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

FORM 10-Q

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

For the quarterly period ended December 31, 2023

OR

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

For the transition period from _____ to _____

Commission File No. 001-38247

AYTU BIOPHARMA, INC.
(Exact name of registrant as specified in its charter)

Delaware	**47-0883144**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
7900 East Union Avenue, Suite 920 , Denver , Colorado 80237	**(720) 437-6580**
(Address of principal executive offices and zip code)	(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value	**AYTU**	**The NASDAQ Stock Market LLC**

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

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

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

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

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

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

As of February 1, 2024, the registrant had 5,567,597 shares of common stock outstanding.

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CAUTIONARY INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This Report on Form 10-Q ("Form 10-Q" or "this report") includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended ("Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended ("Exchange Act"). All statements other than statements of historical facts contained in this report, including statements regarding our anticipated future clinical and regulatory events, future financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. Forward looking statements are generally written in the future tense and/or are preceded by words such as "may," "will," "should," "forecast," "could," "expect," "suggest," "believe," "estimate," "continue," "anticipate," "intend," "plan," or similar words, or the negatives of such terms or other variations on such terms or comparable terminology. Such forward-looking statements include, without limitation: our anticipated future cash position; the planned expanded commercialization of our products and the potential future commercialization of our product candidates; our anticipated future growth rates; anticipated sales increases; anticipated net revenue increases; amounts of certain future expenses and costs of goods sold; our plans to acquire additional assets or dispose of assets, anticipated increases or decreases to operating expenses, and selling, general, and administrative expenses; and future events under our current and potential future collaborations.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including without limitation the risks described in "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the year ended June 30, 2023 (" 2023 Form 10-K"), and in the reports we file with the U.S. Securities and Exchange Commission ("SEC"). These risks are not exhaustive. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Forward-looking statements should not be relied upon as predictions of future events. We can provide no assurance that the events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. We assume no obligation to update or supplement forward-looking statements, except as may be required under applicable law.

This Form 10-Q refers to trademarks, such as Aytu, Aytu BioPharma, Adzenys XR-ODT, Cotempla XR-ODT, Innovus Pharma, Neos, Neos Therapeutics, Poly-Vi-Flor, and Tri-Vi-Flor, which are protected under applicable intellectual property laws and are our property or the property of our subsidiaries. This Form 10-Q also contains trademarks, service marks, copyrights and trade names of other companies, which are the property of their respective owners. Solely for convenience, our trademarks and tradenames referred to in this Form 10-Q may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and tradenames.

PART 1 - FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

AYTU BIOPHARMA, INC.
UNAUDITED CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)

	December 31, 2023	June 30, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 19,529	$ 22,985
Accounts receivable, net	29,403	28,937
Inventories	13,001	11,995
Prepaid expenses	8,105	8,047
Other current assets	1,333	868
Total current assets	71,371	72,832
Non-current assets:		
Property and equipment, net	1,127	1,815
Operating lease right-of-use assets	2,133	2,054
Intangible assets, net	55,711	58,970
Other non-current assets	907	792
Total non-current assets	59,878	63,631
Total assets	**$ 131,249**	**$ 136,463**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 10,473	$ 13,478
Accrued liabilities	43,413	46,799
Short-term line of credit	1,026	1,563
Current portion of debt	39	85
Other current liabilities	9,236	7,090
Total current liabilities	64,187	69,015
Non-current liabilities:		
Debt, net of current portion	14,978	14,713
Derivative warrant liabilities	12,887	6,403
Other non-current liabilities	6,344	6,975
Total non-current liabilities	34,209	28,091
Commitments and contingencies (note 13)		
Stockholders' equity:		
Preferred stock, par value $.0001; 50,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, par value $.0001; 200,000,000 shares authorized; 5,567,347 and 5,517,174 shares issued and outstanding, respectively	1	1
Additional paid-in capital	345,321	343,485
Accumulated deficit	(312,469)	(304,129)
Total stockholders' equity	32,853	39,357
Total liabilities and stockholders' equity	**$ 131,249**	**$ 136,463**

The accompanying Notes to the Unaudited Consolidated Financial Statements are an integral part of this statement.

AYTU BIOPHARMA, INC.
UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Three Months Ended December 31,		Six Months Ended December 31,	
	2023	**2022**	**2023**	**2022**
Product revenue, net	$ 22,934	$ 26,279	$ 45,033	$ 53,934
Cost of sales	6,731	8,986	14,046	18,609
Gross profit	16,203	17,293	30,987	35,325
Operating expenses:				
Selling and marketing	6,576	10,560	13,998	20,662
General and administrative	5,439	8,018	12,395	15,340
Research and development	524	1,710	1,128	2,774
Amortization of intangible assets	1,300	1,198	2,606	2,395
Impairment expense	—	2,600	—	2,600
Loss from contingent consideration	—	75	—	230
Total operating expenses	13,839	24,161	30,127	44,001
Income (loss) from operations	**2,364**	**(6,868)**	**860**	**(8,676)**
Other expense, net	(1,179)	(1,228)	(1,888)	(2,312)
(Loss) gain on derivative warrant liabilities	(577)	1,403	(6,484)	3,594
Income (loss) before income tax	**608**	**(6,693)**	**(7,512)**	**(7,394)**
Income tax expense	828	—	828	—
Net loss	**$ (220)**	**$ (6,693)**	**$ (8,340)**	**$ (7,394)**
Basic and diluted weighted-average common shares outstanding	5,517,670	3,110,304	5,499,951	2,817,979
Basic and diluted net loss per common share	$ (0.04)	$ (2.15)	$ (1.52)	$ (2.62)

The accompanying Notes to the Unaudited Consolidated Financial Statements are an integral part of this statement.

AYTU BIOPHARMA, INC.
UNAUDITED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances, June 30, 2023	**5,517,174**	**$ 1**	**$ 343,485**	**$ (304,129)**	**$ 39,357**
Stock-based compensation expense	13,061	—	930	—	930
Net loss	—	—	—	(8,120)	(8,120)
Balances, September 30, 2023	**5,530,235**	**$ 1**	**$ 344,415**	**$ (312,249)**	**$ 32,167**
Stock-based compensation expense	108	—	820	—	820
Issuance of common stock with exercise of warrants	37,004	—	86	—	86
Net loss	—	—	—	(220)	(220)
Balances, December 31, 2023	**5,567,347**	**$ 1**	**$ 345,321**	**$ (312,469)**	**$ 32,853**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances, June 30, 2022	**1,928,941**	**$ —**	**$ 331,386**	**$ (287,078)**	**$ 44,308**
Stock-based compensation expense	(1,666)	—	1,177	—	1,177
Issuance of common stock, net of issuance cost	1,194,196	—	3,564	—	3,564
Net loss	—	—	—	(701)	(701)
Balances, September 30, 2022	**3,121,471**	**$ —**	**$ 336,127**	**$ (287,779)**	**$ 48,348**
Stock-based compensation expense	(19,228)	—	3,067	—	3,067
Issuance of common stock, net of issuance cost	280,902	—	1,095	—	1,095
Net loss	—	—	—	(6,693)	(6,693)
Balances, December 31, 2022	**3,383,145**	**$ —**	**$ 340,289**	**$ (294,472)**	**$ 45,817**

The accompanying Notes to the Unaudited Consolidated Financial Statements are an integral part of this statement.

AYTU BIOPHARMA, INC.
UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Six Months Ended December 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (8,340)	$ (7,394)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation, amortization and accretion	4,409	4,507
Stock-based compensation expense	1,750	4,244
Loss (gain) on derivative warrant liabilities	6,484	(3,594)
Amortization of senior debt discount	302	315
Inventory write-down	133	82
Impairment expense	—	2,600
Loss from contingent consideration	—	230
Other noncash adjustments	(50)	(33)
Changes in operating assets and liabilities:		
Accounts receivable, net	(466)	(3,834)
Inventories	(1,140)	(2,183)
Prepaid expenses and other current assets	(321)	(4,606)
Accounts payable	(3,032)	(838)
Accrued liabilities	(3,927)	(1,008)
Other operating assets and liabilities, net	3,852	(76)
Net cash used in operating activities	**(346)**	**(11,588)**
Cash flows from investing activities:		
Contingent consideration payment	—	(5)
Other investing activities	(250)	42
Net cash (used in) provided by investing activities	**(250)**	**37**
Cash flows from financing activities:		
Proceeds from issuance of stock and warrants	86	11,573
Net (payments made on) proceeds received from, short-term line of credit	(537)	3,616
Payment made to fixed payment arrangement	(2,204)	(2,433)
Payment of stock issuance costs	(160)	(1,000)
Payments made to borrowings	(45)	—
Other financing activities	—	(64)
Net cash (used in) provided by financing activities	**(2,860)**	**11,692**
Net change in cash and cash equivalents	(3,456)	141
Cash and cash equivalents at beginning of period	22,985	19,360
Cash and cash equivalents at end of period	**$ 19,529**	**$ 19,501**
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 2,170	$ 2,021
Cash paid for income taxes	$ 432	$ —

The accompanying Notes to the Unaudited Consolidated Financial Statements are an integral part of this statement.

AYTU BIOPHARMA, INC.
NOTES TO THE UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

Note 1 - Nature of Business, Financial Condition, Basis of Presentation

Aytu BioPharma, Inc. ("Aytu", or the "Company"), is a pharmaceutical company focused on commercializing novel therapeutics. The Company operates through two business segments (i) the Rx Segment, consisting of prescription pharmaceutical products sold primarily through third party wholesalers and (ii) the Consumer Health Segment, which consists of various consumer healthcare products sold directly to consumers (the "Consumer Health Portfolio"). The Company was originally incorporated as Rosewind Corporation on August 9, 2002, in the State of Colorado and was re-incorporated as Aytu BioScience, Inc. in the state of Delaware on June 8, 2015. Following the acquisition of Neos Therapeutics, Inc. ("Neos") in March 2021, (the "Neos Acquisition") the Company changed its name to Aytu BioPharma, Inc.

On January 6, 2023, the Company effected a reverse stock split in which each common stockholder received one share of common stock for every twenty shares held (the "Reverse Stock Split"). All share and per share amounts in this quarterly report have been adjusted to reflect the effect of the Reverse Stock Split.

The Rx Segment primarily consists of two product portfolios. First the ADHD Portfolio, which consists of Adzenys XR-ODT (amphetamine) extended-release orally disintegrating tablets and Cotempla XR-ODT (methylphenidate) extended-release orally disintegrating tablets for the treatment of attention deficit hyperactivity disorder ("ADHD"). Second the Pediatric Portfolio, which consists of Poly-Vi-Flor and Tri-Vi-Flor, two complementary prescription fluoride-based supplement product lines containing combinations of fluoride and vitamins in various formulations for infants and children with fluoride deficiency, and Karbinal ER, an extended-release antihistamine suspension containing carbinoxamine indicated to treat numerous allergic conditions.

The Consumer Health Segment consists of multiple consumer health products competing in large healthcare categories, including allergy, hair regrowth, diabetes support, digestive health, sexual and urological health and general wellness, commercialized through direct mail and e-commerce marketing channels. To date, the Consumer Health Segment has generated negative cash flows. In fiscal 2023, the Company announced it would wind down the Consumer Health Segment in fiscal 2024.

The Company's strategy is to continue building its portfolio of revenue-generating prescription pharmaceutical products, leveraging its commercial team's expertise to build leading brands within large therapeutic markets. As a result of focusing on building the portfolio of revenue-generating products and generating profitability, in fiscal 2023, the Company indefinitely suspended active development of its clinical development programs including AR101 (enzastaurin) and terminated the license agreements relating to Healight and NT0502 (N-desethyloxybutynin).

As of December 31, 2023, the Company had $ 19.5 million of cash and cash equivalents and $ 29.4 million of accounts receivable. The Company's operations have historically consumed cash and may continue to consume cash in the future. The Company had a net loss of $ 0.2 million and $ 8.3 million during the three and six months ended December 31, 2023, respectively. The Company had an accumulated deficit of $ 312.5 million and $ 304.1 million as of December 31, 2023 and June 30, 2023, respectively. Cash used in operations was $0.4 million and $ 11.6 million during the six months ended December 31, 2023 and 2022, respectively.

In addition, the Company has non-operating liabilities that are scheduled to, or may become, current in the twelve months following the filing of this Form 10-Q, most notably the maturity of the $ 15 million Avenue Capital term note (the "Avenue Note") as discussed further in *Note 11 - Long-term Debt*. The Company expects to refinance the Avenue Note, however, there are no assurances the Company will be able to refinance the Avenue Note. As a result of this, there exists substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include adjustments that might be necessary if the Company is unable to continue as a going concern.

Management plans to mitigate the conditions that raise substantial doubt about its ability to continue as a going concern are primarily focused on (i) improving cash flows from operations, (ii) winding down the Consumer Health Segment, (iii) refinancing its $ 15 million Avenue Note to extend its maturity date, and, (iv), if necessary, raising additional capital through public or private equity offerings, debt offerings, or monetizing additional assets in order to meet its obligations. Management believes that the Company has adequate access to capital resources. However, the Company cannot provide any assurance that it will be able to raise additional capital, monetize assets, or obtain new financing on commercially acceptable terms. If the Company is unable to support its operations and obligations, it may be required to curtail its operations, or delay the execution of its business plan. Alternatively, any efforts by the Company to reduce its expenses may adversely impact its ability to sustain revenue-generating activities or otherwise operate its business. As a result, there can be no assurance that the Company will be successful in implementing its plans to alleviate this substantial doubt about its ability to continue as a going concern.

Basis of Presentation. The unaudited consolidated financial statements contained in this Form 10-Q represent the financial statements of the Company and its wholly owned subsidiaries and have been prepared pursuant to the rules and regulations of the SEC regarding interim financial reporting. Accordingly, certain information and disclosures normally included in the complete financial statements prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") have been omitted pursuant to such rules and regulations. The unaudited consolidated financial statements should be read in conjunction with the Company's 2023 Form 10-K, which included all disclosures required by U.S. GAAP. In the opinion of management, these unaudited consolidated financial statements contain all adjustments necessary for the fair statement of the financial position of the Company and the results of operations and cash flows for the interim periods presented. The consolidated balance sheet as of June 30, 2023, was derived from the audited annual financial statements but does not contain all of the footnote disclosure from the annual financial statements. The results of operations for the period ended December 31, 2023 are not necessarily indicative of expected operating results for the full year or any future period.

Prior Period Reclassification. Certain prior year amounts in the consolidated statements of operations have been reclassified to conform to the current year presentation, including a reclassification of the fair value adjustment from contingent consideration. Net gain or loss from the fair value of contingent consideration was previously included in other expense, net, and is currently recorded in operating expenses on the consolidated statements of operations. This reclassification did not impact net loss or cash flows for the three or six months ended December 31, 2023 and 2022 or the Company's financial position as of December 31, 2023 or June 30, 2023.

Note 2 - Significant Accounting Policies

Use of Estimates

Management uses estimates and assumptions relating to reporting amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In the accompanying unaudited consolidated financial statements, estimates are used for, but not limited to, stock-based compensation, revenue recognition, allowance for credit losses, determination of variable consideration for accruals of chargebacks, administrative fees and rebates, government rebates, returns and other allowances, write-downs for inventory obsolescence, valuation of financial instruments and intangible assets, accruals for contingent liabilities, fair value of long-lived assets, income tax provision, deferred taxes and valuation allowance, determination of right-of-use assets and lease liabilities, the depreciable lives of long-lived assets, classification of warrants equity versus liability, and the valuation of warrants and derivative warrant liability. Because of the uncertainties inherent in such estimates, actual results may differ from those estimates. Management periodically evaluates estimates used in the preparation of the financial statements for reasonableness.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC Topic 815, Derivatives and Hedging ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common shares and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding. Liability and equity classified warrants are valued using a Black-Scholes option model or Monte Carlo simulation model at issuance and for each reporting period when applicable.

Income Taxes

The Company calculates its quarterly income tax provision based on estimated annual effective tax rates applied to ordinary income (or loss) and other known items computed and recognized when they occur. There have been no changes in tax law affecting the tax provision during the three and six months ended December 31, 2023. The effective tax rate was 136.2 % and negative 11.0 % for the three and six months ended December 31, 2023, respectively, primarily driven by the limitations on losses as a result of Section 382 of the Internal Revenue Code changes in ownership coupled with existing valuation allowances. The effective tax rate was 0 % for both the three and six months ended December 31, 2022, respectively, reflecting the full valuation allowance and no impact of Section 382 of the Internal Revenue Code.

An ownership change could limit the Company's ability to offset, post-change, U.S. federal taxable income. Section 382 of the Internal Revenue Code imposes an annual limitation on the amount of post-ownership change taxable income a corporation may offset with pre-ownership change net operating loss carryforwards and certain recognized built-in losses. Previous acquisitions, financing transactions, and equity ownership changes in the past five years have caused a significant limitation on the Company's ability to use the pre-acquisition net operating loss carryovers. The ownership changes could result in increased future tax liability and are a driver of the change from a zero percent effective tax rate.

Employee Retention Credit

On March 27, 2020, the U.S. government enacted the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") to provide certain relief as a result of the COVID-19 pandemic. The CARES Act provides tax relief, along with other stimulus measures, including a provision for an Employee Retention Credit ("ERC"), which allows for employers to claim a refundable payroll tax credit against the employer share of Social Security tax equal to 70% of the qualified wages paid to employees after December 31, 2020 through September 30, 2021. The ERC was designed to encourage businesses to keep employees on the payroll during the COVID-19 pandemic.

As there is no authoritative guidance under U.S. GAAP on accounting for government assistance to for-profit business entities, the Company will account for the ERC by analogy to International Accounting Standard ("IAS") 20, Accounting for Government Grants and Disclosure of Government Assistance ("IAS 20"). In accordance with IAS 20, when management determines reasonable assurance that the Company had substantially met all eligibility requirements of the ERC, the ERC benefit shall be recognized as other income in the consolidated statement of operations (see *Note - 9 Other Liabilities*).

Recently Adopted Accounting Pronouncements

Financial Instruments – ***Credit Losses.*** In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses* ("ASU 2016-13") requiring the measurement of expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions and reasonable forecasts. The main objective of ASU 2016-13 is to provide additional information about the expected credit losses on financial instruments and other commitments to extend credit. The standard was effective for interim and annual reporting periods beginning after December 15, 2019. However, in October 2019, the FASB approved deferral of the adoption date for smaller reporting companies for fiscal periods beginning after December 15, 2022. The effective dates for the amendments in ASU 2022-02 align with those of ASU 2016-13. The Company adopted ASU 2016-13 and ASU 2019-05 on July 1, 2023. The Company evaluated the impact of adoption of ASUs 2016-13, 2019-05, and 2022-02 and concluded that the application of the new standards did not have a material impact on the Company's consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

Debt - ***Debt with Conversion and Other Options.*** In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging— Contracts in Entity's Own Equity (Subtopic 815-40)— Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies the accounting for convertible instruments by removing major separation models currently required. Consequently, more convertible debt instruments will be reported as a single liability instrument with no separate accounting for embedded conversion features. The amendments in this update are effective for public entities that are smaller reporting companies, as defined by the SEC, for the fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted through a modified retrospective or full retrospective method. The Company will adopt the guidance on July 1, 2024 and does not expect the adoption of the standard to have a material impact on the Company's consolidated financial statements.

Segment Reporting - Improvements to Reportable Segment Disclosures. In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ("ASU 2023-07"). ASU 2023-07 was issued to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The guidance should be applied retrospectively unless it is impracticable to do so. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods in fiscal years beginning after December 15, 2024. Early adoption is permitted, including in an interim period. The Company is currently evaluating the provisions of this guidance and assessing the potential impact on the Company's consolidated financial statements and disclosures.

For a complete set of the Company's significant accounting policies, refer to the Company's 2023 Form 10-K. Other than the application of IAS 20 for the ERC, there have been no significant changes to the Company's significant accounting policies during the six months ended December 31, 2023.

Note 3 - Revenues from Contracts with Customers

Net product revenue in the Rx Segment consists of sales of prescription pharmaceutical products, principally to a limited number of wholesale distributors and pharmacies in the United States. Rx Segment net product revenue is recognized at the point in time that control of the product transfers to the customer, which typically aligns with shipping terms (i.e., upon delivery), generally "free-on-board" destination when shipped domestically within the United States, consistent with contractual terms.

The Company generates Consumer Health Segment revenue from sales of various consumer health products through e-commerce platforms and direct-to-consumer marketing channels. Revenue is generally recognized "free-on-board" shipping point, consistent with contractual terms and aligning with the transfer of control of the products. Taxes assessed by a governmental authority that are both imposed on and concurrent with a specific revenue-producing transaction that are collected by the Company from customers are excluded from revenue. Shipping and handling costs associated with outbound freight after control over a product has transferred to a customer are accounted for as a fulfillment cost, and are included in cost of sales.

