statements for the Acquired Business as of and for the years ended January 1, 2023 and January 2, 2022 and the unaudited special purpose abbreviated financial statements for the Acquired Business as of and for the nine months ended October 1, 2023 and October 2, 2022 are filed as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K and incorporated in this Item 9.01(a) by reference.

(b) Pro Forma Financial Information

The unaudited pro forma condensed combined financial statements for the year ended December 31, 2023 giving effect to the acquisition of the Acquired Business are filed as Exhibit 99.3 to this Current Report on Form 8-K and incorporated in this Item 9.01(b) by reference.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
99.1	Audited Special Purpose Abbreviated Financial Statements for the Acquired Business as of and for the years ended January 1, 2023 and January 2, 2022.
99.2	Unaudited Special Purpose Abbreviated Financial Statements for the Acquired Business as of and for the nine months ended October 1, 2023 and October 2, 2022.
99.3	Unaudited pro forma condensed combined financial information for the year ended December 31, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: February 16, 2024

VANDA PHARMACEUTICALS INC.

By: /s/ Timothy Williams

Name: Timothy Williams

Title: Senior Vice President, General Counsel and Secretary

CONSENT OF INDEPENDENT AUDITORS

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-269654) and Form S-8 (No. 333-133368, No. 333-138070, No. 333-141571, No. 333-148924, No. 333-156995, No. 333-164567, No. 333-171962, No. 333-179265, No. 333-186509, No. 333-193614, No. 333-201754, No. 333-209144, No. 333-212255, No. 333-218774, No. 333-225599, No. 333-239103, No. 333-256994, No. 333-265692, and No. 333-272522) of Vanda Pharmaceuticals Inc. of our report dated February 12, 2024 relating to the financial statements of the PONVORY® Product Line of Actelion Pharmaceuticals, Ltd., which appears in this Current Report on Form 8-K.

/s/ PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 16, 2024

SPECIAL PURPOSE ABBREVIATED FINANCIAL STATEMENTS

PONVORY® Product Line
(A Product Line of Actelion Pharmaceuticals Ltd.)

As of and for the Years Ended January 1, 2023 and January 2, 2022

PONVORY® Product Line

Special Purpose Abbreviated Financial Statements
As of and for the Years Ended January 1, 2023 and January 2, 2022

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Report of Independent Auditors

To the Management of Johnson & Johnson

Opinion

We have audited the accompanying special purpose abbreviated financial statements of the PONVORY® Product Line of Actelion Pharmaceuticals, Ltd. (the “Company”), which comprise the special purpose abbreviated statement of assets acquired as of January 1, 2023 and January 2, 2022, and the related special purpose abbreviated statement of revenues and direct expenses for the years then ended, including the related notes (collectively referred to as the “special purpose abbreviated financial statements”).

In our opinion, the accompanying special purpose abbreviated financial statements present fairly, in all material respects, the assets acquired of the PONVORY® Product Line of Actelion Pharmaceuticals, Ltd. as of January 1, 2023 and January 2, 2022, and its revenue and direct expenses for the years then ended in accordance with accounting principles generally accepted in the United States of America.

Basis for Opinion

We conducted our audit in accordance with auditing standards generally accepted in the United States of America (US GAAS). Our responsibilities under those standards are further described in the Auditors’ Responsibilities for the Audit of the Special Purpose Abbreviated Financial Statements section of our report. We are required to be independent of the Company and to meet our other ethical responsibilities, in accordance with the relevant ethical requirements relating to our audit. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Emphasis of Matter

The accompanying special purpose abbreviated financial statements were prepared in connection with Actelion Pharmaceuticals, Ltd.’s divestiture of the PONVORY® Product Line and, as described in Note 2, were prepared for the purpose of complying with the rules and regulations of the Securities and Exchange Commission. These special purpose abbreviated financial statements are not intended to be a complete presentation of the financial position, results of operations or cash flows of the PONVORY® Product Line of Actelion Pharmaceuticals, Ltd. Our opinion is not modified with respect to this matter.

Responsibilities of Management for the Special Purpose Abbreviated Financial Statements

Management is responsible for the preparation and fair presentation of the special purpose abbreviated 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 the special purpose abbreviated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the special purpose abbreviated financial statements, management is required to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern for one year after the date the special purpose abbreviated financial statements are available to be issued.

Auditors’ Responsibilities for the Audit of the Special Purpose Abbreviated Financial Statements

Our objectives are to obtain reasonable assurance about whether the special purpose abbreviated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditors’ 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 US GAAS 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 special purpose abbreviated financial statements.

In performing an audit in accordance with US GAAS, we:

- Exercise professional judgment and maintain professional skepticism throughout the audit.
- Identify and assess the risks of material misstatement of the special purpose abbreviated 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 special purpose abbreviated 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 the Company'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 special purpose abbreviated financial statements.
- Conclude whether, in our judgment, there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company'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.

/s/PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 12, 2024

PONVORY® Product Line
Special Purpose Abbreviated Financial Statements
Statements of Assets Acquired as of January 1, 2023 and January 2, 2022
(In thousands)

	<u>January 1, 2023</u>	<u>January 2, 2022</u>
Intangible asset, net	\$ 36,844	\$ 513,479
Total Assets Acquired	<u>\$ 36,844</u>	<u>\$ 513,479</u>

The accompanying Notes are integral to the Special Purpose Abbreviated Financial Statements.