Savings offers, rebates, and wholesaler chargebacks reflect the terms of underlying agreements, which may vary. Accordingly, actual amounts will depend on the mix of sales by product and contracting entity. Future returns may not follow historical trends. The Company's periodic adjustments of its estimates are subject to time delays between the initial product sale, and the ultimate reporting and settlement of deductions. The Company continually monitors these provisions and does not believe variances between actual and estimated amounts have been or will be material.

Revenues by Segment. Net product revenue disaggregated by segment for the three and six months ended December 31, 2023 and 2022 were as follows:

	Three Months Ended December 31,		Six Months Ended December 31,	
	2023	2022	2023	2022
	(in thousands)			
Consolidated net revenue:				
Rx Segment	$ 18,748	$ 18,029	$ 36,565	$ 36,681
Consumer Health Segment	4,186	8,250	8,468	17,253
Total consolidated net revenue	$ 22,934	$ 26,279	$ 45,033	$ 53,934

Revenues by Product Portfolio. Net product revenue disaggregated by significant product portfolio in the Rx Segment for the three and six months ended December 31, 2023 and 2022 were as follows:

	Three Months Ended December 31,		Six Months Ended December 31,	
	2023	2022	2023	2022
	(in thousands)			
Rx Segment net revenue:				
ADHD Portfolio	$ 16,572	$ 11,120	$ 31,700	$ 22,705
Pediatric Portfolio	2,145	6,328	4,710	12,886
Other	31	581	155	1,090
Total Rx Segment net revenue	$ 18,748	$ 18,029	$ 36,565	$ 36,681

Other includes discontinued products in the Rx Segment. The Consumer Health Segment is comprised of one product portfolio, the Consumer Health Portfolio.

Revenues by Geographic location. The Company's revenues are predominately within the United States, with insignificant sales internationally.

Note 4 - Inventories

Inventories consist of raw materials, work in process and finished goods, and are recorded at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis. The Company periodically reviews the composition of its inventories to identify obsolete, slow-moving or otherwise unsaleable items. In the event that such items are identified and there are no alternate uses for the inventory, the Company will record a charge to reduce the value of the inventory to net realizable value in the period first recognized. The Company incurred inventory write-downs of $ 0.1 million and zero for each of the three months ended December 31, 2023 and 2022, respectfully, and $ 0.1 million for each of the six months ended December 31, 2023 and 2022.

Inventory balances consist of the following:

	December 31, 2023	June 30, 2023
	(in thousands)	
Raw materials	$ 1,654	$ 1,301
Work in process	2,674	2,956
Finished goods	8,673	7,738
Inventories	$ 13,001	$ 11,995

Note 5 - Property and Equipment

Properties and equipment are recorded at cost and depreciated on a straight-line basis over the assets' estimated economic life. Leasehold improvements are amortized over the shorter of the estimated economic life or remaining lease term.

Property and equipment consist of the following:

	December 31, 2023	June 30, 2023
	(in thousands)	
Manufacturing equipment	$ 1,183	$ 2,433
Office equipment, furniture and other	1,146	1,125
Leasehold improvements	999	999
Lab equipment	832	832
Assets under construction	45	107
Property and equipment, gross	4,205	5,496
Less: accumulated depreciation and amortization	(3,078)	(3,681)
Property and equipment, net	$ 1,127	$ 1,815

Depreciation and amortization expense from property and equipment was $ 0.3 million and $ 0.4 million for the three months ended December 31, 2023 and 2022, respectfully, and $ 0.6 million and $ 0.7 million for the six months ended December 31, 2023 and 2022, respectively.

Note 6 - Leases

The Company has entered into various operating lease agreements for certain of its offices, manufacturing facilities and equipment, and finance lease agreements for certain equipment. These leases have original lease periods expiring between fiscal 2024 and fiscal 2029. Most leases include one or more options to renew, and the exercise of a lease renewal option typically occurs at the discretion of both parties. Certain leases also include options to purchase the leased property. The Company's lease agreements generally do not contain any material residual value guarantees or material restrictive covenants.

In May 2023, the Company entered into a lease agreement to relocate its principal office. The space was made available to the Company in September 2023 (lease commencement) with an initial term of five and a half years. The Company recorded an operating lease right-of-use ("ROU") asset of $ 0.7 million and a lease liability of $ 0.7 million at lease commencement. The ROU asset and lease liability were recorded at present value using an incremental borrowing rate of 10.3 %. The Company utilized the practical expedient to not separate lease and non-lease components upon recognition.

The components of lease expenses are as follows:

	Three Months Ended December 31,		Six Months Ended December 31,		
	2023	2022	2023	2022	Statement of Operations Classification
	(in thousands)				
Lease cost:					
Operating lease cost	$ 381	$ 359	$ 741	$ 716	Operating expenses
Short-term lease cost	21	19	44	44	Operating expenses
Finance lease cost:					
Amortization of leased assets	15	19	29	37	Cost of sales
Interest on lease liabilities	1	2	2	5	Other expense, net
Total net lease cost	$ 418	$ 399	$ 816	$ 802	

Supplemental balance sheet information related to leases is as follows:

	December 31, 2023	June 30, 2023	Balance Sheet Classification
	(in thousands)		
Assets:			
Operating lease assets	$ 2,133	$ 2,054	Operating lease right-of-use assets
Finance lease assets	—	159	Property and equipment, net
Total lease assets	$ 2,133	$ 2,213	
Liabilities:			
Current:			
Operating leases	$ 1,369	$ 1,258	Other current liabilities
Finance leases	39	85	Current portion of debt
Non-current:			
Operating leases	845	832	Other non-current liabilities
Total lease liabilities	$ 2,253	$ 2,175	

Remaining lease term and discount rate used are as follows:

	December 31, 2023	June 30, 2023
Weighted-average remaining lease term (years):		
Operating lease assets	2.62	1.72
Finance lease assets	0.37	0.87
Weighted-average discount rate:		
Operating lease assets	8.85%	7.78%
Finance lease assets	6.54%	6.54%

Supplemental cash flow information related to lease is as follows:

	Six Months Ended December 31,	
	2023	2022
	(in thousands)	
Cash flow classification of lease payments:		
Operating cash flows from operating leases	$ 697	$ 716
Operating cash flows from finance leases	$ 2	$ 5
Financing cash flows from finance leases	$ 46	$ 52

As of December 31, 2023, the maturities of the Company's future minimum lease payments were as follows:

	Operating	Finance
	(in thousands)	
2024 (remaining 6 months)	$ 735	$ 40
2025	938	—
2026	282	—
2027	241	—
2028	199	—
Thereafter	151	—
Total lease payments	2,546	40
Less: imputed interest	(332)	(1)
Lease liabilities	$ 2,214	$ 39

Note 7 - Intangible Assets

The following table provides the summary of the Company's intangible assets as of December 31, 2023 and June 30, 2023, respectively. Carrying amounts are net of any impairment charges from prior periods. An intangible asset with zero net carrying amount at the end of a reporting period is not presented in the table of a future reporting period.

	December 31, 2023			
	Carrying Amount	Accumulated Amortization	Net Carrying Amount	Weighted-Average Remaining Life (in years)
	(in thousands)			
Definite-lived intangibles:				
Acquired product technology rights	$ 41,467	$ (11,777)	$ 29,690	11.04
Acquired technology right	30,200	(4,943)	25,257	14.25
Acquired product distribution rights	6,207	(5,443)	764	0.50
Total intangible assets	$ 77,874	$ (22,163)	$ 55,711	12.35

	June 30, 2023			
	Carrying Amount	Accumulated Amortization	Net Carrying Amount	Weighted-Average Remaining Life (in years)
	(in thousands)			
Definite-lived intangibles:				
Acquired product technology rights	$ 42,176	$ (10,881)	$ 31,295	11.49
Acquired technology right	30,200	(4,054)	26,146	14.75
Acquired product distribution rights	6,207	(4,678)	1,529	1.00
Total intangible assets	$ 78,583	$ (19,613)	$ 58,970	12.67

The following table summarizes the estimated future amortization expense to be recognized over the next five fiscal years and periods thereafter:

	December 31, (in thousands)
2024 (remaining 6 months)	$ 3,259
2025	4,989
2026	4,989
2027	4,989
2028	4,988
Thereafter	32,497
Total future amortization expense	$ 55,711

Acquired Product Technology Rights

The acquired product technology rights are related to the rights to production, supply and distribution agreements of various products pursuant to the acquisitions of the Pediatric Portfolio in November 2019 and the Neos Acquisition in March 2021.

Karbinal ER. The Company acquired and assumed all rights and obligations pursuant to the Supply and Distribution Agreement, as Amended, with Tris Pharma, Inc. ("Tris") for the exclusive rights to commercialize Karbinal ER in the United States (the "Tris Karbinal Agreement"). The Tris Karbinal Agreement's initial term terminates in August of 2033, with an optional additional 20 -year extension.

Poly-Vi-Flor and Tri-Vi-Flor. The Company acquired and assumed all rights and obligations pursuant to a Supply and License Agreement and various assignment and release agreements, including a previously agreed to Settlement and License Agreements (the "Poly-Tri Agreements") for the exclusive rights to commercialize Poly-Vi-Flor and Tri-Vi-Flor in the United States.

ADHD Portfolio. As part of the Neos Acquisition, the Company acquired product technology for the production and sale of Adzenys XR-ODT and Cotempla XR-ODT. The formulations for the ADHD products are protected by patented technology. The estimated economic life of these proprietary technologies is 17 years.

Acquired Technology Right

TRRP Technology. As part of the Neos Acquisition, the Company acquired Time Release Resin Particle ("TRRP") proprietary technology, which is a proprietary drug delivery technology protected by the Company as a trade secret that allows the Company to modify the drug release characteristics of each of its respective products. The TRRP technology underlies the ADHD portfolio and can potentially be used in future product development initiatives as well.

Acquired Product Distribution Rights (and customer list)

In connection with the Innovus Acquisition, the Company obtained 35 products with a combination of over 300 registered trademarks and/or patent rights and customer lists. The customer lists are fully amortized. During the fourth quarter of fiscal 2023, the acquired product distribution rights incurred an impairment charge of $ 3.0 million due to the discontinuation of products in the Consumer Health Segment.

Acquired In-Process R&D

IPR&D – NT0502. As part of the Neos Acquisition, the Company acquired in-process research and development associated with NT0502, a new chemical entity being developed for the treatment of sialorrhea, which is excessive salivation or drooling. As this is an indefinite-lived intangible asset, this acquired asset remains an indefinite-lived asset until the completion or abandonment of the associated research and development efforts. If a product using this technology is eventually approved for commercial sale, at that time, the IPR&D will begin amortizing on a straight-line basis over the life of the product. During fiscal 2023, the Company terminated its development program of NT0502. As a result, the Company fully impaired the IPR&D of NT0502, recording impairment expense of $ 2.6 million to its Rx Segment during the three months ended December 31, 2022.

Certain of the Company's amortizable intangible assets include renewal options, extending the expected life of the asset. The renewal periods range between approximately 1 to 20 years depending on the license, patent or other agreement. Renewals are accounted for when they are reasonably assured. Intangible assets are amortized using the straight-line method over the estimated useful lives. Amortization expense of intangible assets was $ 1.6 million and $ 1.5 million for the three months ended December 31, 2023 and 2022, respectively, and $ 3.3 million and $ 3.0 million for the six months ended December 31, 2023 and 2022, respectively.

Note 8 - Accrued Liabilities

Accrued liabilities consist of the following:

	December 31, 2023	June 30, 2023
	(in thousands)	
Accrued savings offers	$ 14,852	$ 15,739
Accrued program liabilities	11,841	11,012
Accrued customer and product related fees	5,699	6,579
Return reserve	5,129	5,777
Accrued employee compensation	3,362	5,675
Other accrued liabilities	2,530	2,017
Total accrued liabilities	$ 43,413	$ 46,799

Accrued savings offers represent programs for the Company's patients covered under commercial payor plans in which the cost of a prescription to such patients is discounted. Accrued program liabilities include government and commercial rebates. Accrued employee compensation includes sales commissions, paid time off earned, accrued payroll and accrued bonus. Accrued customer and product related fees include accrued expenses and deductions for rebates, wholesaler chargebacks and fees, and other product-related fees and deductions such as royalties for Pediatric Portfolio products, accrued distributor fees, and Medicaid liabilities. The return reserve represents the Company's accrual for estimated product returns. Other accrued liabilities consist of various other accruals, none of which individually or in the aggregate represent greater than five percent of total liabilities.

Note 9 - Other Liabilities

	December 31, 2023	June 30, 2023
	(in thousands)	
Fixed payment arrangements	$ 9,043	$ 10,420
Operating lease liabilities	2,214	2,090
Employee retention credit	3,759	—
Other	564	1,555
Total other liabilities	15,580	14,065
Less: current portion	(9,236)	(7,090)
Total other liabilities, non-current	$ 6,344	$ 6,975

Fixed Payment Arrangements

Fixed payment arrangements represent obligations to an investor assumed as part of the acquisition of products from Cerecor, Inc. in 2019, including fixed and variable payments.

The Tris Karbinal Agreement grants the Company exclusive right to distribute and sell the product in the United States. The initial term of the agreement was 20 years. The Company will pay Tris a royalty equal to 23.5 % of net sales. The Tris Karbinal Agreement also contains minimum unit sales commitments, which is based on a commercial year that spans from August 1 through July 31, of 70,000 units annually through 2025. The Company is required to pay Tris a royalty make whole payment of $ 30 for each unit under the 70,000 -unit annual minimum sales commitment through 2025. The Tris Karbinal Agreement make-whole payment is capped at $ 2.1 million each year. The annual payment is due in August of each year. The Tris Karbinal Agreement also has multiple commercial milestone obligations that aggregate up to $ 3.0 million based on cumulative net sales, the first of which is triggered at $ 40.0 million of net revenues. As of December 31, 2023, the fixed payment arrangement balance was $ 1.8 million in other current liabilities, and $ 1.2 million in other non-current liabilities on the consolidated balance sheet.

On May 12, 2022, the Company entered into an agreement with Tris to terminate the Tuzistra XR License, Development, Manufacturing and Supply Agreement dated November 2, 2018 (the “License Agreement”). Pursuant to such termination, the Company agreed to pay Tris a total of approximately $ 9.0 million, which reduced its total liability for minimum payments by approximately $ 8.0 million from the original License Agreement. As of December 31, 2023, the balance was $ 6.0 million in other current liabilities on the consolidated balance sheet.

Operating Lease Liabilities

The Company has entered into various operating lease agreements for certain of its offices, manufacturing facilities and equipment. Please refer to *Note 6 - Leases* for further detail.

Employee Retention Credit

The $ 3.8 million ERC accrual in other non-current liabilities as of December 31, 2023, represents the proceeds the Company received from the ERC program during the first quarter of fiscal 2024. The ERC is a refundable payroll tax credit from the CARES Act enacted by the U.S. government to provide certain relief from the COVID-19 pandemic. The refundable payroll tax credit shall be recognized in the consolidated statement of operations following any adjustments from its regulatory audit or upon further clarifications from the Internal Revenue Service (see *Note 2 – Significant Accounting Policies*). The associated vendor fee of $ 0.4 million was expensed as incurred in the first quarter of fiscal 2024.

Other

Other consists of taxes payable and deferred cost related to the Company’s technology transfer.

Note 10 - Line of Credit

The Company has entered into a secured credit agreement, as amended, with Eclipse Business Capital LLC (f/k/a Encina Business Credit, LLC) (“Eclipse”) as agent for the lenders (the “Eclipse Loan Agreement”). Under the Eclipse Loan Agreement, Eclipse extended up to $ 14.0 million, less a $ 3.5 million availability block, in secured revolving loans (the “Revolving Loans”), against 85 % of eligible accounts receivable. The Revolving Loans thereunder, accrue at variable interest through maturity at the one-month Secure Overnight Financing Rate (“SOFR”), plus 4.50 %. The Eclipse Loan Agreement includes an unused line fee of 0.50 % of the average unused portion of the maximum revolving facility amount during the immediately preceding month. Interest is payable monthly in arrears. The maturity date under the Eclipse Loan Agreement is January 26, 2025.

In the event that, for any reason, all or any portion of the Eclipse Loan Agreement is terminated prior to the scheduled maturity date, in addition to the payment of all outstanding principal and unpaid accrued interest, the Company is required to pay a fee equal to (i) 1.0 % of the Revolving Loans commitment if such event occurs after January 26, 2023 but on or before January 26, 2024, and (ii) 0.5 % of the Revolving Loans commitment if such event occurs after January 26, 2024 but on or before January 26, 2025. The Company may permanently terminate the Eclipse Loan Agreement at any time with at least five business days prior notice to Eclipse.

The Eclipse Loan Agreement contains customary affirmative covenants, negative covenants and events of default, as defined in the agreement, including covenants and restrictions that, among other things, require the Company to satisfy certain capital expenditure limitations and other financial covenants, and restrict the Company’s ability to incur liens, incur additional indebtedness, make certain dividends and distributions with respect to equity securities, engage in mergers and acquisitions or make asset sales without the prior written consent of Eclipse. A failure to comply with these covenants could permit Eclipse to declare the Company’s obligations under the Eclipse Loan Agreement, together with accrued interest and fees, to be immediately due and payable, plus any applicable additional amounts relating to a prepayment or termination, as described above. As of December 31, 2023, the Company was in compliance with the covenants under the Eclipse Loan Agreement.

The Company's obligations under the Eclipse Loan Agreement are secured by substantially all of the Company's assets, with a first priority lien in favor of Eclipse on the ABL Priority Collateral, and a second priority lien in favor of Eclipse on the Term Loan Priority Collateral, as each is defined in the Replacement Term Loan Intercreditor Agreement, as defined in the Eclipse Loan Agreement.

Total interest expense on the Revolving Loans, including amortization of deferred financing costs, was $ 23.2 thousand and $ 176.7 thousand for the three months ended December 31, 2023 and 2022, respectively and $ 50.1 thousand and $ 274.0 thousand for the six months ended December 31, 2023 and 2022, respectively. As of December 31, 2023 and June 30, 2023, the outstanding Revolving Loans under the Eclipse Loan Agreement, as amended, were $ 1.0 million and $ 1.6 million, respectively.

Note 11 - Long-term Debt

Avenue Capital Loan

On January 26, 2022 ("Closing Date"), the Company entered into a Loan and Security Agreement (the "Avenue Capital Agreement") with Avenue Venture Opportunities Fund, L.P. ("Avenue") and Avenue Venture Opportunities Fund II, L.P. (Avenue 2") as lenders (the "Avenue Capital Lenders"), and Avenue Capital Management II, L.P. as administrative agent (the "Avenue Capital Agent", and collectively with the Avenue Capital Lenders, "Avenue Capital"), pursuant to which the Avenue Capital Lenders provided the Company and certain of its subsidiaries with a secured $ 15.0 million loan. The interest rate on the loan is the greater of the prime rate or 3.25 %, plus 7.4 %, payable monthly in arrears. The maturity date of the loan is January 26, 2025. The proceeds from the Avenue Capital Agreement were used to repay the senior secured term credit facility with Deerfield Private Design Fund III, L.P. and Deerfield Partners, L.P., which the Company assumed through the Neos Acquisition.

Pursuant to the Avenue Capital Agreement, the Company made interest only payments for the first 18 months following the Closing Date ("Interest-only Period"). In June 2023, the Company achieved certain defined milestones extending the Interest-Only Period through the maturity date.

In the event the Company prepays the outstanding principal prior to the maturity date, the Company will pay Avenue Capital a fee equal to (i) 2.0 % of the loan if such event occurs after January 26, 2023 but on or before January 26, 2024, and (ii) 1.0 % of the loan if such event occurs after January 26, 2024 but before January 26, 2025. In addition, upon the payment in full of the obligations, the Company shall pay to Avenue Capital a fee in the amount of $ 0.6 million ("Final Payment"). The Company accounted for the Final Payment as additional obligations on the debt, with the corresponding charge being recorded as debt discount.

The Company's obligations under Avenue Capital Agreement are secured by substantially all of the Company's assets, with a first priority lien in favor of the Avenue Capital Agent on the Term Loan Priority Collateral, and a second priority lien in favor of the Avenue Capital Agent on the ABL Priority Collateral, as each is defined in the Intercreditor Agreement, as defined in the Avenue Capital Agreement.

The Avenue Capital Agreement contains customary affirmative covenants, negative covenants and events of default, as defined in the agreement, including covenants and restrictions that, among other things, require the Company to satisfy certain capital expenditure limitations and other financial covenants, and restricts the Company's ability to incur liens, incur additional indebtedness, make certain dividends and distributions with respect to equity securities, engage in mergers and acquisitions or make asset sales without the prior written consent of the Avenue Capital Lenders. A failure to comply with these covenants could permit the Avenue Capital Lenders to declare the Company's obligations under the agreement, together with accrued interest and fees, to be immediately due and payable, plus any applicable additional amounts relating to a prepayment or termination, as described above. As of December 31, 2023, the Company was in compliance with the covenants under the Avenue Capital Agreement.