PONVORY® Product Line
Special Purpose Abbreviated Financial Statements
Statements of Revenues and Direct Expenses for the fiscal years ended January 1, 2023 and January 2, 2022
(In thousands)

	Fiscal years ended	
	January 1, 2023	January 2, 2022
Sales to customers, net	\$ 17,837	\$ 3,855
Direct expenses		
Cost of products sold	52,199	42,359
Selling, marketing and administrative expenses	73,853	97,533
Research and development expense	19,393	24,308
Impairment of intangible asset	426,129	—
Total direct expenses	571,574	164,200
Direct expenses in excess of sales to customers	\$ (553,737)	\$ (160,345)

The accompanying Notes are integral to the Special Purpose Abbreviated Financial Statements.

PONVORY® Product Line
Notes to Special Purpose Abbreviated Financial Statements
(In thousands)

Note 1. Background

Actelion Pharmaceuticals Ltd. (“Actelion”) is a wholly owned subsidiary of Johnson & Johnson (the “Parent” and, together with its subsidiaries, the “Company”).

Actelion has agreed to divest the U.S. and Canadian rights associated with PONVORY® (ponesimod) (collectively the “Product Line”), which is a daily, oral prescription medicine approved by the U.S. Food and Drug Administration (“FDA”) and Health Canada to treat adults with relapsing forms of multiple sclerosis (RMS), which includes clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.

On December 7, 2023, Actelion executed an asset purchase agreement (the “Agreement”) with Vanda Pharmaceuticals Inc., a Delaware Corporation, (“Vanda” or “Buyer”) to sell the U.S. and Canadian rights of PONVORY® (ponesimod) for a total purchase price of \$100 million. The Agreement includes the transfer of patents, trademarks and intellectual property associated with PONVORY®. In connection with the Agreement, Actelion and the Buyer have agreed to enter into a transition agreement.

Note 2. Basis of Presentation

These Special Purpose Abbreviated Financial Statements as of and for the fiscal years ended January 1, 2023 and January 2, 2022 (the “Financial Statements”) are derived from the historical accounting records of the Company and only present the assets acquired and the revenues and direct expenses, including certain allocated direct expenses, of the Product Line. It is impracticable to prepare complete financial statements related to the Product Line as it was not a separate legal entity of the Company and was never operated as a standalone business, division, segment or subsidiary. The Company has never prepared full stand-alone or full carve-out financial statements for the Product Line and has never maintained distinct and separate accounts necessary to prepare such financial statements. These Financial Statements are based upon the Agreement and relief under SEC Rule 3-05(e), *Financial statements of businesses acquired or to be acquired*, as the acquisition by Vanda meets the qualifying conditions established by the Securities and Exchange Commission to provide abbreviated financial statements in lieu of full financial statements of the acquired business.

The Financial Statements have been prepared to reflect the assets acquired by the Buyer in accordance with the Agreement and include costs directly associated with producing revenues, including a reasonable allocation of direct expenses, and exclude expenses (“Omitted Expenses”) not directly involved in revenue producing activities, such as corporate overhead unrelated to the operational activities, interest and income tax. Therefore, these Financial Statements are not intended to be a complete presentation of the financial position, results of operations or cash flows of the Product Line in conformity with accounting principles generally accepted in the United States of America. As the Product Line has historically been managed as part of the operations of the Company and has not been operated as a stand-alone entity, information about the Product Line operating, investing, and financing cash flows is not available. As such, statements of cash flows are not presented in the Financial Statements.

The operations of the Product Line rely, to varying degrees, on the Company for marketing, sales order processing, billing, collection, procurement, customer service, manufacturing, warehousing and distribution, information technology, insurance, human resources, accounting, regulatory, treasury, legal support, and other administrative services, and these expenses have been allocated in these Financial Statements. The Financial Statements are not indicative of the financial condition or results of operations of the Product Line on a go-forward and stand-alone basis because of the exclusion of Omitted Expenses and reliance of the Product Line on Actelion, the Parent and certain of their affiliates.

The Financial Statements include an intangible asset which represents the U.S. and Canadian rights of PONVORY® (ponesimod). The intangible asset was acquired through the Parent’s acquisition of Actelion in 2017 at which time the intangible asset was classified as Purchased In-process Research and Development (IPR&D). Upon FDA approval of PONVORY® on March 19, 2021, and commercialization shortly thereafter, the intangible asset began amortizing over its estimated useful life.

The operations of the Product Line are included in the consolidated federal income tax return of the Parent, to the extent appropriate, and are included in the foreign, state and local returns of certain other affiliates of the Parent. A provision for income taxes has not been presented in these Financial Statements as the Product Line has not operated as a stand-alone entity and no allocation of income tax provision or benefit has been made to the Product Line.

In accordance with the accounting guidance related to the presentation of financial statements, management evaluates whether there are conditions or events, considered in the aggregate that may impact the Product Line’s ability to continue as a going concern for the next twelve months from the date the financial statements are available to be issued. The Financial Statements have been prepared assuming that the Product Line will continue as a going concern, and do not include any adjustments relating to the carrying amounts and classification of assets that may be necessary should the Product Line be unable to continue as a going concern.

The Product Line has incurred net losses of \$553,737 and \$160,345 for the fiscal years ended January 1, 2023 and January 2, 2022, respectively, as a result of costs incurred to market and promote the Product Line, research and development costs incurred for post-marketing studies and non-cash impairment and amortization charges discussed in Note 5. Cash generated from the Product Line's operations is managed by the Company's centralized treasury function and is swept into the Company's bank accounts. The Company has continued to provide financing requirements to the Product Line through the date of the sale of the Product Line on December 7, 2023 after which time the Buyer has assumed responsibility for financing requirements of the Product Line. Accordingly, the Financial Statements have been prepared assuming that the Product Line will continue as a going concern.

Note 3. Certain Expenses and Allocations

Certain costs and expenses, which relate to revenue producing activities, presented in the Financial Statements have been allocated by management to the Product Line based on a specific identification basis or, when specific identification is not practicable, a proportional cost allocation method, depending on the nature of the services rendered. Management considers that such allocations have been made on a reasonable basis but may not necessarily be indicative of the costs that would have been incurred if the Product Line had been operated on a stand-alone basis for the fiscal years presented.

Allocations of corporate overhead cost from the Company unrelated to the operations and revenue producing activities of the Product Line have been excluded from these Financial Statements for all periods presented.

Cost of products sold include allocations for overhead incurred by the Company on behalf of the Product Line and primarily relate to compensation for employees, outside services and shared services. Selling, marketing and administrative expenses, represent operating expenses specifically attributable to the Product Line, including costs such as information technology and administrative costs. These costs are primarily allocated to the Product Line based on revenue or headcount.

Research and development costs primarily relate to the global clinical studies of PONVORY®. Costs incurred prior to regulatory approval (for which FDA approval occurred in the U.S. on March 19, 2021) primarily related to clinical studies evaluating the safety and efficacy of PONVORY®; whereas, costs incurred after regulatory approval primarily related to clinical studies to fulfil post-approval commitments required by various regulatory authorities. As the Product Line and the Company's PONVORY® business in other regions benefitted equally from the global clinical trials, including post-approval commitments, management allocated approximately half of the global worldwide research and development costs incurred by the Company to the Product Line.

Costs incurred by the Company related to the divestiture of the Product Line have not been included in these Financial Statements. These costs comprise of employee related costs, legal, audit and consultancy fees and other costs solely related to the divestiture of the Product Line.

Note 4. Summary of Significant Accounting Policies

Annual Closing Date

The Product Line follows the concept of a fiscal year, which ends on the Sunday nearest to the end of the month of December. The 2022 and 2021 fiscal years consist of 52 weeks, but every five or six years the fiscal year consists of 53 weeks.

Use of Estimates

The preparation of these Financial Statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported. The estimates and associated assumptions are based on historical experience, judgments and various other factors that are believed to be reasonable under the circumstances but are inherently uncertain. The estimation process required to prepare the Financial Statements, includes but is not limited to, allocation of certain direct costs and expenses from the Parent or other subsidiaries, accounting for deductions from revenue (e.g., rebates, sales discounts, and allowances), determination of the useful life of the intangible asset and the assessment of expected cash flows used in evaluating the intangible asset for impairment. Actual results may or may not differ from these estimates. Also, as discussed in Note 3, these Financial Statements include allocations and estimates that are not necessarily indicative of the amounts that would have resulted if the Product Line had been operated on a stand-alone basis.

Recently Adopted Accounting Standards

There were no new material accounting standards adopted in fiscal 2021 or 2022.

Recently Issued Accounting Standards

Not Adopted as of January 1, 2023:

ASU 2022-04: Liabilities-Supplier Finance Programs (Topic 405-50) – Disclosure of Supplier Finance Program Obligations

This update requires that a buyer in a supplier finance program disclose additional information about the program to allow financial statement users to better understand the effect of the programs on an entity's working capital, liquidity, and cash flows. This update will be effective for the Product Line for fiscal years beginning after December 15, 2022, except for the amendment on roll forward information, which is effective for fiscal years beginning after December 15, 2023. Early adoption is permitted.

The Company adopted the standard as of the beginning of fiscal year 2023, which requires that a buyer in a supplier finance program disclose additional information about the program for financial statement users. The Product Line does not have agreements for supplier finance programs with third-party financial institutions.

Intangible Asset

The Product Line's intangible asset represents the U.S. and Canadian rights of PONVORY® (ponesimod), which was IPR&D acquired as part of the Parent's acquisition of Actelion in 2017. The fair value of IPR&D is capitalized as an indefinite-lived intangible asset until the completion or abandonment of the related research and development activities. When the related research and development is completed, the asset will be assigned a useful life and amortized using the straight-line method over the estimated useful life. Accordingly, IPR&D was reclassified to Patents and Trademarks after FDA approval of PONVORY® on March 19, 2021, and began amortizing over its estimated useful life. The amortization expense is recorded in 'Cost of products sold' in the Financial Statements.

The Company reviews its intangible asset for impairment whenever events or changes in circumstances such as asset utilization, commercial events, legal factors or other matters indicate that the carrying value of the asset may not be recoverable. The impairment testing involves comparing the carrying amount of the asset to the forecasted undiscounted future cash flows. In the event the carrying value of the asset exceeds the undiscounted future cash flows, the carrying value is considered not recoverable and an impairment exists. An impairment loss is measured as the excess of the asset's carrying value over its fair value, calculated using discounted future cash flows.

Revenue Recognition

The Product Line recognizes revenue in line with the Company's policies and procedures. Revenue is recognized from product sales when obligations under the terms of a contract with the customer are satisfied; generally, this occurs with the transfer of control of the goods to customers. The Company's global payment terms are typically between 30 to 90 days. Provisions for certain rebates, sales incentives, product returns, discounts to customers and governmental programs are accounted for as variable consideration and recorded as a reduction in sales.

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions. Rebates are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions. Rebates primarily relate to Managed Care, Medicare and Medicaid programs. The Product Line evaluates market conditions primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. Sales returns are estimated and recorded based on historical sales and returns information. In accordance with the Company's accounting policies, the Product Line issues credit to customers for returned goods. The Product Line's sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns are generally not resalable.

The reconciliation of gross sales to customers to sales to customers, net by each significant category of gross-to-net adjustments was as follows:

	Fiscal years ended	
	January 1, 2023	January 2, 2022
Gross sales to customers	\$ 25,446	\$ 5,149
Gross-to-net adjustments:		
Rebates	5,346	581
Sales returns & other discounts	2,263	713
Total gross-to-net adjustments	7,609	1,294
Sales to customers, net	\$ 17,837	\$ 3,855

Shipping and Handling

Shipping and handling costs incurred were \$77 and \$17 for the fiscal years ended January 1, 2023 and January 2, 2022 and are included in 'Selling, marketing and administrative expenses' in the Financial Statements.