On January 26, 2022 ("Issuance Date"), as consideration for entering into the Avenue Capital Agreement, the Company issued warrants to the Avenue Capital Lenders to purchase shares of common stock at an exercise price equal to $ 24.20 per share (the "Avenue Capital Warrants"). The Avenue Capital Warrants provided that in the event the Company were to engage in an equity offering at a price lower than $ 24.20 prior to June 30, 2022, the exercise price would be adjusted to the effective price of such equity offering, and the number of shares of common stock to be issued under the Avenue Capital Warrants would be adjusted as set forth in the agreement. The Avenue Capital Warrants are immediately exercisable and expire on January 31, 2027. The Company accounted for the Avenue Capital Warrants as a liability as the number of warrants was not fixed at the Issuance Date. The fair value of the Avenue Capital Warrants at issuance was approximately $ 0.6 million.

On March 7, 2022, the Company closed on an equity offering of shares of common stock and warrants at an offering price of $ 25.00 per share. As the Avenue Capital Agreement precluded the Company from pursuing any equity financing prior to July 7, 2022, and the effective price of the March 7, 2022 offering was more than the exercise price of the Avenue Capital Warrants, the number of shares of common stock issuable upon exercise of the Avenue Capital Warrants were set to 43,388 at an exercise price of $ 24.20 .

On October 25, 2022, the Company entered into an agreement with Avenue to extend the interest-only period of its existing senior secure loan facility held with Avenue. The amendment to the original loan agreement, which was executed in January 2022, extends the interest-only period to January of 2024. In exchange for this extension of the interest-only period, the Company and Avenue agreed to reset the exercise price of the warrants issued in conjunction with the original loan agreement to $ 8.60 , corresponding to the warrant exercise price associated with the Company's August 2022 equity financing.

In addition to the debt discount discussed above, the Company incurred $ 0.4 million in loan origination, legal and other fees. The debt discount and issuance costs are being amortized over the term of the loan, using the effective interest method resulting in an effective rate of 19.6 %. Total interest expense, including debt discount amortization, was $ 0.7 million for both the three months ended December 31, 2023 and 2022, and $ 1.5 million and $ 1.3 million for the six months ended December 31, 2023 and 2022, respectively.

Long-term debt consists of the following:

	December 31, 2023	June 30, 2023
	(in thousands)	
Long-term debt, due on January 26, 2025	$ 15,000	$ 15,000
Long-term, final payment fee	638	638
Unamortized discount and issuance costs	(660)	(925)
Financing leases, maturing through May 2024	39	85
Total debt	15,017	14,798
Less: current portion	(39)	(85)
Non-current portion of debt	$ 14,978	$ 14,713

Future principal payments of long-term debt, including financing leases, are as follows:

	December 31, (in thousands)
2024 (remaining 6 months)	$ 39
2025	15,638
Future principal payments	15,677
Less: unamortized discount and issuance costs	(660)
Less: current portion	(39)
Non-current portion of debt	$ 14,978

Note 12 - Fair Value Considerations

The Company determines the fair value of financial and non-financial assets and liabilities using the fair value hierarchy, which establishes three levels of inputs that may be used to determine fair value as follows:

- Level 1: Inputs that reflect unadjusted quoted prices in active markets that are accessible to Aytu for identical assets or liabilities;
- Level 2: Inputs that include quoted prices for similar assets and liabilities in active or inactive markets or that are observable for the asset or liability either directly or indirectly; and
- Level 3: Unobservable inputs that are supported by little or no market activity.

The Company's financial instruments include cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities, derivative warrant liabilities, fixed payment arrangements, and short-term and long-term debt. The carrying amounts of certain short-term financial instruments, including cash and cash equivalents, restricted cash, accounts receivable, accounts payable and accrued liabilities approximate their fair value due to their short maturities. Short-term and long-term debt are reported at their amortized costs on the unaudited consolidated balance sheets. The remaining financial instruments and derivative warrant liabilities are reported on the unaudited consolidated balance sheets at amounts that approximate current fair values. The Company's policy is to recognize transfers in and/or out of fair value hierarchy as of the date in which the event or change in circumstances caused the transfer. There were no transfers between Level 1, Level 2, and Level 3 in the periods presented.

Recurring Fair Value Measurements

The following table presents the Company's financial assets and liabilities that were accounted for at fair value on a recurring basis as of December 31, 2023 and June 30, 2023, by level within the fair value hierarchy.

		Fair Value Measurements at December 31, 2023		
	Fair Value at December 31, 2023	(Level 1)	(Level 2)	(Level 3)
		(in thousands)		
Liabilities:				
Derivative warrant liabilities	12,887	—	—	12,887
Total	$ 12,887	$ —	$ —	$ 12,887

		Fair Value Measurements at June 30, 2023		
	Fair Value at June 30, 2023	(Level 1)	(Level 2)	(Level 3)
		(in thousands)		
Liabilities:				
Derivative warrant liabilities	6,403	—	—	6,403
Total	$ 6,403	$ —	$ —	$ 6,403

Summary of Level 3 Input Changes

The following table sets forth a summary of changes to those fair value measures using Level 3 inputs for the six months ended December 31, 2023.

	Derivative Warrant Liabilities (in thousands)
Balance as of June 30, 2023	$ 6,403
Included in earnings	6,484
Balance as of December 31, 2023	$ 12,887

Significant Assumptions

The following table presents the valuation methodologies and key assumptions used for the marked to market fair value measurements of derivative warrant liabilities as of December 31, 2023.

	June 2023 Warrants Tranche A & B	Warrants Other *
	Monte Carlo Simulation & Black-Scholes	*Black-Scholes*
Equivalent term (years)	4.44	3.09 - 3.69
Expected volatility	96.15 %	96.15 %
Risk-free rate	3.88 %	3.95 - 4.01 %
Dividend yield	0.00 %	0.00 %

** Includes August 2022 Warrants, March 2022 Warrants, and Avenue Capital Warrants.*

The Black-Scholes option pricing model is used to value all warrants with significant Level 3 inputs. The Monte Carlo Simulation is used to simulate the exit price and EBITDA forecast; average warrant value per share is from 100,000 Monte Carlo simulations. The Monte Carlo is based on significant inputs including financial projections provided by the Company's management used primarily to forecast future results not observable in the market, and thus, represents a Level 3 measure.

Note 13 - Commitments and Contingencies

Pediatric Portfolio Fixed Payments and Product Milestone

The Tris Karbinal Agreement grants the Company exclusive right to distribute and sell Karbinal ER in the United States. The initial term of the agreement was 20 years. The Company will pay Tris a royalty equal to 23.5 % of net sales.

The Tris Karbinal Agreement also contains minimum unit sales commitments, which is based on a commercial year that spans from August 1 through July 31, of 70,000 units annually through 2025. The Company is required to pay Tris a royalty make-whole payment of $ 30 for each unit under the 70,000-unit annual minimum sales commitment through 2025. The Tris Karbinal Agreement make-whole payment is capped at $ 2.1 million each year. The annual payment is due in August of each year. The Tris Karbinal Agreement also has multiple commercial milestone obligations that aggregate up to $ 3.0 million based on cumulative net sales, the first of which is triggered at $ 40.0 million of product net revenues.

Rumpus Earn Out Payments

On April 12, 2021, the Company acquired substantially all of the assets of Rumpus, pursuant to which the Company acquired certain rights and other assets, including key commercial global licenses with Denovo Biopharma LLC ("Denovo") and Johns Hopkins University ("JHU"), relating to AR101. Upon the achievement of certain regulatory and commercial milestones, up to $ 67.5 million in earn-out payments, which are payable in cash or shares of common stock, generally at the Company's option, are payable to Rumpus. Under the license agreement with Denovo, the Company made a payment of $ 0.6 million for a license fee in April 2022. In addition, upon the achievement of regulatory and commercial milestones, the Company may be required to pay up to $ 101.7 million and escalating royalties based on net product sales ranging in percentage from the low teens to the high teens. Finally, under the license agreement with Johns Hopkins, the Company assumed the responsibility for royalties of 3.0 % of net product sales, with a minimum of $ 20,000 per year, and upon the achievement of certain regulatory and commercial milestones, up to $ 1.6 million. In October 2022, the Company announced the indefinite suspension of its development of AR101.

Legal Matters

Witmer Class-Action Securities Litigation. A stockholder derivative suit filed on September 12, 2022, in the Delaware Chancery Court by Paul Witmer, derivatively and on behalf of all Aytu stockholders, and later amended, against Armistice Capital, LLC, Armistice Capital Master Fund, Ltd., Steve Boyd (Armistice's Chief Investment Officer and Managing Partner, and a former director of Aytu) (collectively "Armistice"), and certain other current and former directors of Aytu, Joshua Disbrow, Gary Cantrell, John Donofrio, Jr, Carl Dockery and Ketan B. Mehta. The amended complaint alleges that (i) Armistice facilitated the sale of assets of Cerecor, Inc., in 2019 and Innovus Pharmaceuticals, Inc., in 2020 to Aytu in exchange for convertible securities, which it subsequently converted and sold at a profit on the open market; (ii) the Armistice defendants breached their fiduciary duties, were unjustly enriched and wasted corporate assets in connection with these acquisitions; (iii) the Armistice defendants breached their fiduciary duties by engaging in insider trading; and (iv) the other directors breached their fiduciary duties, and aided and abetted the Armistice defendants' breaches of fiduciary duties, in connection with these acquisitions. The amended complaint seeks unspecified damages, equitable relief, restitution, disgorgement of profits, enhanced governance and internal procedures, and attorneys' fees. While the Company believes that this lawsuit is without merit and has vigorously defended against it, the Company has agreed to settle the matter, as against it and the director defendants other than Mr. Boyd, for various corporate governance modifications and the payment of plaintiff's attorneys' fees. That settlement is subject to court approval, the hearing on which has not yet been scheduled.

Sabby Litigation. A complaint was filed on February 22, 2023, in the Supreme Court of the State of New York by Sabby Volatility Warrant Master Fund Ltd ("Sabby") and Walleye Opportunities Master Fund Ltd ("Walleye"), holders of certain warrants to purchase common stock, against the Company. The complaint alleges that the Company improperly adjusted the exercise price of the warrants and miscalculated the number of shares the warrant holders may receive, and that the Company failed to provide prompt notice to the warrant holders of such adjustment. The complaint seeks a declaratory judgment of the warrant share calculation, that 575,000 warrant shares be due to Sabby on exercise of its warrants rather than 312,908 shares, and that 100,000 warrant shares be due to Walleye on exercise of its warrants rather than 54,146 shares. In October 2023, the Company entered into a settlement agreement and general release with Sabby and Walleye.

Stein Litigation. Cielo Stein ("Stein"), a former sales specialist, filed a complaint on February 1, 2023, in Jefferson County Circuit Court in Kentucky against the Company and its wholly owned subsidiary Neos Therapeutics. The complaint alleges that Aytu retaliated against Stein in violation of the Kentucky Civil Rights Act after she opposed what she contends was unwelcome behavior by her supervisor. The complaint also alleges that the Company's response to Stein's subsequent complaint to human resources was inadequate. The complaint seeks an award of unspecified compensatory damages, emotional-distress damages, and attorneys' fees and costs. The Company removed the lawsuit to the United States District Court for the Western District of Kentucky and filed a motion to dismiss the complaint, which was denied. The case has been referred to a magistrate judge for, among other things, the entry of a scheduling order and to conduct a settlement conference. Due to the early stage of litigation, and while the Company believes that this lawsuit is without merit, the Company is not able to predict at this time whether this proceeding will have a material impact on its financial condition or results of operations and intend to vigorously defend this case in the event it is not dismissed.

Note 14 - Capital Structure

The Company has 200 million shares of common stock authorized with a par value of $ 0.0001 per share and 50 million shares of preferred stock authorized with a par value of $ 0.0001 per share. Included in the common stock outstanding are 40,017 shares of unvested restricted stock issued to executives, directors and employees.

On June 8, 2020, the Company filed a shelf registration statement on Form S- 3, which was declared effective by the SEC on June 17, 2020. This shelf registration statement covered the offering, issuance, and sale by the Company of up to an aggregate of $ 100.0 million of its common stock, preferred stock, debt securities, warrants, rights and units (the "2020 Shelf"). On June 4, 2021, the Company entered into a sales agreement with a sales agent, to provide for the offering, issuance and sale by the Company of up to $ 30.0 million of its common stock from time to time in "at-the-market" offerings under the 2020 Shelf (the "ATM Sales Agreement"). During the year ended June 30, 2023, the Company issued 699,929 shares of common stock under the ATM Sales Agreement, with total net proceeds of approximately $ 2.9 million. The 2020 Shelf expired in June 2023.

On September 28, 2021, the Company filed a shelf registration statement on Form S-3, which was declared effective by the SEC on October 7, 2021. This shelf registration statement covered the offering, issuance and sale by the Company of up to an aggregate of $ 100.0 million of its common stock, preferred stock, debt securities, warrants, rights and units (the "2021 Shelf"). As of December 31, 2023, approximately $ 82.4 million remained available under the 2021 Shelf. This availability is subject to SEC 1.B.6 limitation to the Form S-3.

On August 11, 2022, the Company closed on an underwritten public offering (the "August 2022 Offering") utilizing the 2021 Shelf, pursuant to which it sold an aggregate of (i) 1,075,290 shares of its common stock, (ii) and, in lieu of common stock to certain investors that so chose, pre-funded warrants to purchase 87,500 shares of its common stock, and (iii) accompanying warrants to purchase 1,265,547 shares of its common stock. The shares of common stock and the pre-funded warrants were each sold in combination with corresponding common warrants, with one common warrant to purchase one share of common stock for each share of common stock or each pre-funded warrant sold. The combined public offering price for each share of common stock and accompanying common warrant was $ 8.60 , and the combined offering price for each pre-funded warrant and accompanying common warrant was $ 8.58 , which equated to the public offering price per share of the common stock and accompanying common warrant, less the $ 0.02 per share exercise price of each pre-funded warrant. The pre-funded warrants were exercised in full in August 2022. The common warrants have an exercise price of $ 8.60 per share of common stock and are exercisable for a period of five years from issuance. The Company raised $ 10.0 million in gross proceeds through the August 2022 Offering before underwriting fees and other expenses of $ 0.9 million. The pre-funded and common warrants have a combined fair value of approximately $ 6.0 million at issuance and are classified as derivative warrant liabilities, with the offset in additional paid in capital in stockholders' equity in the Company's consolidated financial statements (See *Note 16 – Warrants*).

On June 8, 2023, using a placement agency, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with certain institutional investors, pursuant to which the Company issued and sold an aggregate of (i) 1,743,695 shares of the Company's common stock, (ii) pre-funded warrants in lieu of shares to purchase 430,217 shares of common stock (the "Pre-Funded Warrants"), (iii) accompanying Tranche A Warrants to purchase 2,173,912 shares of common stock, (iv) and accompanying Tranche B Warrants to purchase 2,173,912 shares of common stock in a best-efforts offering (the Tranche B Warrants together with the Tranche A Warrants, the "Common Warrants"). The Common Warrants may be exercised for either shares of common stock or pre-funded warrants to purchase common stock at a future exercise price of $ 0.0001 per share in the same form as the Pre-Funded Warrant (the "Exchange Warrants"). Each Pre-Funded Warrant is exercisable for one share of common stock at an exercise price of $ 0.0001 per share. The Pre-Funded Warrants are immediately exercisable and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. The Common Warrants are immediately exercisable at a price of $ 1.59 per share (or $ 1.5899 per Exchange Warrant). The Tranche A Warrants will expire upon the earlier of (i) five years after the date of issuance, and (ii) 30 days following the closing price of the Company's common stock equaling 200% of the exercise price ($ 3.18 per share) for at least 40 consecutive trading days. The Tranche B Warrants will expire upon the earlier of (x) five years after the date of issuance, and (y) 30 days following the Company's achievement of consolidated trailing twelve-month adjusted EBITDA (as defined in the Securities Purchase Agreement) of $ 12 million. The Company raised $ 4.0 million in gross proceeds and net proceeds were approximately $ 3.4 million after deducting offering expenses. The warrants have a combined fair value of approximately $ 5.0 million at issuance and are classified as derivative warrant liabilities. The resulting offset is recorded in other expense along with the issuance costs of $ 0.6 million in the consolidated financial statement of operations (See *Note 16 – Warrants*).

Note 15 - Equity Incentive Plans

2023 Equity Incentive Plan. On May 18, 2023, the Company's stockholders approved the Aytu BioPharma, Inc. 2023 Equity Incentive Plan (the "2023 Equity Incentive Plan"). Prior to the Company's adoption of the 2023 Equity Incentive Plan, the Company awarded equity incentive grants to its directors and employees under the Aytu BioScience, Inc. 2015 Stock Option and Incentive Plan (the "Aytu 2015 Plan") and the Neos Therapeutics, Inc. 2015 Stock Options and Incentive Plan (the "Neos 2015 Plan", and collectively with the Aytu 2015 Plan, the "2015 Plans"). For the 2023 Equity Incentive Plan, the stockholders approved (a) 200,000 new shares, (b) 87,129 shares available for grant under the 2015 Plans be "rolled over" to the 2023 Equity Incentive Plan and (c) any shares that are returned to the company under the 2015 Plans be added to the 2023 Equity Incentive Plan. With the approval of the 2023 Equity Incentive Plan, no additional awards will be granted under the 2015 Plans. All outstanding awards previously granted under previous stock incentive plans will remain outstanding and subject to the terms of the plans. Stock options granted under the 2023 Equity Incentive Plan have contractual terms of 10 years or less from the grant date and a vesting period ranging from 3 to 4 years. The restricted stock awards and restricted stock units have a vesting period of 3 to 4 years. As of December 31, 2023, the Company had 179,732 shares that are available for grant under the 2023 Equity Incentive Plan.

Aytu 2015 Plan. On June 1, 2015, the Company's stockholders approved the Aytu 2015 Plan, which, as amended in July 2017, provides for the award of stock options, stock appreciation rights, restricted stock and other equity awards for up to an aggregate of 150,000 shares of common stock. The shares of common stock underlying any awards that are forfeited, canceled, reacquired by Aytu prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) under the Aytu 2015 Plan will be added back to the shares of common stock available for issuance under the 2023 Equity Incentive Plan. On February 13, 2020, the Company's stockholders approved an increase to 250,000 total shares of common stock in the Aytu 2015 Plan. Stock options granted under this plan have contractual terms of 10 years from the grant date and a vesting period ranging from 3 to 4 years. The restricted stock awards have a vesting period ranging from 4 to 10 years, whereas the restricted stock units have a vesting period of 4 years.

Neos 2015 Plan. Pursuant to the Neos Merger, the Company assumed 3,486 stock options and 1,786 restricted stock units previously granted under the Neos 2015 Plan. Accordingly, on April 19, 2021, the Company registered 5,272 shares of its common stock under the Neos 2015 Plan with the SEC. The terms and conditions of the assumed equity securities remained the same as they were previously under the Neos 2015 Plan. The Company allocated costs of the replacement awards attributable to pre-combination and post-combination service periods. The pre-combination service costs were included in the considerations transferred. The remaining costs attributable to the post-combination service period are being recognized as stock-based compensation expense over the remaining terms of the replacement awards. Stock options granted under this plan have contractual terms of 10 years from the grant date and a vesting period ranging from 1 to 4 years.

Stock Options

Stock option activity is as follows:

	Number of Options		Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years
Outstanding June 30, 2023	52,762	$	18.37	9.06
Granted	112,000	$	1.73	9.61
Forfeited/cancelled	(15,060)	$	2.94	—
Expired	(615)	$	184.80	—
Outstanding at December 31, 2023	149,087	$	6.43	9.17
Exercisable at December 31, 2023	20,470	$	30.18	8.02

The weighted-average grant date fair value of options granted during the six months ended December 31, 2023 was $ 1.73 . As of December 31, 2023, there was $ 0.4 million total unrecognized compensation costs related to non-vested stock options granted under the Company's equity incentive plans. The unrecognized compensation cost is expected to be recognized over a weighted average period of 1.85 years.

Restricted Stock

Restricted stock activity is as follows:

	Number of Shares		Weighted Average Grant Date Fair Value
Unvested at June 30, 2023	38,075	$	142.20
Granted	12,500	$	1.77
Vested	(12,189)	$	130.45
Forfeited/cancelled	(457)	$	136.80
Unvested at December 31, 2023	37,929	$	99.75

As of December 31, 2023, there was $ 2.0 million total unrecognized compensation costs related to non-vested restricted stock granted under the Company's equity incentive plan. The unrecognized compensation cost is expected to be recognized over a weighted average period of 1.9 years.