Research and Development

All costs associated with research and development activities are expensed as incurred. Research and development costs incurred prior to regulatory approval (for which FDA approval occurred in the U.S. on March 19, 2021) primarily related to global clinical studies evaluating the safety and efficacy of PONVORY®; whereas, costs incurred after regulatory approval primarily related to clinical studies for post-approval commitments required by various regulatory bodies.

Advertising

Costs associated with advertising are expensed in the fiscal year incurred and are included in 'Selling, marketing, and administrative expenses' on these Statements of Revenues and Direct Expenses. Such expenses were \$17,721 and \$45,559 for the fiscal years ended January 1, 2023 and January 2, 2022.

Stock Based Compensation

Certain eligible employees of the Company have been awarded stock option grants or restricted stock units under the Company's stock option plans. These stock options and restricted stock grants are accounted for under the fair value method of equity-based compensation accounting principles and have been recognized in these Financial Statements. Stock based compensation expense recognized was \$371 and \$352 for the fiscal years ended January 1, 2023 and January 2, 2022. Certain eligible employees of the Company also participated in various other Company benefit plans, as described in Note 6.

Concentration

In fiscal year 2022, the Product Line utilized four specialty distributors that represented approximately 42%, 25%, 18% and 15% of gross revenues, respectively. In fiscal year 2021, the Company utilized the same four specialty distributors that represented approximately 40%, 22%, 18% and 20% of gross revenues, respectively.

Note 5. Intangible asset, net

As of January 1, 2023 and January 2, 2022 the gross and net amounts of the intangible asset were:

	<u>January 1, 2023</u>	<u>January 2, 2022</u>
Gross carrying amount	\$ 555,567	\$ 555,567
Less: accumulated amortization	92,594	42,088
Less: impairment	426,129	—
Intangible asset, net	<u>\$ 36,844</u>	<u>\$ 513,479</u>

The intangible asset represents the U.S. and Canadian rights of PONVORY®. The intangible asset was acquired through the Parent's acquisition of Actelion in 2017 at which time the intangible asset was classified as In-process Research and Development (IPR&D). Upon FDA approval of PONVORY® on March 19, 2021, and commercialization shortly thereafter, the intangible asset began amortizing over its estimated useful life of 11 years for which as of January 1, 2023 there are 9 years remaining. The amortization expense recognized was \$50,506 and \$42,088 for the fiscal years ended January 1, 2023, and January 2, 2022, respectively.

Carrying amount changes from fiscal year 2021 to fiscal year 2022 are driven by impairment charges. Intangible assets with finite lives are tested for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Impairment charges associated with these assets are included in 'Impairment of intangible asset' in the Statements of Revenues and Direct Expenses. The Product Line continues to monitor the recoverability of its definite lived intangible asset and tests the asset for impairment if indicators of impairment are present.

The amortization expense for the five succeeding years is approximately \$4 million per year.

The Product Line recognized an impairment of \$426,129 resulting from the assessment of recoverability of the asset following the Company's decision at the end of the fourth quarter in 2022 to reduce commercial support for PONVORY® in the U.S. due to performance of the business to date and is reflected in 'Impairment of intangible asset' within the Financial Statements. In management's assessment of recoverability and determination of fair value, a discounted cash flow methodology was used which requires significant judgement and estimation. The fair value measurement was based on Level 3 inputs including estimated net sales to customers, cost of products sold, research and development costs, selling and marketing costs and discount rate. While management believes the assumptions used are reasonable and commensurate with the views of a market participant, changes in key assumptions for the intangible asset, including increasing the discount rate, lowering sales to customers forecasts, lowering the operating margin, could result in a future impairment. Other market factors and conditions could also result in downward revisions of the forecasts on future projected cash flows of the intangible asset.

Note 6. Employee benefit plans

These Financial Statements include certain employee benefit expenses. These benefits include medical, dental, comprehensive and preventive for active employees, group life insurance and employer match pursuant to the U.S. 401(k) savings plan. These are managed on a centralized basis by the Company and are calculated using charge-out rates for these benefits. The costs and charge-out rates are determined annually by the Company for allocation purposes among its affiliates.

For the fiscal years ended January 1, 2023 and January 2, 2022, \$1,241 and \$574 of employee benefit expenses are included within these Financial Statements.

Note 7. Subsequent events

The Financial Statements are derived from the accounts of the Company, which issued its most recent annual financial statements on February 16, 2023. Accordingly, the Product Line has evaluated transactions for recognition or disclosure in the annual financial statements through February 16, 2023. Additionally, the Product Line has evaluated transactions for purposes of disclosure of unrecognized subsequent events through February 12, 2024, the date these Financial Statements were available to be issued.

SPECIAL PURPOSE ABBREVIATED FINANCIAL STATEMENTS (UNAUDITED)

PONVORY® Product Line
(A Product Line of Actelion Pharmaceuticals Ltd.)

Statements of Assets Acquired as of October 1, 2023 (Unaudited) and January 1, 2023
Unaudited Statements of Revenues and Direct Expenses for the nine months ended October 1, 2023 and October 2, 2022

PONVORY® Product Line

Special Purpose Abbreviated Financial Statements (Unaudited)
Statements of Assets Acquired as of October 1, 2023 (Unaudited) and January 1, 2023
Statements of Revenues and Direct Expenses (Unaudited) for the nine months ended October 1, 2023 and October 2, 2022

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PONVORY® Product Line
Special Purpose Abbreviated Financial Statements (Unaudited)
Statements of Assets Acquired as of October 1, 2023 (Unaudited) and January 1, 2023
(In thousands)

	<u>October 1, 2023</u>	<u>January 1, 2023</u>
Intangible asset, net	\$ 33,829	\$ 36,844
Total Assets Acquired	<u>\$ 33,829</u>	<u>\$ 36,844</u>

The accompanying Notes are integral to the Special Purpose Abbreviated Financial Statements.