As of December 31, 2023, there was $ 0.3 million total unrecognized costs related to non-vested restricted stock outside of the Company's equity incentive plan. The unrecognized compensation cost is expected to be recognized over a weighted average period of 1.1 years. As of December 31, 2023, 2,088 shares of restricted stock remain unvested.

Restricted Stock Units

Restricted stock units ("RSU" or "RSUs") activity is as follows:

	Number of Shares		Weighted Average Grant Date Fair Value
Unvested at June 30, 2023	4,963	$	25.62
Vested	(1,126)	$	24.28
Forfeited	(939)	$	31.60
Unvested at December 31, 2023	2,898	$	24.19

As of December 31, 2023, there was $ 0.1 million total unrecognized compensation costs related to non-vested RSUs granted under the Company's equity incentive plans. The unrecognized compensation cost is expected to be recognized over a weighted average period of 1.2 years.

Stock-based compensation expense related to the fair value of stock options, restricted stock, and RSUs was included in the consolidated statements of operations as set forth in the below table:

	Three Months Ended December 31,		Six Months Ended December 31,	
	2023	2022	2023	2022
	(in thousands)			
Cost of sales	$ 1	$ 3	$ 1	$ 8
Research and development	2	14	3	23
Selling and marketing	—	3	—	6
General and administrative	817	3,047	1,746	4,207
Total stock-based compensation expense	$ 820	$ 3,067	$ 1,750	$ 4,244

Note 16 - Warrants

Liability Classified Warrants

On June 8, 2023, the Company entered into a securities purchase agreement (the “Securities Purchase Agreement”) pursuant to which the Company issued and sold an aggregate of (i) 1,743,695 shares of the Company’s common stock, (ii) pre-funded warrants in lieu of shares to purchase 430,217 shares of common stock, (iii) accompanying Tranche A Warrants to purchase 2,173,912 shares of common stock, (iv) and accompanying Tranche B Warrants to purchase 2,173,912 shares of common stock in a best-efforts offering. The Tranche A Warrants and Tranche B Warrants may be exercised for either shares of common stock or pre-funded exchange warrants to purchase common stock at a future exercise price of $ 0.0001 per share in the same form as the pre-funded warrant. Each pre-funded warrant is exercisable for one share of common stock at an exercise price of $ 0.0001 per share. The pre-funded warrants are immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full. The Tranche A Warrants and Tranche B Warrants are immediately exercisable at a price of $ 1.59 per share (or $ 1.5899 per pre-funded exchange warrant). The Tranche A Warrants will expire upon the earlier of (i) five years after the date of issuance, and (ii) 30 days following the closing price of the Company’s common stock equaling 200% of the exercise price ($ 3.18 per share) for at least 40 consecutive trading days. The Tranche B Warrants will expire upon the earlier of (x) five years after the date of issuance, and (y) 30 days following the Company’s achievement of consolidated trailing twelve-month adjusted EBITDA (as defined in the Securities Purchase Agreement) of $ 12 million (see *Note 14 – Capital Structure*).

On August 11, 2022, the Company closed an offering (the “August 2022 Offering”), pursuant to which, the Company issued pre-funded warrants to purchase 87,500 shares of its common stock and common warrants to purchase 1,265,547 shares of its common stock. The shares of common stock and the pre-funded warrants were each sold in combination with corresponding common warrants, which one common warrant to purchase one share of common stock for each share of common stock or each pre-funded warrant was sold. The pre-funded warrants had an exercise price of $ 0.02 per share of common stock and were exercised in full in August 2022. The common warrants have an exercise price of $ 8.60 per share of common stock and are exercisable for a period of five years from issuance. The common warrants provide that if there occurs any stock split, stock dividend stock recapitalization, or similar event (a “Stock Combination Event”), then the warrant exercise price will be adjusted to the greater of the quotient determined by dividing (x) the sum of the VWAP of the common stock for each of the five lowest trading days during the 20 consecutive trading day period ending immediately preceding the 16th trading day after such Stock Combination Event, divided by (y) five; or $ 2.32 , and the number of shares of common stock to be issued would be adjusted proportionately as set forth in the agreement limited to a maximum of 2,325,581 shares. The common warrants also provide that in the event the Company were to engage in an equity offering at a common stock price lower than the warrant exercise price prior to the second anniversary of a Stock Combination Event, the exercise price would be adjusted to the greater of the effective price of such equity offering or $ 2.32 (see *Note 14 – Capital Structure*).

In November 2022 and throughout the quarter ended December 31, 2022, the Company sold shares through its ATM Sales Agreement. Per the warrant agreement in the August 2022 Offering, these sales qualified as an equity offering and the sales price was less than the current exercise price of $ 8.60 . As a result, the common warrants exercise price was adjusted to $ 3.30 . On January 6, 2023, the Company consummated a 20 to 1 reverse stock split. Pursuant to the warrant agreement described above, the Company triggered a Stock Combination Event and the warrant exercise price and number to be issued was adjusted based on the average of each of the lowest five trading days during the twenty-day consecutive trading day period beginning on December 30, 2022. Subsequently, as a result of the Securities Purchase Agreement in June 2023, the common warrants from the August 2022 Offering had an adjusted exercise price of $ 2.32 .

Certain outstanding warrants are classified as derivative warrant liabilities in the consolidated balance sheets and are marked to market at each reporting period (see *Note 12 – Fair Value Considerations*).

A summary of warrants is as follows:

	Number of Warrants		Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years
Outstanding June 30, 2023	6,538,052	$	4.42	4.71
Warrants exercised	(37,004)	$	2.32	—
Warrants expired	(20,958)	$	300.00	—
Outstanding December 31, 2023	6,480,090	$	3.48	4.22

Note 17 - Earnings Per Share

Basic loss per common share is calculated by dividing the net loss available to the common stockholders by the weighted average number of common shares outstanding during that period. Diluted net loss per share reflects the potential of securities that could share in the net loss of the Company.

The following table sets forth securities that are considered anti-dilutive, and therefore excluded from the calculation of diluted earnings per share.

	December 31,	
	2023	2022
Warrants to purchase common stock - liability classified	6,498,980	1,642,235
Warrant to purchase common stock - equity classified	39,072	56,486
Employee stock options	149,087	52,861
Employee unvested restricted stock	40,017	48,280
Employee unvested restricted stock units	2,898	8,167
Total	6,730,054	1,808,029

Note 18 - License Agreements

Teva

On December 21, 2018, Neos and Teva Pharmaceuticals USA, Inc. (“Teva”) entered into an agreement granting Teva a non-exclusive license to certain patents owned by Neos by which Teva has the right to manufacture and market its generic version of Cotempla XR-ODT under an Abbreviated New Drug Application (“ANDA”) filed by Teva beginning on July 1, 2026, or earlier under certain circumstances.

Actavis

On October 17, 2017, Neos entered into an agreement granting Actavis a non-exclusive license to certain patents owned by Neos by which Actavis (now Teva, following Teva’s acquisition of Actavis’ generic products) has the right to manufacture and market its generic version of Adzenys XR-ODT under its ANDA beginning on September 1, 2025, or earlier under certain circumstances.

Note 19 - Segment Reporting

The Company's chief operating decision maker ("CODM"), who is the Company's Chief Executive Officer, allocates resources and assesses performance based on the Company's financial information. The CODM reviews financial information presented for each reportable segment for the purpose of making operating decisions and assessing financial performance.

The Company manages and aggregates its operational and financial information in accordance with two reportable segments: Rx and Consumer Health. The Rx Segment consists of the Company's prescription products. The Consumer Health Segment contains the Company's consumer healthcare products. For purposes of determining operating income or loss by segment, the Company allocates common expenses such as corporate administration, executive and board compensation, insurance, and fees associated with being a publicly traded entity, among others, to the Rx Segment. The Rx Segment also includes pipeline research and development. The CODM does not regularly review asset information by segment, accordingly, asset information is not provided by segment.

Select financial information for these segments is as follows:

	Rx	Consumer Health	Consolidated
		(in thousands)	
Three Months Ended December 31, 2023			
Product revenue, net	$ 18,748	$ 4,186	$ 22,934
Income (loss) from operations	$ 3,146	$ (782)	$ 2,364
Depreciation and amortization	$ 1,510	$ 389	$ 1,899
Stock-based compensation expense	$ 707	$ 113	$ 820
Three Months Ended December 31, 2022			
Product revenue, net	$ 18,029	$ 8,250	$ 26,279
Loss from operations	$ (5,464)	$ (1,404)	$ (6,868)
Depreciation and amortization	$ 1,572	$ 281	$ 1,853
Impairment expense	$ 2,600	$ —	$ 2,600
Stock-based compensation expense	$ 2,987	$ 80	$ 3,067

	Rx	Consumer Health	Consolidated
		(in thousands)	
Six Months Ended December 31, 2023			
Product revenue, net	$ 36,565	$ 8,468	$ 45,033
Income (loss) from operations	$ 2,280	$ (1,420)	$ 860
Depreciation and amortization	$ 3,064	$ 776	$ 3,840
Stock-based compensation expense	$ 1,432	$ 318	$ 1,750
Six Months Ended December 31, 2022			
Product revenue, net	$ 36,681	$ 17,253	$ 53,934
Loss from operations	$ (6,457)	$ (2,219)	$ (8,676)
Depreciation and amortization	$ 3,146	$ 562	$ 3,708
Impairment expense	$ 2,600	$ —	$ 2,600
Stock-based compensation expense	$ 4,149	$ 95	$ 4,244

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This discussion should be read in conjunction with the Company 's 2023 Form 10-K. The following discussion and analysis contain forward-looking statements that involve risks and uncertainties. Actual results could differ materially from those projected in the forward-looking statements. For additional information regarding these risks and uncertainties, please see the risk factors included in the Company's 2023 Form 10-K, and in Part II Item 1A of this Form 10-Q.

Objective

The purpose of the Management's Discussion and Analysis (the "MD&A") is to present information that management believes is relevant to an assessment and understanding of our results of operations and cash flows for the three and six months ended December 31, 2023, and our financial condition as of December 31, 2023. The MD&A is provided as a supplement to, and should be read in conjunction with, our Unaudited Consolidated Financial Statements and Notes to the Unaudited Consolidated Financial Statements.

Overview

We are a pharmaceutical company focused on commercializing novel therapeutics. We operate through two business segments (i) the Rx Segment, consisting of prescription pharmaceutical products sold primarily through third party wholesalers and (ii) the Consumer Health Segment, which consists of various consumer health products sold directly to consumers. We currently manufacture our products for the treatment of attention deficit hyperactivity disorder ("ADHD") at our manufacturing facility and use third party manufacturers for our other prescription and consumer health products. We are in the process of moving production of our ADHD products to a third-party manufacturer to improve the profitability of these products.

We have incurred significant losses in each year since inception. Our net loss was $0.2 million and $8.3 million for the three and six months ended December 31, 2023, respectively. As of December 31, 2023, and June 30, 2023, we had accumulated deficits of $312.5 million and $304.1 million, respectively. As of December 31, 2023, and largely as a result of the January 2025 maturity of the Avenue Note, there is significant uncertainty about our ability to fund planned operations for the twelve months following the filing date of this Form 10-Q, which raises substantial doubt about our ability to continue as a going concern.

Company Strategy

In the first quarter of fiscal 2023, we announced that we will focus our efforts on accelerating the growth of our Rx business and achieving operating cash flows. To achieve these goals, we indefinitely suspended active development of our clinical development programs. The suspension of these programs is expected to save over $20 million in projected future study costs over the next three fiscal years. In addition, we announced that we would wind down our Consumer Health Segment in fiscal 2024, which has not generated cash flows since we acquired the business in February 2020, to allow us to focus our efforts on improving the performance of our Rx Segment.

Business Environment

We have continued to experience significant inflationary pressure and have experienced supply chain disruptions related to the sourcing of raw materials, energy, logistics and labor during fiscal 2023 and 2024. While we do not have sales or operations in Russia, Ukraine, or the Middle East, it is possible that the conflict or actions taken in response, could adversely affect some of our markets and suppliers, economic and financial markets, costs and availability of energy and materials, or cause further supply chain disruptions. We continue to closely monitor the impact of, and responses to, COVID-19 variants, including government-imposed lockdowns, on demand conditions and our supply chain. We expect that inflationary pressures and supply chain disruptions could continue to be significant across the business throughout fiscal 2024. The Company has not experienced stock outages for its ADHD products since the launch of those products, and the pediatric product supply has remained adequate to satisfy demand for the preceding three years.

Results of Operations

The results of operations for the three and six months ended December 31, 2023, compared to the three and six months ended December 31, 2022 is as follows:

	Three Months Ended December 31,			Six Months Ended December 31,		
	2023	2022	Change	2023	2022	Change
			(in thousands)			
Product revenue, net	$ 22,934	$ 26,279	$ (3,345)	$ 45,033	$ 53,934	$ (8,901)
Cost of sales	6,731	8,986	(2,255)	14,046	18,609	(4,563)
Gross profit	16,203	17,293	(1,090)	30,987	35,325	(4,338)
Operating expenses:						
Advertising and direct marketing	1,358	4,595	(3,237)	2,689	9,047	(6,358)
Other selling and marketing	5,218	5,965	(747)	11,309	11,615	(306)
General and administrative	5,439	8,018	(2,579)	12,395	15,340	(2,945)
Research and development	524	1,710	(1,186)	1,128	2,774	(1,646)
Amortization of intangible assets	1,300	1,198	102	2,606	2,395	211
Impairment expense	—	2,600	(2,600)	—	2,600	(2,600)
Loss from contingent consideration	—	75	(75)	—	230	(230)
Total operating expenses	13,839	24,161	(10,322)	30,127	44,001	(13,874)
Income (loss) from operations	**2,364**	**(6,868)**	**9,232**	**860**	**(8,676)**	**9,536**
Other expense, net	(1,179)	(1,228)	49	(1,888)	(2,312)	424
(Loss) gain on derivative warrant liabilities	(577)	1,403	(1,980)	(6,484)	3,594	(10,078)
Income (loss) before income tax	**608**	**(6,693)**	**7,301**	**(7,512)**	**(7,394)**	**(118)**
Income tax expense	828	—	828	828	—	828
Net loss	**$ (220)**	**$ (6,693)**	**$ 6,473**	**$ (8,340)**	**$ (7,394)**	**$ (946)**

Product revenue, net

During the three and six months ended December 31, 2023, net product revenue decreased by $3.3 million, or 13% and decreased by $8.9 million, or 17%, compared to the same period ended December 31, 2022. The decrease during the three and six months ended December 31, 2023 was primarily due to the decrease in revenue from the Consumer Health Segment, with some of the decrease in revenue attributed to a decline in revenue from the Pediatric Portfolio in the Rx Segment. These declines were partially offset by an increase in revenue from the ADHD Portfolio in the Rx Segment.

Gross margin

During the three and six months ended December 31, 2023, gross profit decreased by 6% and by 12%, respectfully, compared to the same period ended December 31, 2022. Gross margin percentage was 71% and 69% for the three and six months ended December 31, 2023, respectfully, compared to 66% and 65% for the same period ended December 31, 2022. The improvements were primarily due to higher net revenues and cost saving efficiencies in the Pediatric Portfolio and a decline in the lower-margin Consumer Health Segment. Gross margin improvements in the ADHD Portfolio were due to efficiencies in production related to higher demand for Adzenys XR-ODT and Cotempla XR-ODT.

Advertising and direct marketing

During the three and six months ended December 31, 2023, advertising and direct marketing expense decreased $3.2 million, or 70% and $6.4 million or 70%, compared to the same periods ended December 31, 2022. Advertising and direct marketing expense include direct-to-consumer marketing, advertising, sales, and customer support and processing fees related to our Consumer Health Segment and have decreased as we continue to wind down our Consumer Health Segment.

Other selling and marketing

During the three and six months ended December 31, 2023, other selling and marketing expense decreased by $0.7 million, or 13% and $0.3 million, or 3%, compared to the same periods ended December 31, 2022. The decreases were primarily driven by commission expense based on prescriptions generated by our sale force and commercial marketing program fees that decrease as product sales decrease.

General and administrative

During the three and six months ended December 31, 2023, general and administrative expense decreased by $2.6 million, or 32% and $2.9 million, or 19% compared to the same periods ended December 31, 2022. The decrease is primarily a result of ongoing cost-cutting initiatives and operational improvements.

Research and development

During the three and six months ended December 31, 2023, research and development expense decreased by $1.2 million, or 69% and $1.6 million, or 59%, compared to the same periods ended December 31, 2022. Our research and development costs were primarily associated with AR101 and to a lesser extent, the development of Healight and support for our commercialized products. In October 2022, we announced the suspension of the development of AR101 and Healight to focus on our commercial operations. As a result, research and development spending has significantly declined. We expect our research and development expenses to decrease from historical levels as a result of our focus on commercial operations.

Amortization of intangible assets

In the three and six months ended December 31, 2023, amortization expense of intangible assets, excluding amounts included in cost of sales, were relatively consistent compared to the same periods ended December 31, 2022.

Impairment expense

In the three and six months ended December 31, 2023, no impairment expense was recorded.

Due to increased focus on our Rx business efforts, we ceased active development of our NT0502 product candidate. As a result, we returned the intellectual property and terminated the Exclusive License Agreement with NeuRx Pharmaceuticals entered in October 2018. In the three and six months ended December 31, 2022, we incurred an impairment charge of $2.6 million related to these decisions.

Other expense, net

In the three and six months ended December 31, 2023, other expense, net, decreased by $49.0 thousand, or 4% and $0.4 million, or 18% compared to the same periods ended December 31, 2022, primarily due to $0.5 million in other income from insurance proceeds for damage of inventory in the first quarter of fiscal 2024. Other expense, net, include interest expense, accretion from fixed payment arrangements, and other income.

(Loss) gain on derivative warrant liabilities

The fair value of derivative warrant liabilities is calculated using either the Black-Scholes option model or the Monte Carlo simulation model and is revalued at each reporting period. For the three and six months ended December 31, 2023, we recognized unrealized losses of $0.6 million and $6.5 million, respectively, from the fair value adjustments.

Income tax expense

For both the three and six months ended December 31, 2023, income tax expense was $0.8 million with an effective tax rate of 136.2% and negative 11.0% for the three and six months ended December 31, 2023, respectively. This income tax expense was primarily driven by the limitations on losses as a result of Section 382 of the Internal Revenue Code changes in ownership coupled with existing valuation allowances.

For both the six months ended December 31, 2023 and 2022, income tax expense was zero with an effective tax rate of zero percent for both the six months ended December 31, 2023 and 2022, reflecting the full valuation allowance and no impact of Section 382 of the Internal Revenue Code.

Liquidity and Capital Resources

Sources of Liquidity

We have obligations related to our loan agreements, and in the form of contingent consideration related to our acquisitions, milestone payments for licensed products, and manufacturing purchase commitments.

We finance our operations through a combination of sales of our common stock and warrants, borrowings under our line of credit facility, and from cash generated from operations.

Shelf Registrations

On September 28, 2021, we filed a shelf registration statement on Form S-3, which was declared effective by the SEC on October 7, 2021. This shelf registration statement covered the offering, issuance and sale by the Company of up to an aggregate of $100.0 million of its common stock, preferred stock, debt securities, warrants, rights and units (the "2021 Shelf"). As of December 31, 2023, approximately $82.4 million remains available under the 2021 Shelf. This availability is subject to SEC 1.B.6 limitations of Form S-3.

Eclipse Loan Agreement

The Eclipse Loan Agreement, as amended, provides us with up to $14.5 million, less a $3.5 million availability block, in Revolving Loans, against 85% of eligible accounts receivable. The Revolving Loans bore interest at LIBOR, plus 4.50% through April 2022. Beginning in May 2022 through maturity, the Revolving Loans bear interest at the Secured Overnight Financing Rate ("SOFR") plus 4.50%. In addition, we are required to pay an unused line fee of 0.50% of the average unused portion of the maximum Revolving Loans amount during the immediately preceding month. Interest is payable monthly in arrears. The maturity date under the Eclipse Loan Agreement, as amended, is January 26, 2025.

Cash Flows

The following table shows cash flows for the six months ended December 31, 2023 and 2022:

	Six Months Ended December 31,		
	2023	2022	Change
		(in thousands)	
Net cash used in operating activities	$ (346)	$ (11,588)	$ 11,242
Net cash (used in) provided by investing activities	$ (250)	$ 37	$ (287)
Net cash (used in) provided by financing activities	$ (2,860)	$ 11,692	$ (14,552)

Net Cash Used in Operating Activities

Net cash used in operating activities during these periods primarily reflected our net losses, partially offset by changes in working capital and non-cash charges including impairment, stock-based compensation expense, gain or loss on derivative warrant liabilities, depreciation, amortization and accretion, and other charges.

During the six months ended December 31, 2023, net cash used in operating activities totaled $0.4 million. The use of cash was primarily the result of the decrease in accrued liabilities, partially offset by funds from the Employee Retention Credit program recorded in other operating liabilities (see *Note 9 - Other Liabilities*). Additionally, these were partially offset by positive cash earnings (net loss offset by non-cash depreciation, amortization and accretion, derivative warrant liabilities adjustment, and stock compensation expense).

During the six months ended December 31, 2022, net cash used in operating activities totaled $11.6 million. The use of cash was primarily the result of the decrease in inventory, prepaid expenses, and accrued liabilities. These were partially offset by positive cash earnings (net loss offset by non-cash depreciation, amortization and accretion, in addition to stock compensation expense and impairment charges).

Net Cash (Used in) Provided by Investing Activities

Net cash flows from investing activities were nominal during each of the six months ended December 31, 2023 and 2022.

Net Cash (Used in) Provided by Financing Activities

Net cash used in financing activities of $2.7 million during the six months ended December 31, 2023, was primarily from payments made to fixed payment arrangements.

Net cash provided by financing activities of $11.7 million during the six months ended December 31, 2022, was primarily from $9.1 million of proceeds from our August 2022 equity raise, $3.6 million of additional net borrowing made under our short-term line of credit, and $1.5 million from our sales under our ATM Sales Agreement.

Inflation

Inflation has resulted in increased costs for our suppliers and our customers. In addition, the U.S. Government has responded to inflation by raising interest rates, which has increased the cost of capital. We believe this has resulted in some of our customers making decisions to reduce their costs as well as increased costs of our operations, which has negatively impacted the results of our operations during the three and six months ended December 31, 2023. We maintain strategies to mitigate the impact of higher material, energy and commodity costs, including cost reduction, alternative sourcing strategies, and passing along cost increases to customers, which may offset only a portion of the adverse impact.

Contractual Obligations, Commitments and Contingencies

As a result of our acquisitions and licensing agreements, we are contractually and contingently obliged to pay, when due, various fixed and contingent milestone payments. See *Note 13 – Commitments and Contingencies* in the accompanying Notes to the Unaudited Consolidated Financial Statements for further information.

On May 12, 2022, we entered into an agreement with Tris Pharma Inc. (“Tris”) to terminate the Tuzistra License, Development, Manufacturing and Supply Agreement dated November 2, 2018 (the “Tuzistra License Agreement”). Pursuant to such termination, we agreed to pay Tris a total of $6 million to $9 million, which reduced our total liability for minimum payments by approximately $8 million from the original Tuzistra License Agreement. As of December 31, 2023, the total remaining liability for minimum payments was $6.0 million. Pursuant to the settlement agreement, if the Company does not make timely payments, it is required to pay interest on any outstanding balances at a rate equal to the greater of (i) 2.5% per month and (ii) the maximum interest rate permitted by applicable law.

Upon closing of the acquisition of a line of prescription pediatric products from Cerecor, Inc. in October 2019, we assumed payment obligations that require us to make fixed and product milestone payments based on sales. As of December 31, 2023, up to $3.0 million of fixed and product milestone payments based on net sales remain.

In connection with our acquisition of the assets from Rumpus VEDS, LLC, Rumpus Therapeutics, LLC, Rumpus Vascular, LLC (collectively, “Rumpus”), and only if we resume and ultimately complete clinical development of AR101, we may be required to pay up to $67.5 million in regulatory and commercial-based earn-out payments to Rumpus, which are primarily paid against commercial milestone achievements. Under the licensing agreement with Denovo Biopharma LLC (“Denovo”), we made a payment of $0.6 million for a license fee in April 2022. In addition, upon the achievement of regulatory and commercial milestones, we may be required to pay up to $101.7 million. Under the licensing agreement with Johns Hopkins University (“JHU”), upon achievement of regulatory and commercial milestone, we may be required to pay up to $1.6 million to JHU. In fiscal 2022, two milestones payable to Rumpus were achieved totaling $4.0 million, which were paid in 109,447 shares of common stock and $2.6 million in cash. The Company also assumed the responsibility for royalties of 3.0% of net product sales, with a minimum of $20,000 per year, and upon the achievement of certain regulatory and commercial milestones, up to $1.6 million. With clinical development currently suspended, only if we resume and ultimately complete clinical development of AR101, are substantially all milestones payable to these parties.

Critical Accounting Estimates

The discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates based on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. For a detailed discussion about the Company's significant accounting policies, refer to our 2023 Form 10-K.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources and would be considered material to investors.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide information under this item.

ITEM 4. CONTROLS AND PROCEDURES

As required by Rules 13a-15 and 15d-15 under the Exchange Act, our Chief Executive Officer and Chief Financial Officer carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2023. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not effective, due to the material weakness in our internal control over financial reporting related to the Company's accounting for complex financial instruments with regards to warrants, and the valuation of inventory. As a result, we performed additional analysis as described below to ensure that our financial statements were prepared in accordance with U.S. GAAP. Accordingly, management believes that the financial statements present fairly in all material respects our financial position, results of operations and cash flows for the period presented.

Changes in Internal Control over Financial Reporting

Previous Disclosure of Material Weakness in Internal Controls Over Financial Reporting

Warrants. As disclosed in our September 30, 2022 Form 10-Q/A, we identified a material weakness in controls over the accounting for complex warrant issuances and the classification of these issued warrants. This material weakness resulted in the failure to prevent material adjustments in accounting for the warrants as equity classification when the warrants should have been classified as liabilities and marked to market each reporting period. While we have processes to properly identify and evaluate the appropriate accounting technical pronouncements, other literature, and consultation with third-party experts, we did not classify the warrants correctly.

Inventory. In connection with the preparation of our financial statements for the period ended June 30, 2023 in our 2023 Form 10-K, we concluded that we had a material weakness in internal control over financial reporting related to our analysis for the accounting for valuation of our inventory. At fiscal year end, it was determined that the analysis of over/under absorbed manufacturing costs was not performed, which could have led to material misstatement of our financial statement. If not addressed, the deficiency could result in a material misstatement in the future. In response, we have incorporated the process for quantifying any over or under absorbed manufacturing costs, and having the appropriate level of management evaluate the analysis and materiality of any over or under absorption.

Remediation Plan

Our Audit Committee is conducting an internal investigation to identify and determine a plan to remediate the material weaknesses described above and to enhance our overall control environment. We will not consider the material weakness remediated until our enhanced controls are operational for a sufficient period of time and tested, enabling management to conclude that the enhanced controls are operating effectively. Our remediation plan includes the implementation of controls over the process of reviewing significant and complex contracts and agreements, and the valuation of inventory.

Inherent Limitations

Our management team, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdown can occur because of simple errors or mistakes. In particular, many of our current processes rely upon manual reviews and processes to ensure that neither human error nor system weakness has resulted in erroneous reporting of financial data.

Changes in Internal Control Over Financial Reporting

Except for the material weaknesses noted above, there have been no changes in the Company's internal control over financial reporting that occurred during the three months ended December 31, 2023 that have a material effect, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION
ITEM 1. LEGAL PROCEDINGS

Sabby Litigation. A complaint was filed on February 22, 2023 in the Supreme Court of the State of New York by Sabby Volatility Warrant Master Fund Ltd ("Sabby") and Walleye Opportunities Master Fund Ltd ("Walleye"), holders of certain warrants to purchase common stock, against the Company. The complaint alleges that the Company improperly adjusted the exercise price of the warrants and miscalculated the number of shares the warrant holders may receive, and that the Company failed to provide prompt notice to the warrant holders of such adjustment. The complaint seeks a declaratory judgment of the warrant share calculation, that 575,000 warrant shares be due to Sabby on exercise of its warrants rather than 312,908 shares, and that 100,000 warrant shares be due to Walleye on exercise of its warrants rather than 54,146 shares. In October 2023, we entered into a settlement agreement and general release with Sabby and Walleye.

ITEM 1A. RISK FACTORS

Our business faces significant risks and uncertainties. Certain important factors may have a material adverse effect on our business prospects, financial condition, and results of operations, and you should carefully consider them. There have not been any material changes to our risk factors from those reported in our 2023 Form 10-K.

ITEM 5. OTHER INFORMATION

Rule 10b5-1 Trading Plans

During the fiscal quarter ended December 31, 2023, none of our directors or executive officers (as defined in Rule 16a-1 under the Exchange Act) adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement" (as those terms are defined in Item 408 of Regulation S-K).

ITEM 6. EXHIBITS

Exhibit No.	Description
10.1*,†	Commercial Manufacturing Services Agreement, dated November 13, 2023, by and between Aytu BioPharma, Inc. and Halo Pharmaceutical, Inc.
31.1*	Certificate of the Chief Executive Officer of Aytu BioPharma, Inc. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certificate of the Chief Financial Officer of Aytu BioPharma, Inc. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certificate of the Chief Executive Officer and the Chief Financial Officer of Aytu BioPharma, Inc. pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase.
101.DEF*	Inline XBRL Taxonomy Extension Definition Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase.
104	Cover Page Interactive Data File - formatted as Inline XBRL and contained in Exhibit 101.

* Filed herewith.
** Furnished herewith.
† Pursuant to Item 601(b)(10) of Regulation S-K, portions of this exhibit (indicated by asterisks) have been omitted as the registrant has determined that (1) the omitted information is not material and (2) the omitted information would likely cause competitive harm to the registrant if publicly disclosed.

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.

AYTU BIOPHARMA, INC.

Date: February 14, 2024

By: /s/ Joshua R. Disbrow
Joshua R. Disbrow
Chairman and Chief Executive Officer
(Principal Executive Officer)

Date: February 14, 2024

By: /s/ Mark K. Oki
Mark K. Oki
Chief Financial Officer
(Principal Financial Officer)
(Principal Accounting Officer)

Exhibit 10.1

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE AND CONFIDENTIAL.

COMMERCIAL MANUFACTURING SERVICES AGREEMENT

This Commercial Manufacturing Services Agreement (this " **Agreement**") is effective as of November 13, 2023 (the " **Effective Date**") by and between Halo Pharmaceutical, Inc., a Delaware corporation ("**Halo**"), and Aytu BioPharma, Inc., a Delaware corporation (" **Client**"). Each of Halo and Client may be referred to herein individually as a "**Party**" or collectively as the " **Parties**."

RECITALS

A. Client develops, markets, and sells pharmaceutical products.

B. Halo provides commercial manufacturing and related analytical services to the pharmaceutical industry on a contract basis.

C. Client desires to engage Halo to provide certain services to Client, and Halo desires to provide such services, on the terms and subject to the conditions set out below.

ARTICLE 1
DEFINITIONS

1.1. **Glossary**. The following capitalized terms have the indicated meanings, with grammatical variations having corresponding meanings:

"**Affiliate**" means, with respect to a Person, any other Person that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Person. For the purposes of this definition only, "**control**" and, the terms "**controlled by**" and **"under common control with**", shall mean (a) the possession, directly or indirectly, of the power to direct the management or policies of a Person, whether through the ownership of voting securities, by contract or otherwise; or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a Person.

"**API**" means the active pharmaceutical ingredient(s), whether chemical or biologic in nature, listed on Schedule E (as updated from time to time pursuant to the terms hereof) and provided by Client in accordance with Section 3.3 (API) for inclusion in Product.

"**API Cost**" means Client's cost to purchase and deliver API to Halo in accordance with Section 3.3 (API). In lieu of determining an actual cost on a case-by-case basis, the Parties will use the cost set forth on Schedule E (as updated from time to time pursuant to the terms hereof) as the API Cost for purposes of this Agreement; *provided*, *that* upon Halo's reasonable request from time to time, Client shall provide Halo with reasonable documentary evidence substantiating the validity of the API Cost.

“**Applicable Law**” means all laws, statutes, ordinances, regulations, rules, judgments, decrees or orders, as amended from time to time during the Term, of any Authority: (a) with respect to Halo, in the United States and in any other jurisdiction in which Halo performs a given Service; and (b) with respect to Client, in any jurisdiction in which Client operates or performs activities in respect of this Agreement and/or in any jurisdiction in which API or Product is produced, marketed, distributed, made available, used or sold by or for Client. The term “**Applicable Law**” includes cGMPs unless the Parties agree in writing to the contrary on a case-by-case basis.

“**Authority**” means any governmental authority, department, body or agency or any court, tribunal, bureau, commission, or other similar body, whether international, supranational, federal, state, provincial, county, or municipal.

“**Aytu Facility**” means that certain facility owned and operated by Aytu which is located at 2940 North Highway 360, Suite 100 Grand Prairie, TX 75050 with FDA registration number 3019769579.

“**Batch**” means a defined quantity of Product as set forth in the Specifications.

“**Business Day**” means any day except Saturday, Sunday, or any other day on which commercial banks located in New York, New York, USA are authorized or required by Applicable Law to be closed for business.

“**cGMPs**” means current good manufacturing practices promulgated by Regulatory Authorities: (a) with respect to Halo, in the United States and in any other jurisdiction in which Halo performs a given Service; and (b) with respect to Client, in any jurisdiction in which Client operates or performs activities in respect of this Agreement and/or in any jurisdiction in which API or Product is produced, marketed, distributed, made available, used or sold; in each case as amended from time to time during the Term. In the United States, cGMPs include, but are not limited to, 21 C.F.R. Parts 210 and 211; outside of the United States cGMPs include, but are not limited to, the International Council for Harmonization (ICH) guide Q7A “ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients.

“**Components**” means, collectively, all raw materials and ingredients, other than API, that are incorporated into or used to produce Product in accordance with the Specifications. The term Components includes Exclusive Components.

“**DEA**” means the United States Drug Enforcement Administration or any successor thereto performing similar functions.

“**Exclusive Components**” means any Components that are unique to any Product (i.e., that Halo does not procure for any other customer or drug product).

“**Facility**” means the facility operated by Halo located at 30 North Jefferson Road, Whippany, New Jersey, 07981, USA.

“**Fault**” means a Party’s recklessness, gross negligence, willful misconduct, fraud, material violation of Applicable Law or material breach of the Quality Agreement.

“**FDA**” means the United States Food and Drug Administration or any successor thereto performing similar functions.

“**Intellectual Property**” means all intellectual property and embodiments thereof, including patents, patent applications, trademarks, trademark applications, tradenames, copyrights, industrial designs, trade secrets, and know-how, as well as all industrial and other intellectual property rights, and all rights, interests, and protections that are associated with, equivalent or similar to, or required for the exercise of, any of the foregoing, however arising, in each case whether registered or unregistered and including all registrations and applications for, and renewals or extensions of, these rights or forms of protection under the Applicable Laws of any jurisdiction throughout in any part of the world.

“**Invention**” means any innovation, improvement, development, discovery, method, know-how, process, technique, work of authorship, or similar invention, whether or not written or otherwise fixed in any form or medium and whether or not patentable or copyrightable, that is generated, conceived, or reduced to practice by either Party (or any of its employees, independent contractors, subcontractors or agents), or jointly by the Parties, in connection with this Agreement and all Intellectual Property rights therein.

“**Inventory**” means all stocks and inventories of Exclusive Components and Product-Specific Items purchased, produced, held, or maintained by Halo in accordance with this Agreement, including any excess material purchased by reason of a vendor’s minimum purchase requirements and any long lead time material. The term Inventory does not include any API.

“**Latent Defect**” means any non-conformity that causes Product to be Non-Conforming Product and that could not reasonably be detected by visual inspection or the analytical methods used to characterize the Product at the time of release.

“**Non-Conforming Product**” means Product resulting from Services hereunder that has been delivered by Halo hereunder and that fails to meet the warranty set forth in Section 9.3(d) (Product Warranty) due to Halo’s Fault.

“**Person**” means any individual, corporation, company, partnership, association, joint-stock corporation, trust, unincorporated organization, or Authority.

“**Product**” means that certain pharmaceutical product identified on Schedule A, as more specifically described in the Specifications.

“**Recall**” means any action (a) by Client to recover title to or possession of, or to issue a field alert or field correction with respect to, quantities of Product sold or shipped to Third Parties, including any voluntary withdrawal of Product from the market; or (b) by any Regulatory Authority to recall, withdraw from the market, order any corrective action, or otherwise detain or destroy any Product.

"**Regulatory Authority**" means any Authority responsible for granting marketing, distribution, and related approvals for pharmaceutical, medicinal, or therapeutic device products intended for human use in the Territory and/or in the jurisdictions in which the Facility is located. The term Regulatory Authority includes the FDA and DEA, as applicable.

"**Representatives**" means a Party's Affiliates and its and their respective directors, officers, employees, independent contractors, accountants, attorneys, professional consultants and agents.

"**Services**" means the manufacturing (including processing, preparation, fill, finish, pressing, coating, etc. as applicable), quality control and assurance, testing, and storage that Halo shall perform under this Agreement to produce Products from API and Components. The term Services excludes Additional Services.

"**Specifications**" means, with respect to a Product, the written specifications for such Product in its final configuration for purposes of this Agreement, comprised of a list of tests, references to analytical procedures, and appropriate acceptance criteria, which are numerical limits, ranges, or other objective criteria for the tests described, as agreed in writing by the Parties and appended to the Quality Agreement.

"**Split**" means, with respect to a Batch, the division of the bulk blend into different presentations of the applicable Product, to the extent permitted by cGMPs. (*For example only, 50% of one Batch of bulk blend could be compressed into [***] strength Product, and the remaining 50% could be compressed into [***]strength Product.*) Splitting of Batches, outside of the standard batch size detailed in Schedule A or as agreed upon in writing by both Parties, is done at Client's request only and is subject to an additional fee as set forth on Schedule A.

"**Territory**" means the United States of America (including its territories, military bases, possessions and protectorates, such as Puerto Rico).

"**Third Party**" means any Person that is not a Party or an Affiliate of a Party.

"**Year**" means, (a) with respect to the first year of this Agreement, the period from the Effective Date up to and including December 31 of the same calendar year; (b) with respect to the last year of this Agreement, the period from January 1 of such last calendar year up to and including the date of termination or expiration of this Agreement; and (c) for all periods in between, a calendar year.

1.2. **Index**. The following capitalized terms are defined in the section of this Agreement indicated below, with grammatical variations having corresponding meanings:

Term	Section
Additional Services	2.2(b)
Agreement	Introductory paragraph
Client	Introductory paragraph
Client Indemnitees	10.2(a)
Client Inventions	12.2(a)
Commitment	3.1
Confidential Information	11.1(a)
Deficiency Notice	6.1(a)
Discloser	11.1(a)
Dispute	13.1
Effective Date	Introductory paragraph
Exclusive Components Purchasing Summary	4.3(b)
Facilitator	13.1
Firm Order	4.1(b)
First Production Year	5.1(a)
Forecast	3.1
Halo	Introductory paragraph
Halo Indemnitees	10.2(b)
Halo Inventions	12.2(b)
Losses	10.2(a)
Price	5.1(a)
Product-Specific Items	2.1(b)(iii)
Proprietary IP	12.1
Purchase Order	4.1(a)
Quality Agreement	7.8
Recipient	11.1(a)
Records	7.3
Rejected Product	6.1(c)
Supply Committee	7.2(a)
Term	8.1
Third Party Claim	10.2(a)

ARTICLE 2
SERVICES

2.1. **Manufacturing Services**.

(a) Arrangement. In consideration of Client's payment of the fees due under, and the other terms and conditions of, this Agreement, Halo shall perform the manufacturing Services at the Facility in order to supply Product to Client. Client shall purchase one hundred percent (100%) of its requirements for Product from Halo except (i) for Products produced in the Aytu Facility as determined by Client in its sole discretion; or (ii) to the extent otherwise expressly permitted in this Agreement.

(b) Conversion of API and Components . Subject to the terms of this Agreement, Halo shall convert API and Components into Products in accordance with this Agreement. To this end:

(i) API. Subject to the terms of this Agreement, Client will deliver, or cause the delivery of, all API to Halo in accordance with Section 3.3 (API). Halo shall (A) upon receipt of API, compare shipping documents against labeling to verify identity and quantity received; (B) perform conformance testing of the API to the extent required by the Quality Agreement; (C) promptly, and in any event within [***] days after receipt of API at the Facility (or such other period as may be specified in the Quality Agreement), notify Client if it detects a defect in API and follow Client's reasonable written instructions in respect of return or disposal of defective API, at Client's cost; (D) store API in a manner designed to avoid adulteration or loss of efficacy, and in accordance with the specifications therefor and Applicable Law; (E) turn over inventory of API in accordance with cGMP to optimize its shelf life; (F) maintain the API free and clear of any encumbrances imposed as a result of any act or omission of Halo; (G) use API only to provide the Services; and (H) notify Client if it anticipates that additional amounts of API will be needed for Halo to meet the first [***]months of Client's then-current Forecast. If any API is a controlled substance within the meaning of Applicable Law, Halo, at its sole cost, shall request appropriate quota allowances for such API from the DEA based on the most recent Forecast submitted by Client at the time requests for quota are due.