PONVORY® Product Line
Special Purpose Abbreviated Financial Statements (Unaudited)
Statements of Revenues and Direct Expenses (Unaudited) for the nine months ended October 1, 2023 and October 2, 2022
(In thousands)

	Nine months ended	
	October 1, 2023	October 2, 2022
Sales to customers, net	\$ 23,684	\$ 12,266
Direct expenses		
Cost of products sold	4,040	39,145
Selling, marketing and administrative expenses	11,908	57,151
Research and development expense	12,337	15,284
Total direct expenses	28,285	111,580
Direct expenses in excess of sales to customers	\$ (4,601)	\$ (99,314)

The accompanying Notes are integral to the Special Purpose Abbreviated Financial Statements.

PONVORY® Product Line
Notes to Special Purpose Abbreviated Financial Statements (Unaudited)
(In thousands)

Note 1. Background

Actelion Pharmaceuticals Ltd. (“Actelion”) is a wholly owned subsidiary of Johnson & Johnson (the “Parent” and, together with its subsidiaries, the “Company”).

Actelion has agreed to divest the U.S. and Canadian rights associated with PONVORY® (ponesimod) (collectively the “Product Line”), which is a daily, oral prescription medicine approved by the U.S. Food and Drug Administration (“FDA”) and Health Canada to treat adults with relapsing forms of multiple sclerosis (RMS), which includes clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.

On December 7, 2023, Actelion executed an asset purchase agreement (the “Agreement”) with Vanda Pharmaceuticals Inc., a Delaware Corporation, (“Vanda” or “Buyer”) to sell the U.S. and Canadian rights of PONVORY® (ponesimod) for a total purchase price of \$100 million. The Agreement includes the transfer of patents, trademarks and intellectual property associated with PONVORY®. In connection with the Agreement, Actelion and the Buyer have agreed to enter into a transition agreement.

Note 2. Basis of Presentation

These Special Purpose Abbreviated Statements of Assets Acquired as of October 1, 2023 and January 1, 2023 and the related Special Purpose Abbreviated Statements of Revenues and Direct Expenses for the nine months ended October 1, 2023 and October 2, 2022 (collectively the “Financial Statements”) are derived from the historical accounting records of the Company and only present the assets acquired and the revenues and direct expenses, including certain allocated direct expenses, of the Product Line. The unaudited interim financial statements include all adjustments (consisting only of normal recurring adjustments) and accruals necessary in the judgment of management for a fair statement of the results for the periods presented. It is impracticable to prepare complete financial statements related to the Product Line as it was not a separate legal entity of the Company and was never operated as a standalone business, division, segment or subsidiary. The Company has never prepared full stand-alone or full carve-out financial statements for the Product Line and has never maintained distinct and separate accounts necessary to prepare such financial statements. These Financial Statements are based upon the Agreement and relief under SEC Rule 3-05(e), *Financial statements of businesses acquired or to be acquired*, as the acquisition by Vanda meets the qualifying conditions established by the Securities and Exchange Commission to provide abbreviated financial statements in lieu of full financial statements of the acquired business.

The Financial Statements have been prepared to reflect the assets acquired by the Buyer in accordance with the Agreement and include costs directly associated with producing revenues, including a reasonable allocation of direct expenses, and exclude expenses (“Omitted Expenses”) not directly involved in revenue producing activities, such as corporate overhead unrelated to the operational activities, interest and income tax. Therefore, these Financial Statements are not intended to be a complete presentation of the financial position, results of operations or cash flows of the Product Line in conformity with accounting principles generally accepted in the United States of America. As the Product Line has historically been managed as part of the operations of the Company and has not been operated as a stand-alone entity, information about the Product Line operating, investing, and financing cash flows is not available. As such, statements of cash flows are not presented in the Financial Statements.

The operations of the Product Line rely, to varying degrees, on the Company for marketing, sales order processing, billing, collection, procurement, customer service, manufacturing, warehousing and distribution, information technology, insurance, human resources, accounting, regulatory, treasury, legal support, and other administrative services, and these expenses have been allocated in these Financial Statements. The Financial Statements are not indicative of the financial condition or results of operations of the Product Line on a go-forward and stand-alone basis because of the exclusion of Omitted Expenses and reliance of the Product Line on Actelion, the Parent and certain of their affiliates.

The Financial Statements include an intangible asset which represents the U.S. and Canadian rights of PONVORY® (ponesimod). The intangible asset was acquired through the Parent’s acquisition of Actelion in 2017 at which time the intangible asset was classified as Purchased In-process Research and Development (IPR&D). Upon FDA approval of PONVORY® on March 19, 2021, and commercialization shortly thereafter, the intangible asset began amortizing over its estimated useful life.

The operations of the Product Line are included in the consolidated federal income tax return of the Parent, to the extent appropriate, and are included in the foreign, state and local returns of certain other affiliates of the Parent. A provision for income taxes has not been presented in these Financial Statements as the Product Line has not operated as a stand-alone entity and no allocation of income tax provision or benefit has been made to the Product Line.

In accordance with the accounting guidance related to the presentation of financial statements, management evaluates whether there are conditions or events, considered in the aggregate, that may impact the Product Line's ability to continue as a going concern for the next twelve months from the date the financial statements are available to be issued. The Financial Statements have been prepared assuming that the Product Line will continue as a going concern, and do not include any adjustments relating to the carrying amounts and classification of assets that may be necessary should the Product Line be unable to continue as a going concern.

The Product Line has incurred net losses of \$4,601 and \$99,314 for the nine months ended October 1, 2023 and October 2, 2022, respectively, as a result of costs incurred to market and promote the Product Line, research and development costs incurred for post-marketing studies and non-cash amortization charges discussed in Note 4. Cash generated from the Product Line's operations is managed by the Company's centralized treasury function and is maintained in the Company's bank accounts. The Company has continued to provide financing requirements to the Product Line through the date of the sale of the Product Line on December 7, 2023 after which time the Buyer has assumed responsibility for financing requirements of the Product Line. Accordingly, the Financial Statements have been prepared assuming that the Product Line will continue as a going concern.

Note 3. Certain Expenses and Allocations

Certain costs and expenses, which relate to revenue producing activities, presented in the Financial Statements have been allocated by management to the Product Line based on a specific identification basis or, when specific identification is not practicable, a proportional cost allocation method, depending on the nature of the services rendered. Management considers that such allocations have been made on a reasonable basis but may not necessarily be indicative of the costs that would have been incurred if the Product Line had been operated on a stand-alone basis for the periods presented.

Allocations of corporate overhead cost from the Company unrelated to the operations and revenue producing activities of the Product Line have been excluded from these Financial Statements for all periods presented.

Cost of products sold include allocations for overhead incurred by the Company on behalf of the Product Line and primarily relate to compensation for employees, outside services and shared services incurred. Cost of products sold and selling, marketing and administrative expenses, represent operating expenses, specifically attributable to the Product Line, including costs such as information technology and administrative costs. These costs are primarily allocated to the Product Line based on revenue or headcount.

Research and development costs primarily relate to the global clinical studies of PONVORY®. Costs incurred prior to regulatory approval (for which FDA approval occurred in the U.S. on March 19, 2021) primarily related to clinical studies evaluating the safety and efficacy of PONVORY®; whereas, costs incurred after regulatory approval primarily related to clinical studies to fulfil post-approval commitments required by various regulatory authorities. As the Product Line and the Company's PONVORY® business in other regions benefitted equally from the global clinical trials, including post-approval commitments, management allocated approximately half of the global worldwide research and development costs incurred by the Company to the Product Line.

Costs incurred by the Company related to the divestiture of the Product Line have not been included in these Financial Statements. These costs comprise of employee related costs, legal, audit and consultancy fees and other costs solely related to the divestiture of the Product Line.

Note 4. Summary of Significant Accounting Policies

Use of Estimates

The preparation of these Financial Statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported. The estimates and associated assumptions are based on historical experience, judgments and various other factors that are believed to be reasonable under the circumstances but are inherently uncertain. The estimation process required to prepare the Financial Statements, includes but is not limited to, allocation of certain direct costs and expenses from the Parent or other subsidiaries, accounting for deductions from revenue (e.g., rebates, sales discounts, and allowances), determination of the useful life of the intangible asset and the assessment of expected cash flows used in evaluating the intangible asset for impairment. Actual results may or may not differ from these estimates. Also, as discussed in Note 3, these Financial Statements include allocations and estimates that are not necessarily indicative of the amounts that would have resulted if the Product Line had been operated on a stand-alone basis.

Recently Adopted Accounting Standards

ASU 2022-04: Liabilities-Supplier Finance Programs (Topic 405-50) – Disclosure of Supplier Finance Program Obligations The Company adopted the standard as of the beginning of fiscal year 2023, which requires that a buyer in a supplier finance program disclose additional information about the program to allow financial statement users to better understand the effect of the programs on an entity's working capital, liquidity, and cash flows. The Product Line does not have agreements for supplier finance programs with third-party financial institutions.

There were no new material accounting standards issued in the nine months ended October 1, 2023.

Intangible Asset

The Product Line’s intangible asset represents the U.S. and Canadian rights of PONVORY® (ponesimod), which was IPR&D acquired as part of the Parent’s acquisition of Actelion in 2017. The fair value of IPR&D is capitalized as an indefinite-lived intangible asset until the completion or abandonment of the related research and development activities. When the related research and development is completed, the asset will be assigned a useful life and amortized using the straight-line method over the estimated useful life. Accordingly, IPR&D was reclassified to Patents and Trademarks after FDA approval of PONVORY® on March 19, 2021, and began amortizing over its estimated useful life of 11 years. The amortization expense is recorded in ‘Cost of products sold’ in the Financial Statements.

The Company reviews its intangible asset for impairment whenever events or changes in circumstances such as asset utilization, commercial events, legal factors or other matters indicate that the carrying value of the asset may not be recoverable. The impairment testing involves comparing the carrying amount of the asset to the forecasted undiscounted future cash flows. In the event the carrying value of the asset exceeds the undiscounted future cash flows, the carrying value is considered not recoverable and an impairment exists. An impairment loss is measured as the excess of the asset’s carrying value over its fair value, calculated using discounted future cash flows. The Product Line recognized an impairment of \$426,129 resulting from the assessment of recoverability of the asset following the Company’s decision at the end of the fourth quarter in 2022 to reduce commercial support for PONVORY® in the U.S. due to the performance of the business to date.

Intangible asset amortization expense was \$3,015 and \$37,881 for the nine months ended October 1, 2023, and October 2, 2022, respectively.

Revenue Recognition

The Product Line recognizes revenue in line with the Company’s policies and procedures. Revenue is recognized from product sales when obligations under the terms of a contract with the customer are satisfied; generally, this occurs with the transfer of control of the goods to customers. The Company’s global payment terms are typically between 30 to 90 days. Provisions for certain rebates, sales incentives, product returns, discounts to customers and governmental programs are accounted for as variable consideration and recorded as a reduction in sales.