(ii) Components. Subject to the terms of this Agreement, Halo shall purchase all Components as required by the Specifications and as further described in Section 4.3 (Procurement) from vendors identified in the Quality Agreement or otherwise agreed to in writing by the Parties. Halo shall test all Components after receipt at the Facility as required by the Quality Agreement. Halo shall turn over Component inventory in accordance with cGMP to optimize the shelf life of such items.

(iii) Product-Specific Items. Subject to the terms of this Agreement, Halo shall purchase all tooling, consumables, and any other Product-specific items pre-approved in writing by Client reasonably necessary for Halo to perform the Services ("**Product-Specific Items**"). Halo shall charge through to Client all Third-Party vendor fees for such purchases at Halo's actual cost plus a [***] administrative fee.

(iv) Equipment. Halo shall provide at its sole cost all equipment needed to perform the Services, subject to the terms of this Section 2.1(b)(iv). If, following the Effective Date, (1) the volume of Client's requirements for Product hereunder make it reasonably necessary for Halo to purchase additional equipment for exclusive use in providing the Services hereunder to Client (i.e., to use a given item solely to provide Services to Client) or (2) an amendment to this Agreement (e.g., the addition of a new Product) or a change to the Specifications (as contemplated by Section 5.1(e) (Technical Changes)) requires the use of equipment necessary to provide the revised Services that Halo does not then own, then Halo will so inform Client of the need and cost of such new equipment, whereupon such equipment, subject to Client's reasonable approval, may be either (A) purchased by Halo and charged through to Client at Halo's actual cost plus a [***] administrative fee; or (B) purchased directly by Client and supplied to Halo DDP (Incoterms 2020) the Facility at Client's sole cost.

(c) Batch Number. Halo shall assign each Batch a unique batch number using Halo's batch numbering system. This batch number will appear on all documents relating to the particular Batch.

(d) Quality Control. Halo shall perform Product quality control and quality assurance testing as and to the extent required by the Quality Agreement. Batch review and release to Client shall be the responsibility of Halo's quality assurance group. Halo shall perform such Batch review and release responsibilities in accordance with Halo's standard operating procedures. Client shall review and respond to any Batch investigational report provided by Halo within ten (10) Business Days of receipt of such report. Each time Halo delivers a Batch to Client, Halo shall provide Client with a certificate of compliance and any other certificates required under the Quality Agreement, which shall include, if Halo is responsible for Product testing, a certificate of analysis. At Client's reasonable request, Halo will provide copies of additional Batch documentation, such as Batch manufacturing records, equipment data printouts, raw material data, and laboratory notebooks.

2.2. **Expanded Services**.

(a) Additional Products and Territories. Additional products and countries may be added to this Agreement upon the Parties' written agreement in accordance with Section 14.6 (Entire Agreement; Amendments; Waivers). Subject to the terms hereof, the Parties shall amend or supplement this Agreement (including the Schedules) as necessary to reflect their agreement on modifications to Product-specific or Territory-specific terms, including Price.

(b) Product Related Services. In addition to the Services, Halo shall perform any services in connection with Product as the Parties may agree in writing from time to time ("**Additional Services**"). The Parties' written agreement shall specify the scope, timing, parameters (including protocols, if applicable), fees payable by Client, and other matters pertinent to the Additional Services. To the extent the Parties have agreed to any such matters as of the Effective Date, they are set forth on Schedule B. The terms and conditions of this Agreement shall govern the provision and receipt of any Additional Services.

(c) Post Marketing Stability Testing. At Client's request, as an Additional Service and in consideration of the fees set forth on Schedule B, Halo shall conduct post marketing stability testing on Product in accordance with such commercial and Product stability protocols as the Parties may agree in writing.

2.3. **API Yield**. The following shall apply solely in respect of API provided and paid for by Client. Within sixty (60) days after the end of each Year:

(a) Inventory Reports. Halo shall provide Client with an inventory report, as of the end of each calendar month, for each API held at the Facility. Each inventory report shall be in substantially the form set forth on Schedule C, shall be based on data from Halo's manufacturing resource planning (MRP) system or Batch manufacturing records.

(b) Annual Yield Calculation. Halo shall perform the annual yield calculation and reconciliation procedures set forth on Schedule C and notify Client of the results thereof.

2.4. **Storage**. If Client fails to take possession of Product upon tender of delivery under Section 4.4 (Shipment), Halo will move Product into storage at the Facility. Such storage shall comply with cGMP. Storage shall be free of charge for the first three (3) months following Product release by Halo's quality group. Client shall thereafter pay Halo the monthly storage fee set forth in Schedule B for storing such Product. Upon two (2) weeks' written notice to Client, Halo shall have the option to ship to Client, at Client's cost, (a) any released Product that is or contains a controlled substance, (b) any released Product that has been held by Halo in storage longer than twelve (12) months or (c) any Exclusive Components or API that have been held by Halo in inventory longer than six (6) months and that are not reasonably expected to be needed for Halo to manufacture Product based on Client's then-current Forecast.

ARTICLE 3
CLIENT OBLIGATIONS

3.1. **Rolling Forecasts**. Concurrently with the signing of this Agreement, Client shall provide Halo with a written [***] month forecast of the volume of each Product that Client anticipates it will require Halo to supply during each month of that [***] -month period (the "**Forecast**"). Client shall provide Halo with an updated Forecast in writing (a) on or before the tenth (10th) day of each calendar month on a rolling [***] -month basis; and (b) promptly, and within three (3) Business Days, following any determination by Client that the volumes set forth in the Forecast most recently provided to Halo have changed [***] percent ([***]) or more. Subject to the terms of this Agreement, the first [***] months of each Forecast shall be binding on Client with respect to the quantities of Product specified therein (the "**Commitment**"), and the balance shall be a non-binding, good faith estimate. Client shall place orders for Services against the Forecast as specified in Article 4 (Orders & Shipment). Except as provided herein, the Forecast shall not be binding on Client.

3.2. **Specifications**. Prior to the Effective Date, Client has provided Halo with a preliminary copy of the Specifications pertaining to Product, which are attached to Schedule A. Prior to Client placing its first Purchase Order, Client shall provide Halo with originally executed copies of final Specifications and any other Product-related information reasonably requested by Halo in connection with the Services. If such final Specifications are different from the preliminary Specifications attached to Schedule A, Section 5.1(e) (Technical Changes) shall apply. Thereafter, Client may revise the Specifications from time to time, subject to Section 5.1(e) (Technical Changes).

3.3. **API**. Client shall, at its sole cost and expense, deliver the API to Halo DDP (Incoterms 2020) the Facility in such quantities and at such times as the Parties may agree so as to enable Halo to timely provide the Services on a non-rush basis, but in any event (a) in quantities (subject to DEA quotas) sufficient to satisfy Client's Product requirements set forth in the first [***] months of Client's most recent Forecast; and (b) at least [***] prior to the scheduled compounding date of the Batch in which such API will be used; *provided*, that, should the delivery timeframes in either or both of the foregoing clauses (a) and (b) cause Halo difficulties in testing and releasing API on a timely basis in advance of scheduled manufacturing (without expediting), the Parties will discuss a resolution in good faith. Client shall be responsible at its expense for securing any necessary export or import, or similar clearances or governmental permits required in respect of the provision of API to Halo. Title to and risk of loss of the API shall at all times remain with Client, and Client will insure the API at Client's cost; *provided*, that Halo will be responsible for loss of API to the extent caused by Halo's Fault. If Client refuses or fails to timely supply API, or the parties are unable, despite good faith discussions, to resolve any problems caused by the delivery timeframes in either or both of the foregoing clauses (a) and (b), Halo reserves the right to treat such delay as a cancellation of the applicable Firm Order by Client under Section 4.1(b) (Firm Orders). Halo will promptly, and within three (3) Business Days, notify Client in writing of any such election.

3.4. **Quality Control; Safety**. Client shall have sole responsibility for the release of Product to the market and for handling customer matters as contemplated by Section 6.4 (Customer Inquiries). Prior to the Effective Date (or the effective date of the applicable amendment to this Agreement, in the case of Products added to this Agreement after the Effective Date), Client shall have provided Halo with all environmental, health and safety information relating to API and Product, including material safety data sheets; *provided*, that Halo acknowledges that Client does not draft, and is not responsible for, any information on the API, which is provided to Client by the API manufacturer. Client shall promptly, and within ten (10) Business Days, provide Halo any updates to such documentation that become available.

3.5. **Product Discontinuation**. Client shall use commercially reasonable efforts to provide at least [***] months' advance notice to Halo if it intends to no longer order Services for a Product.

ARTICLE 4
ORDERS & SHIPMENT

4.1. **Orders**.

(a) Purchase Orders. From time to time as provided in this Section 4.1(a), Client shall submit to Halo a binding, non-cancellable purchase order for Services identifying an order number, the Product to be manufactured (including the strength), the number of Batches, the Batch size (to the extent the Specifications permit Batches of different sizes), Client's requested delivery date for each Batch, and any other elements necessary to ensure the timely production and delivery of Product (each, a "**Purchase Order**"). For Product strengths that utilize less than 100% of an ODT blend batch (as indicated on Schedule A, in the columns titled "Product"), any Purchase Order that includes quantities of such strength must also specify other Product strengths and quantities (in any combination) that result in the use of 100% of an ODT blend batch. *(For example only, if Client orders a Batch of Adzenys XR ODT Bulk in* [***] *strength, which utilizes* [***] *of an ODT blend batch, Client must also order one or more Products that collectively utilize the remaining* [***] *of the ODT blend batch, such as:* [***] *of Adzenys XR ODT Bulk in* [***] *strength; or* [***] *of Adzenys XR ODT Bulk in* [***] *strength; or* [***] *of* [***] *of Adzenys XR ODT Bulk in* [***] *strength).* Client shall submit Purchase Orders at least [***] months in advance of the delivery date requested in the Purchase Order.

(b) Firm Orders. Halo will confirm in writing each Purchase Order, including the Product, quantity and expected delivery date, within [***] Business Days of receipt. If Halo is unable to meet the delivery date requested by Client in its Purchase Order, Halo shall so notify Client in Halo's confirmation of such Purchase Order and provide to Client an alternative delivery date, which shall not be more than [***] days earlier or later than the initial delivery date requested by Client in its Purchase Order. Only upon Halo's confirmation of Client-issued Purchase Orders will such orders become firm (each, a "**Firm Order**"). Halo may change the expected delivery date of any Firm Order within a +/- [***] day window upon written notice to Client.

(c) Cancellation or Modification of Firm Orders by Client . Except as expressly provided herein, Client may not cancel or modify any Firm Order without Halo's prior written consent, which consent shall not be unreasonably withheld, delayed, or conditioned; *provided*, that

(i) if Client requests a cancellation of a Firm Order, Halo reserves the right to condition its consent to such request on Client's payment of the "conversion cost" portion of the Price of the cancelled Batches; and

(ii) Halo shall use its best efforts to accommodate any Client request to:

(A) Split any Batch that was not already Split in the Firm Order, subject to payment of both a Split Batch fee and a change fee as set forth on Schedule B;

(B) Revise the Split of a Batch in any manner (e.g. strengths, quantities; including to remove a Split) where the Firm Order already included a Split, subject to payment of a change fee as set forth on Schedule B;

(C) Substitute one [***] ODT blend batch strength under a Firm Order for a different [***] ODT blend batch strength, subject to payment of a change fee as set forth on Schedule B; or

(D) designate the priority of Products to be delivered in a Firm Order (i.e., where a Firm Order is for multiple Batches (whether or not Split) compressed into multiple Product Presentations, or for one Split Batch, to designate which Product presentation(s) specified in such Firm Order should be manufactured before the others in such Firm Order; or where multiple Firm Orders have similar delivery dates, to designate which of such Firm Orders should be fulfilled before the others; but

(iii) *so long as*, in each and every case set forth above ((i), (ii)(A), (ii)(B), (ii)(C), and (ii)(D)), Client's request for cancellation, Splitting, modification or prioritization, as applicable, is submitted to Halo in writing at least [***] prior to the scheduled delivery date for the applicable Firm Order (or, where more than one Firm Order is involved, the earliest scheduled delivery date as among the applicable Firm Orders) *but in any event* at least [***] prior to the commencement of Batch manufacture (or, where more than one Batch is involved, prior to the commencement of manufacturing of any of the applicable Batches). The commencement of Batch manufacturing shall be deemed to occur on the date Halo weighs and dispenses the first material (whether API or any Component) necessary to manufacture such Batch.

For the avoidance of doubt, Halo may withhold its consent, in its sole discretion, to any Client request to cancel or modify any Firm Order if such request is not in accordance with the foregoing clauses (i), (ii) and (iii).

(d) Rejection; Excess Volume. Subject to the following sentence, Halo may reject any Purchase Order without penalty or liability to Client (i) for Product quantities in excess of the Commitment; (ii) if Halo has an insufficient DEA procurement quota in respect of the applicable API; or (iii) the Purchase Order is not given in accordance with this Agreement. Halo shall use commercially reasonable efforts to supply Client with quantities of Product that are up to [***] of Commitment quantities and to accommodate the delivery date requested by Client in its Purchase Order. Without breaching the terms of this Agreement or incurring any additional cost or expense hereunder, Client may purchase from Third Parties or manufacture internally any quantities of Product requested in Purchase Orders that Halo rejects based on clause (i) or (ii) above.

4.2. **Minimum Order Quantity**. Subject to any greater or lesser minimum order quantities provided for in Schedule A, each Purchase Order submitted by Client shall be for at least [***]; however, [***] may be Split.

4.3. **Procurement**.

(a) Reliance on Forecast. Subject to the terms of this Agreement, Client understands and acknowledges that Halo will rely on the Forecast, Commitment and Firm Orders to procure the Components necessary for Halo to fulfill its obligations to supply Product under this Agreement. Accordingly, Client authorizes and instructs Halo to purchase Components sufficient to satisfy Client's Product requirements set forth in the [***] of Client's most recent Forecast (or any longer period the Parties may agree in writing from time to time), plus, for each Exclusive Component, any additional amounts necessary to satisfy the applicable vendor's minimum order quantity requirements, if any (as set forth in the Exclusive Component Purchasing Summary, discussed below). Client acknowledges that the foregoing authorization enables and requires Halo to purchase quantities of Components beyond those needed to satisfy the Commitment, and that such excess quantities are intended to comprise safety stock hereunder. In the event that any Component becomes subject to purchase lead time beyond [***], the Parties will negotiate in good faith an appropriate amendment to this Section 4.3(a) (Reliance on Forecast).

(b) Exclusive Components.

(i) List of Exclusive Components. Set forth on Schedule D (as amended from time to time) is a list of Exclusive Components that Halo expects to be required to purchase pursuant to Section 2.1(b)(ii) (Components) in connection with its provision of the Services hereunder. From time to time as set forth herein, Halo shall provide Client with a written purchasing summary of all Exclusive Components that reflects and updates the information set forth on Schedule D (the "**Exclusive Components Purchasing Summary**"), in keeping with the Product volumes set forth in the then-current Forecast, Commitment and Firm Orders. Halo shall provide a preliminary Exclusive Components Purchasing Summary within [***] of the Effective Date, a revised version following receipt of final Specifications, and thereafter an updated version on a [***] basis. The list set forth on Schedule D and each Exclusive Components Purchasing Summary shall indicate those Exclusive Components that have a long lead time or limited shelf life and/or that are subject to minimum order quantities as specified by the Third-Party vendor.

(ii) Obsolete Exclusive Components. Client shall reimburse Halo its documented costs for procuring and testing any Exclusive Components that become obsolete for manufacturing of the Products hereunder. An Exclusive Component shall be deemed obsolete as follows: (A) for items that do not have an expiration or re-test date, the item will be obsolete on the last day of the month that is [***] after the Forecasted month in respect of which such purchase were made; and (B) for items that have an expiration or re-test date, the item will be obsolete on such date, *so long as* (and to the extent) Halo procured such Exclusive Components for use under this Agreement in the quantities and at the times specified in Section 4.3(a) (Reliance on Forecast) and the then-applicable Exclusive Components Purchasing Summary. Notwithstanding the foregoing, for Exclusive Components that have a re-test date, at Client's request and cost, Halo will re-test any such Exclusive Component for efficacy and if, based on such test results, such Exclusive Component can still be used by Halo to provide Services, then Halo shall retain such Exclusive Component in inventory and [***]; *however*, this Section 4.3(b)(ii) shall apply anew to such re-tested Exclusive Component retained by Halo, with the new re-test date being substituted for the most recent re-test date. Any reimbursement due under this Section 4.3(b)(ii) shall be invoiced in accordance with Section 5.3(d) (Other Amounts) and payable in accordance with Section 5.4 (Payment Terms).

(iii) Audit of Exclusive Component Vendors. Client shall be responsible for auditing and qualifying all Exclusive Component vendors; *however*, at Client's written request, Halo will perform any such vendor audit on Client's behalf at the applicable fee set forth on Schedule B.

(c) Delays. Halo shall not be liable for any delay in delivery of Product if Halo is unable to obtain any Component in a timely manner so long as Halo placed orders for such Component in keeping with this Section 4.3 and in the quantity and subject to the lead time imposed by the applicable vendor and [***]. In addition, for any API or Component that is a controlled substance, Halo shall not be liable for any delay in delivery of Product where Halo does not receive the necessary DEA quota or other approvals even though Halo filed for such quota or other approvals in accordance with Applicable Law and in quantities consistent with Client's most recent Forecast available at the time such filings are due under Applicable Law. In the event of any such delay (actual or anticipated), Halo shall notify Client, whereupon the Parties shall discuss in good faith the cause, the anticipated duration and effect thereof, and projected cost, as well as ways to mitigate such effects, which may include Client negotiating directly with the applicable vendor to secure an adequate and timely supply of the applicable Component.

4.4. **Shipment**. Halo shall deliver Product and other deliverables to Client or its designee FCA (Incoterms 2020) at the Facility. [***]. Halo shall pack and label shipping containers in accordance with Applicable Law and transport guidelines, the Specifications, and Client's written instructions (to the extent not inconsistent with any of the foregoing). Client shall arrange for insurance and shall select the freight carrier to be used to ship Products.

ARTICLE 5
PRICING & PAYMENT

5.1. **Price for Manufacturing Services**.

(a) Consideration. Subject to the terms of this Agreement, Client shall pay Halo the total per-unit sale price for Product set forth on Schedule A, as the same may be adjusted in accordance with the terms and conditions of this Agreement (the "**Price**").

(b) Initial Price. Each Price set forth on Schedule A as of the Effective Date (or the effective date of any amendment adding a new Product to the scope of this Agreement) is valid through the first full Year of commercial production of the relevant Product under this Agreement (i.e., excluding Product manufactured under any development agreement, such as validation batches) (the "**First Production Year**"); *provided*, that Halo reserves the right to revise the Price (i) if such commercial manufacturing under this Agreement has not commenced within [***] of the Effective Date and (ii) to the extent otherwise permitted by this Agreement. (*For example only, and subject to the foregoing proviso, if such commercial production of a Product included on Schedule A as of the Effective Date begins on November 15, 2023, then the Price set forth on Schedule A as of the Effective Date for such Product shall be valid through December 31, 2024*).

(c) Subsequent Year Price Adjustments. Effective on January 1 of each Year following the First Production Year, the Price shall be adjusted to reflect (i) inflation, which adjustment shall be based on the increase in the Producer Price Index (PPI) for Pharmaceutical Preparations PCU325412325412 published by the U.S. Department of Labor, Bureau of Labor Statistics, in September of the then-current Year compared to the same month of the preceding Year; and (ii) documented changes in Component costs so as to pass on to Client the actual amount of any increase or decrease in such costs. Halo shall provide in writing to Client by November 1 of each Year the updated Price for the subsequent Year, with appropriate supporting documentation; *provided*, *that* Halo may redact confidential portions of any supporting documents subject to obligations of confidentiality between Halo and its vendors. Such revised Price shall be effective with respect to any Product [***].

(d) Current Year Price Adjustments. During any Year of this Agreement, the Price shall be adjusted in accordance with this Section 5.1(d) to reflect material changes in Component costs (whether individually or in the aggregate) due to market conditions [***]. To the extent that a Price has been previously adjusted pursuant to Section 5.1(c) (Subsequent Year Price Adjustments) or this Section 5.1(d) to reflect an increase or decrease in the cost of one or more Components, the adjustments provided for herein shall operate based on the costs attributed to such Component(s) at the time the last such adjustment was made. Halo shall provide in writing to Client the revised Price, with documentation to support both Halo's normal forecasted cost and new materially changed cost; *provided*, that Halo may redact confidential portions of any supporting documents subject to obligations of confidentiality between Halo and its vendors. Such revised Price shall be effective with respect to any Product delivered by Halo [***] after Client's receipt of Halo's notice.