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions. Rebates are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions. Rebates primarily relate to Managed Care, Medicare and Medicaid programs. The Product Line evaluates market conditions primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. Sales returns are estimated and recorded based on historical sales and returns information. In accordance with the Company’s accounting policies, the Product Line issues credit to customers for returned goods. The Product Line’s sales returns reserves are accounted for in accordance with the U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns are generally not resalable.

The reconciliation of gross sales to customers to sales to customers, net by each significant category of gross-to-net adjustments was as follows:

	Nine months ended	
	October 1, 2023	October 2, 2022
Gross sales to customers	\$ 33,589	\$ 16,429
Gross-to-net adjustments:		
Rebates	8,175	2,865
Sales returns & other discounts	1,730	1,298
Total gross-to-net adjustments	9,905	4,163
Sales to customers, net	\$ 23,684	\$ 12,266

Shipping and Handling

Shipping and handling costs incurred were \$102 and \$53 for the nine months ended October 1, 2023 and October 2, 2022, and are included in 'Selling, marketing and administrative expenses' in the Financial Statements.

Research and Development

All costs associated with research and development activities are expensed as incurred. Research and development costs incurred prior to regulatory approval (for which FDA approval occurred in the U.S. on March 19, 2021) primarily related to global clinical studies evaluating the safety and efficacy of PONVORY®; whereas, costs incurred after regulatory approval primarily related to clinical studies for post-approval commitments required by various regulatory bodies.

Advertising

Costs associated with advertising are expensed in the fiscal year incurred and are included in 'Selling, marketing, and administrative expenses' on these Statements of Revenues and Direct Expenses. Such expenses were \$1,431 and \$16,514 for the nine months ended October 1, 2023 and October 2, 2022.

Stock Based Compensation

Certain eligible employees of the Company have been awarded stock option grants or restricted stock units under the Company's stock option plans. These stock options and restricted stock grants are accounted for under the fair value method of equity-based compensation accounting principles and have been recognized in these Financial Statements. Stock based compensation expense recognized was \$145 and \$278 for the nine months ended October 1, 2023 and October 2, 2022. Certain eligible employees of the Company also participated in various other Company benefit plans.

Concentration

In the fiscal nine months ended October 1 2023, the Product Line utilized four specialty distributors that represented approximately 41%, 27%, 20% and 12% of gross revenues, respectively. In the fiscal nine months ended October 2, 2022, the Company utilized the same four specialty distributors that represented approximately 42%, 27%, 13% and 18% of gross revenues, respectively.

Note 5. Subsequent events

The Financial Statements are derived from the accounts of the Company, which issued its financial statements for the fiscal nine months ended October 1, 2023 on October 27, 2023. Accordingly, the Product Line has evaluated transactions for recognition or disclosure in these Financial Statements through October 27, 2023. Additionally, the Product Line has evaluated transactions for purposes of disclosure of unrecognized subsequent events through February 12, 2024, the date these Financial Statements were available to be issued.

VANDA PHARMACEUTICALS INC.
PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS (unaudited)

On December 7, 2023, Vanda Pharmaceuticals Inc. (Vanda or the Company) entered into an Asset Purchase Agreement to acquire certain assets comprising the exclusive rights to market and sell PONVORY® within the United States (U.S.) and Canada (Ponvory or Purchased Assets) from Actelion Pharmaceuticals Ltd. (Janssen), a Johnson & Johnson Company, and the closing of the transaction took place simultaneously with signing (the Acquisition). PONVORY® is a once-daily oral selective sphingosine-1-phosphate receptor 1 modulator, indicated to treat adults with relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease.

The pro forma information presented herein consists of unaudited pro forma condensed combined statements of operations for the year ended December 31, 2023. The presentation of the unaudited pro forma condensed combined statements of operations for the year ended December 31, 2023 reflects the combined results as if the Acquisition had occurred on January 1, 2023, the beginning of the Company's 2023 fiscal year. Ponvory's historical financial statements of the Purchased Assets as included in these unaudited pro forma condensed combined financial statements include activities from January 2, 2023 through the December 7, 2023 date of acquisition. The one day difference in fiscal year start date was not material for adjustment in these unaudited pro forma condensed combined financial statements. Ponvory's balance sheet has already been reflected in the Consolidated Balance Sheet of the Company in the annual report on Form 10-K (Annual Report) for the fiscal year ended December 31, 2023.

The unaudited pro forma condensed combined financial statements include adjustments that reflect the accounting for the Acquisition in accordance with accounting principles generally accepted in the United States (U.S. GAAP). The transaction accounting adjustments consist of those necessary to account for the Acquisition.

As discussed in Note 2 to the unaudited pro forma condensed combined financial statements, the Company has concluded, in accordance with U.S. GAAP, that the Acquisition does not meet the definition of a business. However, for purposes of this Form 8-K/A, and in accordance with S-X 11-01, the Acquisition is considered the purchase of a business.

The unaudited pro forma condensed combined financial statements should be read in conjunction with (i) the historical financial statements of the Company included in its Annual Report for the year ended December 31, 2023 filed with the SEC on February 8, 2024 and (ii) the Special Purpose Abbreviated Financial Statements of Ponvory as of and for the years ended January 1, 2023 and January 2, 2022, and as of October 1, 2023 and for the nine months ended October 1, 2023 and October 2, 2022, included in Exhibits 99.1 and 99.2 of this Form 8-K/A.

The unaudited pro forma condensed combined financial statements are provided for informational purposes only and are not necessarily indicative of results that would have occurred had the Acquisition been completed as of the date indicated. In addition, the unaudited pro forma condensed combined financial statements do not purport to be indicative of the future financial position or operating results of the combined operations. Actual financial conditions and results of operations may differ significantly from the pro forma amounts reflected herein due to a variety of factors.