(e) Technical Changes. Amendments to a Product's master batch record, Specifications or the applicable Quality Agreement requested by either Party will be implemented only following a technical and cost review by the Parties and are subject to Client and Halo reaching agreement on appropriate revisions to the Price and any other impacted fees under this Agreement, other relevant terms of this Agreement, and on a timeframe for implementation by Halo. If the Parties proceed with such amendment and Client accepts a proposed fee revision, the Parties shall memorialize the amendment in writing (and where the amendment is to Specifications, Client shall provide Halo with originally executed copies of such revised Specifications), Halo shall implement the proposed amendment on the agreed timeframe, and the revised fee shall apply only to Products that are manufactured under the amended master batch record, Specifications or Quality Agreement, as applicable. Client shall either, at its election, (i) purchase from Halo any Inventory, Product and work-in-process rendered obsolete as a result of such amendment or (ii) reimburse Halo for such items together with the costs of its destruction thereof.

5.2. **Supplemental Charges**.

(a) Taxes. All taxes, duties and other amounts assessed by any Authority (excluding tax based on net income or real property and franchise taxes) on API, Product, Services, Additional Services or other amounts due hereunder are the responsibility of Client, and Client shall reimburse Halo for all such taxes, duties and amounts required to be paid by Halo to any Authority (or such sums will be added to invoices directed at Client, where applicable). Halo shall reasonably cooperate with Client to utilize any legally available reductions or exemptions from any such taxes, duties, or assessments.

(b) Annual Product Review. Halo shall have the right to charge Client the annual product review fee set forth on Schedule B for the services provided pursuant to Section 7.4 (Reports).

(c) Retesting. Halo reserves the right to charge Client for retesting and required investigational studies performed that are not directly due to Halo's Fault. Any tests or investigations requested by Client that are not required pursuant to the Quality Agreement will be charged to Client at Halo's then-current standard rates.

5.3. **Invoicing**.

(a) Recipient. Halo shall send invoices by fax or email to such fax number or email address as Client may provide to Halo in writing from time to time.

(b) Product Invoices. If Halo is responsible for Product release testing under the Quality Agreement, Halo shall invoice Client for Product on the date on which Halo notifies Client that Product is released by Halo's quality assurance department and is ready for shipment. If Halo is not responsible for Product release testing under the Quality Agreement, Halo shall invoice Client for Product upon completion of manufacturing and issuance of certificate of manufacture. Each Product invoice shall identify Client's Purchase Order number, Batch numbers, Product names and quantities, Price, freight charges and the total amount to be remitted by Client. Halo shall also submit to Client with each shipment of Product an invoice covering such shipment.

(c) Component Reimbursement. Halo shall invoice Client for any reimbursement to which Halo is entitled under Section 4.3(b) (Exclusive Components) when the applicable Component has not been used within the required time period or has expired. Halo shall deliver to Client documentation reasonably sufficient to support the amount of such reimbursement; *provided*, *that* Halo shall not be obligated to provide specific pricing information regarding any Component that is subject to confidentiality obligations between Halo and its vendor. In respect of any unused, but unexpired, Components reimbursed by Client hereunder, to the extent such Components are incorporated into or used in connection with Product subsequent to such reimbursement, Halo will credit Client for the amount reimbursed to Halo.

(d) Other Amounts. Halo shall invoice Client for all other fees due under this Agreement (such as in connection with Additional Services or permitted cancellations of Firm Orders pursuant to Section 4.1(b) (Firm Orders)) as and when earned or accrued. Any fees assessed on an annual basis will be invoiced as of the first day of each Year. Each such invoice shall reference this Agreement and identify in reasonable detail the nature of the charges therein.

5.4. **Payment Terms**. Client shall pay all invoiced amounts that are not subject to a good faith dispute by Client in full within [***] days following the invoice date. Client shall make payment in (and all prices, fees and charges set forth in this Agreement are quoted in) U.S. dollars to the account indicated in the applicable invoice. If any payment is not received by Halo by its due date, Halo shall have the right, in addition to any other remedies available at law or in equity, to take one or more of the following actions: (a) terminate for breach in accordance with Section 8.2(a) (Breach); (b) suspend performance until all overdue amounts are paid in full; (c) charge to Client interest on the outstanding sum from the due date (both before and after any judgment) at [***] per month (or, if less, the maximum amount permitted by Applicable Law) until paid in full, plus all reasonable costs of collection of late payments, including reasonable attorneys' fees and court costs, incurred through the date of actual payment; (d) require Client to pre-pay for Components to be procured by Halo; and/or (e) change the payment terms under this Agreement upon written notice to Client, including to require all or a portion of payment in advance of shipment of Product. For the avoidance of doubt, Halo's delivery obligations under this Agreement shall be tolled during any period in which the foregoing clause (b) is invoked.

5.5. **Pre-Validation Batches**. Client shall be responsible for the cost of each Batch produced under this Agreement (including Batches necessary to support the validation portion of Client's submissions for Product approvals by Regulatory Authorities and any Batch manufactured following (a) a change in Specifications or (b) a scale-up in the manufacturing process to produce greater quantities of Product), even if the Batch fails to meet the Specifications, until all manufacturing, testing and storage methods and processes have been validated in accordance with industry standards (including production of at least [***] Batches of each strength that meet the then-applicable Specifications); *provided*, that the foregoing shall not apply to the extent Halo was grossly negligent, engaged in willful misconduct, or violated cGMPs (to the extent applicable) in the manufacturing of the out-of-Specification Batch. In cases where Halo is responsible for an out-of-Specification Batch pursuant to the foregoing proviso, Halo will also be responsible for the cost of destroying the out-of-Specification Batch and its components. In all other cases, Client will be responsible for the cost of destroying the out-of-Specification Batch and its components. Halo and Client shall cooperate in good faith to determine and resolve any problems causing the out-of-Specification Batch.

ARTICLE 6
PRODUCT CLAIMS AND RECALLS

6.1. **Product Claims**.

(a) Non-Conforming Product. Client has the right to reject any portion of any shipment of Product that is alleged to be Non-Conforming Product without invalidating any remainder of such shipment. Upon receipt of each Product shipment under this Agreement, Client shall visually inspect each Batch and perform any testing that the Quality Agreement requires Client to perform. Client shall give Halo written notice of any claim that a Batch is Non-Conforming Product and a sample of the allegedly Non-Conforming Product (together, a "**Deficiency Notice**") within [***] after Client's receipt of such Batch or, in the case of a Latent Defect, within [***] after Client's discovery of the Latent Defect, but in no event after the expiration date of the Batch in question. If Client fails to timely provide Halo with a Deficiency Notice hereunder the Batch shall be deemed accepted by Client.

(b) Evaluation. If Halo disagrees with a Deficiency Notice, Halo shall give Client written notice of such disagreement within [***] after receiving the Deficiency Notice. If, within [***] after Client's receipt of Halo's disagreement notice, Client and Halo fail to agree as to whether each Batch identified in the Deficiency Notice is Non-Conforming Product, the Parties shall mutually select an independent laboratory or qualified person, as appropriate, to evaluate whether such Products are Non-Conforming Product and the cause of any non-conformity. Such evaluation shall be binding on the Parties. If the evaluation confirms that a Batch is Non-Conforming Product (or if Halo does not timely disagree with a Deficiency Notice), then (i) the applicable Batch(es) shall be deemed properly rejected under this Agreement, (ii) Halo shall bear the cost of the evaluation, and (iii) Section 6.1(c) (Remedies) shall apply. If the evaluation determines that a Batch is not Non-Conforming Product, then (A) the applicable Batch(es) shall be deemed accepted by Client; and (B) Client shall bear the cost of the evaluation.

(c) Remedies. In respect of any Batch properly rejected under this Section 6.1 as Non-Conforming Product (" **Rejected Product**"), Halo will replace the Rejected Product [***], so long as Client provides the necessary API [***], calculated as the volume of API necessary to replace the Rejected Product [***]) and pay for the destruction or return shipping of the Rejected Product (so long as Client destroys or returns the Rejected Product at Halo's direction).

(d) Validated Testing. Any tests conducted by Client under Section 6.1(a) (Non-Conforming Product) or by a Third Party under Section 6.1(b) (Evaluation) shall employ only the validated methods and procedures required to be used by Client or Halo, as applicable, under the Specifications or Quality Agreement.

6.2. **Product Recalls**. Each Party shall promptly, and within [***], notify the other Party by telephone (confirmed by written notice) of any information of which it becomes aware that might affect the safety, efficacy, or marketability of any Product and/or that could reasonably be expected to result in a Recall. The conduct of and regulatory filings for any Recall shall be controlled, implemented, and made by Client, and Halo will co-operate in such Recall as reasonably requested by Client, having regard to all Applicable Law. Client shall provide Halo with an advance copy of any proposed submission to a Regulatory Authority in respect of any Recall and shall consider in good faith any comments from Halo. Client shall bear the cost of any Recall and reimburse Halo for the expenses incurred by Halo in connection with any Recall, unless such Recall is caused solely by Halo's gross negligence or willful misconduct, in which case Halo will reimburse Client for Client's reasonable, actual, and documented out-of-pocket expenses of conducting such Recall and bear the expenses incurred by Halo in connection with such Recall (subject, for the avoidance of doubt, to Section 10.1 (Limitation of Liability). For clarity, to the extent that a Recall involves Product that is alleged to be Non-Conforming Product, the Parties' respective rights and remedies with respect to such Product shall be governed by Section 6.1 (Product Claims).

6.3. **Disposition of Product**. Client shall not use or sell any Product that does not, or that Client has reason to believe does not, meet the Specifications or comply with Applicable Law. Client shall not, without Halo's prior written consent (which consent shall not be unreasonably withheld, delayed, or conditioned), return, destroy, or otherwise dispose of any Non-Conforming Products or Recalled Products in relation to which it intends to assert a claim against Halo. Halo shall bear the cost of destroying Rejected Products and Recalled Products to the extent it is deemed liable for such products under Section 6.1 (Product Claims) or 6.2 (Product Recalls), respectively. In all other circumstances, Client shall bear the cost of such destruction.

6.4. **Customer Inquiries**. Client shall have the sole responsibility for responding to questions and complaints from Client's customers, for handling customer returns of Product and for all other pharmacovigilance activities. Halo will promptly, and within [***], refer to Client in writing any questions or complaints that it receives from Client's customers. At Client's request and cost, Halo shall reasonably co-operate with Client to allow Client to determine the cause of, respond to, and resolve any customer questions and complaints.

6.5. **Limitations**. For the avoidance of doubt, Halo shall have no obligation for Product or Services if any deficiencies in, or other liabilities associated with, such Product or Services (a) are caused by incorrect, unlawful or deficient Specifications (including artwork and labeling), by problems relating to the safety, efficacy or marketability of Product that occur even when the Product conforms with the Specifications, or by Product distribution and commercialization activities (including off-label marketing), (b) result from any defect in API or other materials supplied by Client that Halo could not reasonably discover by visual inspection or testing as required under Section 2.1(b)(i) (API), (c) are caused by actions of Client or Third Parties occurring after Product is tendered for delivery by Halo pursuant to Section 4.4 (Shipment), or (d) are caused by any breach of Client's obligations, representations, warranties or covenants under this Agreement.

6.6. **Sole Remedy. The remedies described in this Article 6 shall be Halo's sole liability and Client's sole remedy for any Non-Conforming Product**.

ARTICLE 7
COOPERATION

7.1. **Liaisons; Quarterly Review**. Promptly, and within [***], following the signing of this Agreement, each Party shall appoint one of its employees to be a relationship manager responsible for liaising between the Parties with respect to the Products. The relationship managers shall meet quarterly to review the current status of the business relationship and manage any issues that have arisen. The Parties shall cooperate in good faith to ensure a stable supply of Product to Client within the terms of this Agreement by timely providing relevant information to one another through the relationship managers.

7.2. **Supply Committee**.

(a) Formation. Promptly following the Effective Date, the Parties shall establish a supply committee which shall be comprised of at least [***] from each of Client and Halo representing technical, operations and quality functions having the appropriate credentials, knowledge and experience (the "**Supply Committee**"). The Supply Committee may agree on reasonable written guidelines and procedures to facilitate regular and efficient communications and to keep appropriate records of the interactions and decisions.

(b) General Remit. The Supply Committee shall serve as the coordinating body for the manufacture and supply of Product under this Agreement and shall regularly review the status of the Parties' respective performance of this Agreement. Without derogating from Article 6 (Product Claims and Recalls) or Article 13 (Dispute Resolution), the Supply Committee shall also work to resolve any disagreements between the Parties relating to the Services.

(c) Meetings. The Supply Committee shall meet (in person, by telephone or as otherwise agreed by the Parties) on a regular basis, but not less frequently than [***] until the first Product's commercial launch, and thereafter not less frequently than [***] during the Term, unless otherwise agreed by the Supply Committee. Meeting agendas shall include as appropriate information on (i) anticipated market demand for Product, including any changes, (ii) the Parties' inventory positions of API and Halo's inventory position on Raw Materials, (iii) any capacity concerns, unusual production situations, or prioritization issues, including changes to delivery or sourcing, (iv) any quality related issues, (v) any proposed changes to the manufacturing process or Specifications, and (vi) any other matters which may impact or influence the Product supply chain.

(d) Costs. Each Party shall be responsible for its own costs arising out of participation in the Supply Committee, including in respect of travel and accommodations for personnel attending in person meetings.

7.3. **Records and Retain Samples**. Halo shall keep materially complete and accurate records of the manufacture, testing, storage, and shipping of Product, including master batch records, completed Batch records, quality control documentation and results for all acceptance tests performed (collectively, "**Records**") and retain samples of Product in accordance with its standard operating procedures and as necessary to comply with Applicable Law. Copies of Records and all retain samples shall be retained for a period of [***] following the date of Product expiry, or longer if required by Applicable Law. Before destroying Records, Halo will contact Client to offer Client the opportunity to take delivery and possession of such Records at Client's cost.

7.4. **Reports**. [***], Halo will provide Client with a copy of all Product data in its control (including release test results, complaint test results, and all investigations in manufacturing, testing and storage) that Client reasonably requires in order to complete any filing required by any Regulatory Authority, including an annual report within the meaning of 21CFR314.81(b)(2). At Client's request, Halo will provide Client with a copy of the annual product review report within the meaning of 21CFR211.180(e). Any additional reports requested by Client beyond the scope of cGMPs and requirements of Regulatory Authorities shall be subject to an additional fee to be agreed upon between Halo and Client.

7.5. **Client Inspections**. [***] period during the Term (or, if for cause, more frequently as reasonably agreed by the Parties), upon at least [***] prior written notice, Halo shall grant Client access, during normal business hours, to areas of the Facility in which API or Product is manufactured, handled, stored or shipped in order to verify that Halo is performing the Services in accordance with the Specifications and cGMPs. During any such inspection, Halo shall also permit Client to inspect Records, samples, and reports relating to this Agreement. The Parties' relationship managers shall arrange such inspections. Inspections shall be designed to minimize disruption of operations at the Facility and shall be limited to [***] for up to [***]. A Halo representative shall be present at all times during each inspection. Client's representatives shall comply with the Facility's rules. Client shall indemnify and hold harmless Halo for any act or omission of Client's representatives while on Halo's premises.

7.6. **Regulatory Inspections**.

(a) Information Sharing. Each Party shall promptly, and [***], notify the other Party of any planned or actual Facility inspection by any Regulatory Authority specifically involving a Product. Client acknowledges that it may not direct the manner in which Halo fulfills its obligations to permit inspection by and to communicate with Regulatory Authorities related to such inspection. Halo shall notify Client within [***] of receipt of any Form 483s, warning letters or other significant regulatory action that could reasonably be expected to impact the regulatory status of the Products or Halo's ability to perform the Services in accordance with the terms of this Agreement. Halo shall provide Client with copies of the sections of all Form 483s or comparable regulatory notices that are specific to any Product, redacted as necessary to preserve the confidentiality of Halo's other information. Likewise, Client shall provide Halo [***] with any material correspondence with any Regulatory Authority, including any FDA refusal to file, rejection, or warning letters, that could reasonably be expected to impact the timing and volume of Client's Product purchases under this Agreement.

(b) Costs. If an inspection by a Regulatory Authority is [***] related to a Product (such as a pre-approval inspection or in connection with adding a jurisdiction pursuant to Section 2.2(a)), Client shall pay Halo at the hourly rate set forth on Schedule B for time spent, and reimburse Halo for all reasonable and documented costs incurred, in connection with such inspection. [***]. If an inspection by a Regulatory Authority pertains to the Facility generally, Halo shall bear the costs of such inspection.

7.7. **Regulatory Filings**.

(a) Approvals & Permits. Client shall have the sole responsibility for filing, and shall file, all Product-specific documents with all Regulatory Authorities and for taking, and shall take, any other actions that may be required for the receipt and/or maintenance of Regulatory Authority approval for the commercial manufacture and sale of the Products. Halo shall assist Client, to the extent consistent with Halo's obligations under this Agreement, to obtain Regulatory Authority approval for the commercial manufacture of all Products as quickly as reasonably possible. Halo shall have the sole responsibility for filing, and shall file, all documents with Regulatory Authorities and for taking, and shall take, any other actions that may be required for the receipt and/or maintenance of Regulatory Authority licensure of the Facility.

(b) Verification of Data & CMC. From time to time during the Term, Client may desire to file documents with a Regulatory Authority in connection with obtaining regulatory approval of a Product, including a document that is, or is equivalent to, the FDA's Chemistry and Manufacturing Controls (CMC). If any such document incorporates or relies on data generated by Halo, Client shall provide Halo with a copy of the document at least [***] prior to its filing so as to permit Halo to verify the accuracy of such document solely as it relates to the Halo-generated data, including that the CMC accurately describes the Services that Halo has performed and the manufacturing processes that Halo will perform pursuant to this Agreement. Thereafter, Client shall provide Halo at the time of submission a final copy of any portion of any filing with a Regulatory Authority that contains chemistry, manufacturing or controls information that is derived from data regarding the Product generated by Halo.

(c) Deficiencies. If, acting reasonably, Halo determines that any of the information provided by Client in accordance with clause (b) above is inaccurate or deficient, Halo shall notify Client in writing of such matter within [***] of receipt of documents from Client. The Parties shall work together to have such matters resolved prior to Client's submission of such information to the Regulatory Authority.

7.8. **Quality Agreement**. The Parties acknowledge that, prior to the Effective Date, they signed an agreement setting out the quality assurance standards and protocols applicable to the Services and the Parties' responsibilities in respect thereof ("**Quality Agreement**"). The Parties acknowledge and agree that the Quality Agreement is required by Applicable Law and is intended only to operationalize quality-based activities relating to the Services. As such, (i) the Quality Agreement shall not determine a Party's financial responsibility for the performance or non-performance of the responsibilities set forth therein, (ii) any breach of the Quality Agreement by a Party shall be deemed a breach of this Agreement and shall be subject to the terms and conditions of this Agreement, including Section 8.2(a) ([Termination for] Breach) and Article 10 (Indemnities & Insurance), and (iii) neither Party shall have a cause of action for breach of the Quality Agreement except as a cause of action for breach of this Agreement. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to quality-based activities, the provisions of the Quality Agreement shall govern. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to any commercial matters, including allocation of risk, liability and financial responsibility, the provisions of this Agreement shall govern.

ARTICLE 8
TERM & TERMINATION

8.1. **Term**. This Agreement shall commence as of the Effective Date and shall expire on the fifth (5th) anniversary of the date on which Client placed its first Firm Order, unless terminated earlier in accordance with Section 8.2 (Termination). This Agreement shall automatically extend for successive [***] unless and until either Party gives the other Party at least [***] written notice of its desire to terminate this Agreement as of the end of the then-current term. The period of effectiveness of this Agreement, as extended in accordance with this Section 8.1 and/or terminated in accordance with Section 8.2 (Termination), is referred to as the "**Term**".

8.2. **Termination**.

(a) Breach. Either Party may terminate this Agreement upon written notice to the other Party if the other Party has failed to remedy a material breach of this Agreement within [***] following receipt of a written notice that describes the breach in reasonable detail and expressly states that it is a notice under this Section 8.2(a).

(b) Bankruptcy. Either Party may terminate this Agreement immediately without further action in the event that (i)) in the case of Client, if Halo is declared insolvent or bankrupt by a court of competent jurisdiction, and such declaration or order remains in effect for a period of [***] or if Halo files a voluntary petition of bankruptcy in any court of competent jurisdiction; (ii) in the case of Halo, if Client is liquidated in connection with a bankruptcy filing; or (iii) this Agreement is assigned by such other Party for the benefit of creditors.

(c) Regulatory Considerations. In the event that (i) any Authority takes any action that prevents Client from importing, exporting, purchasing or selling a Product in all or part of the Territory or (ii) subject to Section 3.5 (Product Discontinuation), Client elects to discontinue selling a Product or otherwise withdraws a Product from the market in all or part of the Territory, Client may terminate this Agreement as to any Product and applicable portion of the Territory upon [***] prior written notice to Halo.