VANDA PHARMACEUTICALS INC.
PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS (Unaudited)
For the year ended December 31, 2023

<i>(in thousands, except for share and per share amounts)</i>	Vanda (Historical)	Ponvory (Historical) for the Nine Months Ended October 1, 2023 Adjusted for Reclassifications (Note 2)	Ponvory (Historical) for the Period October 2, 2023 to December 7, 2023 Adjusted for Reclassifications (Note 2)	Transaction Accounting Adjustments	Notes	Pro Forma Condensed Combined
Revenues:						
Net product sales	\$ 192,640	\$ 23,684	\$ 5,345	\$ —		\$ 221,669
Total revenues	192,640	23,684	5,345	—		221,669
Operating expenses:						
Cost of goods sold excluding amortization	14,796	1,025	321	—		16,142
Research and development	76,823	12,337	1,453	—		90,613
Selling, general and administrative	112,883	11,908	1,438	—		126,229
Intangible asset amortization	2,090	3,015	748	3,753	2a	9,606
Total operating expenses	206,592	28,285	3,960	3,753		242,590
Income (loss) from operations	(13,952)	(4,601)	1,385	(3,753)		(20,921)
Other income	20,291	—	—	—		20,291
Income (loss) before income taxes	6,339	(4,601)	1,385	(3,753)		(630)
Provision (benefit) for income taxes	3,830	—	—	(1,558)	2b	2,272
Net income (loss)	<u>\$ 2,509</u>	<u>\$ (4,601)</u>	<u>\$ 1,385</u>	<u>\$ (2,195)</u>		<u>\$ (2,902)</u>
Net income (loss) per share:						
Basic	<u>\$ 0.04</u>					<u>\$ (0.05)</u>
Diluted	<u>\$ 0.04</u>					<u>\$ (0.05)</u>
Weighted average shares outstanding:						
Basic	<u>57,380,975</u>					<u>57,380,975</u>
Diluted	<u>57,557,911</u>					<u>57,380,975</u>

See accompanying notes to unaudited pro forma condensed combined financial information.

VANDA PHARMACEUTICALS INC.
NOTES TO PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS (Unaudited)

1. Basis of Presentation

The unaudited pro forma condensed combined financial information and related notes are prepared in accordance with Article 11 of Regulation S-X. The Company and Ponvory's financial statements included in the unaudited pro forma condensed combined financial statements have been prepared in accordance with U.S. GAAP. The historical financial statements have been adjusted in the unaudited pro forma condensed combined financial statements to give effect to pro forma events that reflect the accounting for the Acquisition in accordance with U.S. GAAP.

The unaudited pro forma condensed combined financial statements have been prepared in a manner consistent with the accounting policies adopted by the Company. The accounting policies of PONVORY® have been determined to be similar in all material respects to the Company's accounting policies. Other than the reclassification discussed below, no adjustments for accounting policy differences have been reflected in the unaudited pro forma condensed combined financial statements.

2. Transaction Accounting and Reclassification Adjustments

The Company accounted for the Acquisition as an asset acquisition in accordance with ASC 805-50 because substantially all of the fair value of the assets acquired is concentrated in a single asset, the PONVORY® product rights. The PONVORY® products rights consist of certain patents and trademarks, regulatory approvals, marketing assets, and other records, and are considered a single asset as they are inextricably linked. The total consideration for the acquisition was \$104.9 million consisting of cash paid to Janssen and acquisition-related transaction costs, of which \$4.2 million of the consideration was accrued as of December 31, 2023. The total consideration was fully allocated to the acquired intangible asset for the U.S. and Canada rights to PONVORY®.

The Purchase Agreement includes customary representations, warranties and covenants, as well as standard mutual indemnities covering losses arising from any material breach of the Purchase Agreement or inaccuracy of representations and warranties. Janssen has agreed to indemnify the Company against losses arising from its activities prior to the closing, and the Company has agreed to indemnify Janssen against losses arising from the Company's activities pertaining to PONVORY® after the closing. Simultaneously and in connection with the Purchase Agreement, the parties have also entered into certain supporting agreements, including a customary transition agreement, pursuant to which, during a transition period, Janssen will continue PONVORY® operations and the Company and Janssen will transition regulatory and supply responsibility for PONVORY® to the Company.

Reclassification adjustments

The amortization expense for the Ponvory intangible asset of \$3.0 million for the nine months ended October 1, 2023 and \$0.7 million for the period from October 2, 2023 to December 7, 2023 has been reclassified from the cost of goods sold line to the intangible asset amortization line to conform to the Company's financial statement presentation.

Adjustments to Unaudited Pro Forma Condensed Combined Statements of Operations

(2a) Intangible asset amortization

The PONVORY® intangible asset is being amortized on a straight-line basis through 2035, which is the estimated economic useful life of the related product rights. The table below reflects the adjustment to eliminate the historical intangible asset amortization expense and record the new intangible asset amortization expense.

<i>(in thousands)</i>	December 31, 2023
Amortization of PONVORY® product rights	\$ 7,516
Reversal of historical Ponvory amortization	(3,763)
Pro forma adjustment	<u>\$ 3,753</u>

(2b) Income tax provision (benefit)

The pro forma presentation of the effect on income tax provision (benefit) was calculated using a U.S. estimated statutory rate of 22.4%. The adjustments are summarized in the following table.

<i>(in thousands, except for statutory tax rate)</i>	Loss before income taxes	Statutory tax rate	Income tax benefit
Ponvory historical	\$ (3,216)	22.4%	\$ (719)
Transaction accounting adjustments	(3,753)	22.4%	(839)
Pro forma adjustment			<u>\$ (1,558)</u>