8.3. **Obligations on Termination**. Expiration or termination of this Agreement shall be without prejudice to any rights or obligations that accrued to either Party prior to such expiration or termination. Upon expiration or termination of this Agreement:

(a) Work In Process. At Client's election, Halo shall either (i) complete any Product that is a work in process, which Product shall be subject to Section 8.3(b) (Product), or (ii) cease such work and transfer such work in process into storage containers, and Client shall be obligated to pay Halo a pro rata amount of all work to date; it being understood that if Client fails to timely make such an election or if termination is by Halo under Section 8.2(a) (Breach) or 8.2(b) (Bankruptcy), clause (ii) above shall automatically apply;

(b) Product. Client shall take delivery of and pay for, at the Price in effect at the time, all completed, undelivered Product that Halo has produced pursuant to a Firm Order;

(c) Inventory. Client shall purchase, at Halo's cost (to the extent not already paid for by Client in accordance with Section 2.1(b)(iii) (Product Specific Items)), all Inventory then in stock or that is later delivered by a Third Party vendor pursuant to non-cancellable orders, and shall reimburse Halo for any cancellation fees assessed by Third Party vendors for Inventory orders that are cancellable;

(d) Client-Owned Materials. Halo shall return to Client all unused API and deliver to Client all Inventory paid for by Client pursuant to clause (c) above;

(e) Records & Samples. Halo shall maintain reserve samples and Batch production records in accordance with Applicable Law and this Agreement; and

(f) Stability. At Client's election, Halo shall either (i) continue to perform any ongoing stability testing or (ii) ship the stability samples to Client; it being understood that if Client fails to timely make such an election or if termination is by Halo under Section 8.2(a) (Breach) or 8.2(b) (Bankruptcy), clause (ii) above shall automatically apply.

Any costs incurred by Halo to comply with the foregoing obligations, including shipping and related expenses, shall be borne by Client, except in the event of termination of this Agreement by Client for Halo's uncured material breach under Section 8.2(a) (Breach), in which case Halo shall bear all such expenses (excluding fees under clause (f)(i), which shall be borne by Client in all events). In lieu of taking possession of any of the materials described in this Section 8.3, Client may direct Halo to destroy such items, which Halo shall cause to be done at Client's cost.

8.4. **Survival**. Notwithstanding any expiration or termination of this Agreement for any reason, the Parties' rights and obligations under the following provisions shall survive and continue in effect in accordance with their respective terms: Sections 2.4 (Storage), 4.4 (Shipment), 5.2 (Supplemental Charges), 5.3 (Invoicing), 5.4 (Payment Terms), 7.3 (Records), 7.8 (Quality Agreement), 8.3 (Obligations on Termination), 8.4 (Survival) and 9.3(f) (Limited Warranty), and Articles 6 (Product Claims & Recalls), 10 (Indemnities & Insurance), 11 (Confidentiality), 12 (Intellectual Property), 13 (Dispute Resolution) and 14 (Miscellaneous).

ARTICLE 9
REPRESENTATIONS & WARRANTIES

9.1. **Authority**. Each Party represents and warrants to the other that (a) it has the full right and authority to enter into this Agreement, (b) it is in good standing in its jurisdiction of organization and all jurisdictions in which it operates, (c) the execution and delivery of this Agreement and the performance of such its obligations hereunder do not conflict with, or constitute a default or require any consent under, any contractual obligation of such Party, and (d) it will comply with all Applicable Law in performing its obligations under this Agreement.

9.2. **Client Warranties**. Client covenants, represents, and warrants to Halo that:

(a) Rights to Specifications. Client owns or has a valid right and license to use all Specifications for each Product and Client may lawfully disclose all Specifications to Halo for Halo's use in connection with providing Services;

(b) Rights to Intellectual Property. All Intellectual Property (other than Halo's Intellectual Property) provided by Client to Halo for use in connection with providing Services (i) may lawfully be used by Halo in connection with providing Services and (ii) so long as Halo uses such Intellectual Property solely as contemplated by this Agreement, such use does not and will not infringe, violate, or misuse any rights held by Third Parties;

(c) Third Party Intellectual Property. There are no rights held by Third Parties related to Client's Intellectual Property that would be infringed, violated, or misused by Client's performance of this Agreement and, as of the Effective Date, Client has no knowledge of any claims of infringement that have been made by Third Parties against Client in connection with the Product; and

(d) API Warranty. All API provided to Halo hereunder have been manufactured in accordance with Applicable Law, including cGMPs, and shall at the time of receipt by Halo meet all relevant Specifications and not be adulterated, misbranded, or mislabeled within the meaning of Applicable Law;

(e) API Cost. The API Cost fairly and accurately reflects Client's actual, out-of-pocket cost to procure the API from its Third-Party vendors and provide it to Halo;

(f) Use of Product. All Product delivered to Client by Halo hereunder shall be held, stored, used, distributed, sold, and otherwise disposed of by or on behalf of Client in accordance with all Applicable Law; and

(g) Not Generic. No Product is a "generic" drug product (e.g., filed for marketing approval in the United States under an Abbreviated New Drug Application).

9.3. **Halo Warranties**. Halo covenants, represents, and warrants to Client that:

(a) Third Party Intellectual Property. To the best of Halo's knowledge, there are no rights held by Third Parties related to Halo's Intellectual Property that would be infringed, violated, or misused by Halo's performance of this Agreement;

(b) Claims. As of the Effective Date, it has no knowledge of any claims, actions or other actual or threatened legal proceedings by any Regulatory Authority or other Third Party, the subject of which is the infringement, violation, or misuse of any rights in Intellectual Property held by Third Parties related to any Halo's Intellectual Property;

(c) Debarment. It does not and will not use in the performance of its obligations under this Agreement the services of any Person debarred or suspended under 21 U.S.C. §335(a) or (b); and it does not have and will not hire as an officer or employee any Person who has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the U.S. Federal Food, Drug, and Cosmetic Act, as amended;

(d) Product Warranty. It shall have performed the manufacturing of all Products provided to Client hereunder in accordance with Applicable Law (including cGMPs), and all Products provided to Client hereunder shall, at the time of delivery under Section 4.4 (Shipment), meet all Specifications and not be adulterated, misbranded or mislabeled within the meaning of Applicable Law; *provided*, that a Product will not fail to comply with the foregoing representation and warranty to the extent such failure results solely from (and Halo shall not be liable for any defect in Product attributable to) matters not caused by Halo's Fault; *provided further*, that Halo makes no representation or warranty with respect to any Product or circumstance that is expressly excluded from liability under Section 6.5 (Limitations);

(e) No Liens. Upon delivery of Products to Client, Halo shall convey, and Client shall have, good and marketable title to such Products, free and clear of any encumbrances imposed as a result of any act or omission of Halo; and

(f) Facility. The Facility has, and during the Term will maintain, a current FDA establishment registration and, as of the Effective Date, it has no knowledge of any claims, actions or other actual or threatened legal proceedings by the FDA or DEA, the subject of which is its violation of any Applicable Law that is within the jurisdiction of such Regulatory Authority. [***].

9.4. **Limited Warranty**. NEITHER PARTY MAKES ANY REPRESENTATION, WARRANTY OR GUARANTEE OF ANY KIND, EITHER EXPRESS OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS ARTICLE 9. HALO EXPRESSLY DISCLAIMS THE IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE AND ANY WARRANTY OF MERCHANTABILITY WITH RESPECT TO THE PRODUCTS AND SERVICES.

ARTICLE 10
INDEMNITIES & INSURANCE

10.1. **Limitation of Liability**.

(a) No Consequential Damages. Under no circumstances whatsoever shall either Party be liable to the other Party in contract, tort, negligence, breach of statutory duty or otherwise for (i) any direct or indirect loss of profits, revenues, production, anticipated savings, data, business or goodwill or (ii) any other liability, damage, cost or expense of any kind incurred by the other Party of an indirect, incidental, consequential, punitive or special nature, regardless of any notice of the possibility of such damages.

(b) API. Subject to 2.3(b) (Annual Reconciliation), and Section 3.3 (API), under no circumstances whatsoever shall Halo be responsible for any loss or damage to API.

(c) Maximum Liability. Halo's maximum liability under this Agreement for any reason whatsoever (in the aggregate and including any amounts payable pursuant to clause (b) above) shall not exceed the greater of (i) [***].

(d) Exclusions. The foregoing clauses (a), (b) and (c) shall not limit (i) damages arising from a Party's gross negligence or willful misconduct or (ii) damages arising from a Party's breach of Article 11 (Confidentiality).

10.2. **Indemnification**.

(a) By Halo. Halo shall defend, indemnify, and hold harmless Client, its Affiliates, and their respective directors, officers and employees (" **Client Indemnitees**") from and against any and all losses, damages, costs, expenses (including reasonable attorneys' fees and reasonable investigative costs), judgments and liabilities ("**Losses**") in connection with any suit, demand, claim or action by any Third Party (" **Third Party Claim**") arising or resulting from (i) a material breach by Halo of any of its obligations, warranties, or representations under this Agreement, including Section 9.1(d); (ii) Halo's gross negligence or willful misconduct; or (iii) [***]; *in each case*, except to the extent that such Losses arise or result from the breach of this Agreement by Client or the gross negligence or willful misconduct of any Client Indemnitee.

(b) By Client. Client shall defend, indemnify and hold harmless Halo, its Affiliates, and their respective directors, officers and employees (" **Halo Indemnitees**") from and against any and all Losses in connection with any Third Party Claim arising or resulting from (i) a material breach by Client of any of its obligations, warranties, or representations under this Agreement, (ii) Client's gross negligence or willful misconduct, (iii) any actual or alleged infringement, violation or misuse of any rights held by Third Parties in respect of any aspect of any Product (other than solely by reason of Halo's practice of Halo's Intellectual Property), or (iv) any distribution, sale or use of or exposure to any API or Product; *in each case*, except to the extent that such Losses arise or result from the gross negligence or willful misconduct of any Halo Indemnitee.

(c) Procedure. In the event a Party seeks indemnity under this Section 10.2, it shall: (i) promptly, and within [***], notify the indemnifying Party of the Third Party Claim subject to indemnification (*provided*, that any delay in providing such notice shall not relieve the indemnifying Party from any of its indemnification obligations hereunder except to the extent it is actually prejudiced in the defense of the Third Party Claim due to such delay); (ii) use commercially reasonable efforts to mitigate the effects of such Third Party Claim; (iii) reasonably cooperate with the indemnifying Party in the defense of such Third Party Claim; (iv) not settle or compromise such Third Party Claim or make any admission relating thereto; and (v) permit the indemnifying Party to control the defense and settlement of such Third Party Claim using counsel reasonably satisfactory to the indemnified Party, all at the indemnifying Party's cost and expense. The indemnified Party may be represented by its own counsel in connection with such Third-Party Claim, and such representation shall be at the indemnified Party's own expense unless the indemnifying Party fails to assume the defense of such Third Party Claim as required hereunder. The indemnifying Party shall have the right to settle any such Third-Party Claim without the consent of any indemnitee so long as such settlement does not admit to any wrongdoing by any indemnitee, does not impose any liability or obligation (whether financial or otherwise) on any indemnitee and fully releases the indemnitees from liability in connection with such Third-Party Claim. The indemnified Party's consent to any other settlement shall be required.

10.3. **Insurance**. During the Term and for at least [***] thereafter, each Party shall obtain from and maintain, with reputable and financially secure insurance carriers, prudent insurance coverage appropriate to cover its activities related to and obligations under this Agreement. Each Party shall provide to the other Party a certificate evidencing such insurance upon the other Party's request.

10.4. **Reasonable Allocation of Risk**. The Parties agree that (a) the provisions of this Agreement (including this Article 10) are reasonable and create a reasonable allocation of risk having regard to the relative profits the Parties respectively expect to derive from the Products; (b) Halo, in its fees for the provision of the Services, has not accepted a greater degree of the risks arising from the manufacture, distribution, sale and use of the Products based on the fact that Client has developed the Products and requires Halo to manufacture and label the Products strictly in accordance with the Specifications; and (c) Client and not Halo is in a position to inform and advise potential users of the Products as to the circumstances and manner of use of the Products.

ARTICLE 11
CONFIDENTIALITY

11.1. **Confidential Information**.

(a) Definition. In this Agreement, "**Confidential Information**" means any and all information disclosed by or on behalf of one Party ("**Discloser**") to the other Party ("**Recipient**") or any of its Representatives, (i) whether before, on, or after the Effective Date, (ii) whether tangible or intangible, (iii) whether written, electronic, oral, visual (e.g., obtained by observation at a site visit), or in any other form or medium, and (iv) whether or not marked with a legend such as "Confidential" or "Proprietary". For the avoidance of doubt, the term Confidential Information shall be construed as "Discloser's Confidential Information."

(b) Inclusions. Confidential Information includes but is not limited to (i) research and development activities; marketing plans, business strategies, and business opportunities; pricing, costs, and financial information; data, specifications, formulae, models, and processes; customers and vendors; regulatory strategies and information; and non-public intellectual property (e.g., knowhow and trade secrets), (ii) information of Affiliates and Third Parties, (iii) any copies, extracts, summaries and other analyses of other Confidential Information prepared by or for Recipient or any of its Representatives (collectively, "**Notes**"), and (iv) the existence and terms of this Agreement.

(c) Exclusions. Confidential Information excludes any information that, as proven by competent evidence, (i) is or, other than by a breach of confidentiality owed to Discloser, becomes available to the general public, (ii) was known to Recipient or any of its Representatives without any limitation on use or disclosure prior to its receipt from or on behalf of Discloser, as shown by Recipient's records, (iii) is received by Recipient or any of its Representatives from a Third Party without any obligation of confidentiality owed to Discloser, as shown by Recipient's records, or (iv) is independently developed by or for Recipient or any of its Representatives without reference to or reliance on any Confidential Information, as shown by Recipient's records. For the avoidance of doubt, Confidential Information shall not be deemed to be in the public domain or in the prior possession of a Person where it is merely embraced by or contained in more general information that is in the public domain or such Person's possession.

11.2. **Confidentiality and Non-Use**. In consideration of receiving Confidential Information, Recipient shall use Confidential Information only for performing its obligations and exercising its rights under this Agreement and shall not disclose Confidential Information to any Person other than as expressly permitted by this Agreement or as authorized in writing by Discloser. Recipient may disclose Confidential Information to those of its Representatives who (a) have a need to know such information in connection with Recipient's performance of its obligations and the exercise of its rights under this Agreement, (b) have been advised of Recipient's obligations under this Agreement, and (c) are bound to Recipient by obligations of confidentiality and non-use at least as stringent as those contained in this Article 11 (Confidentiality). Recipient shall be liable to Discloser for any breach of this Article 11 (Confidentiality) caused by Recipient's Representatives.

11.3. **Standard of Care**. Recipient shall (a) protect Confidential Information with the same degree of care that it uses to protect its own confidential information, but no less than a reasonable degree of care, (b) comply with all Applicable Law relating to Confidential Information, including in respect of data privacy and the export of information outside of national borders, (c) not remove or obscure any copyright or trademark notice, proprietary legend, indication of confidentiality, or other restrictive notation on any Confidential Information, and (d) promptly notify Discloser of any actual or suspected disclosure, use, or loss of Confidential Information in contravention of this Article 11 (Confidentiality), including a description of the circumstances, Persons involved, steps taken to mitigate resulting damage, and steps taken to prevent any further such disclosure, use, or loss.

11.4. **Compelled Disclosure**. Recipient may disclose Confidential Information to the extent required by Applicable Law or by the listing standards, rules, or agreements of any public exchange on which any securities of Recipient or its Affiliates are listed, so long as Recipient (a) uses reasonable efforts to give Discloser as much prior notice of such required disclosure as circumstances permit, (b) allows Discloser to contest such disclosure or to seek a protective order or similar remedy, and reasonably cooperates with Discloser in any such efforts, at Discloser's request and expense, and (c) limits the disclosure to only the information required to be disclosed.

11.5. **Ownership**. As between the Parties, Confidential Information is the property of Discloser, and Discloser shall retain all right, title and interest in and to its Confidential Information. The disclosure of Confidential Information to Recipient or any of its Representatives does not, in itself, grant or imply to Recipient or any such Representative any right or license to use or practice any Intellectual Property of Discloser. Any such right or license shall be solely as set forth in Article 12 (Intellectual Property).

11.6. **Return of Information**. Upon termination of this Agreement or Discloser's earlier written request, Recipient shall immediately cease using all Confidential Information and promptly either, as directed by Discloser, return it to Discloser or destroy it (and certify as to such destruction), including all Notes; *provided*, that Recipient may destroy, and need not deliver to Discloser, such Notes. Notwithstanding the foregoing, (a) Recipient may retain a single copy of Confidential Information in the secure files of its legal counsel or a senior executive for the sole purpose of proving what was disclosed, (b) Recipient is not required to return or destroy any Confidential Information if doing so would violate (or result in the violation of) any Applicable Law, (c) Recipient is not required to expunge any minutes or written consents of its board of directors (or equivalent governance body), and (iv) to the extent that Recipient's computer back-up or archiving procedures create copies of Confidential Information, Recipient may retain such copies for the period it normally archives backed-up computer records, so long as such copies are not readily accessible and are not used or consulted for any purpose other than disaster recovery. Any Confidential Information retained pursuant to the foregoing sentence shall remain subject to this Agreement until destroyed or no longer deemed Confidential Information based on Section 11.1(c) (Exclusions).

11.7. **Securities Law Compliance**. Halo acknowledges that it understands that: (a) Client's Confidential Information or other information disclosed by Client hereunder may contain or constitute material non-public information concerning the Client; and (b) trading in the Client's securities while in possession of material nonpublic information or communicating that information to any other Person who trades in such securities could subject Halo and its Representatives to liability under the U.S. federal and state securities laws, and the rules and regulations promulgated thereunder, including Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. Halo agrees that it and its Representatives will not trade in the Client's securities while in possession of material nonpublic information or at all until Halo and its Representatives can do so in compliance with all applicable laws and without breach of this Agreement.

11.8. **Injunctive Relief**. The Parties acknowledge and agree that, due to the unique nature of the Confidential Information, the breach of this Article 11 (Confidentiality) by Recipient may cause irreparable damage to Discloser for which monetary damages would be inadequate. Accordingly, Discloser shall be entitled to seek injunctive relief or other remedies in connection with a threatened or actual breach of any of Recipient's obligations under this Article 11 (Confidentiality), and the Parties waive the requirement of any bond being posted as security in any application for such relief.

11.9. **Publicity**. Subject to Section 11.4 (Compelled Disclosure), neither Party will use the other Party's name in any public context or make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby, including identifying the other Party as a business partner or in connection with any scholarly or industry publications or presentations, without the other Party's express prior written consent, which consent shall not be unreasonably withheld, conditioned, or delayed, except to the extent such use or disclosure is required by Applicable Law, by any Authority, or by the rules of any public exchange on which the securities of such Party are listed, in which case such Party shall use commercially reasonable efforts to obtain the approval of the other Party as to the form, nature and extent of the press release or public disclosure prior to issuing or making the disclosure.

11.10. **Survival**. This Article 11 (Confidentiality) shall survive the expiration or termination of this Agreement for [***]; *provided*, that Confidential Information that is otherwise protected by law or regulation (e.g., trade secret and data privacy) shall remain protected as, and for as long as, such law or regulation permits or requires (unless and until such information loses such protection other than due to a breach of this Article 11 (Confidentiality) by Recipient.

ARTICLE 12
INTELLECTUAL PROPERTY

12.1. **Proprietary Intellectual Property**. For purposes of this Agreement: (a) all Intellectual Property owned by a Party or any of its Affiliates as of the Effective Date shall be deemed owned by such Party; (b) all Intellectual Property licensed to a Party or any of its Affiliates by a Third Party at any time shall be deemed, solely as between the Parties, owned by such Party; and (c) all Intellectual Property generated, conceived or reduced to practice by or for a Party or any of its Affiliates outside the scope of activities under this Agreement shall be deemed owned by such Party (collectively, such Party's "**Proprietary IP**").

12.2. **Inventions**.

(a) Client Inventions. As between the Parties, all Inventions to the extent (i) specific to the development, manufacture, use or sale of Client's Product or (ii) dependent on Client's Proprietary IP, shall be the exclusive property of Client ("**Client Inventions**").

(b) Halo Inventions. As between the Parties, all Inventions that (i) do not comprise Client Inventions and (ii) either (A) have application to manufacturing processes for drug products or drug delivery systems generally or (B) are dependent on Halo's Proprietary IP shall be the exclusive property of Halo ("**Halo Inventions**").

(c) Disclosure. Halo shall submit to Client a written description of all Inventions of which it becomes aware during the Term. Client may, in its sole discretion, disclose Halo Inventions in any patent application claiming Client's Inventions, as Client may reasonably require to support the claimed subject matter of such patent application, subject to Halo's prior written approval, which shall not be unreasonably withheld.

(d) Cooperation; Costs. The Parties shall cooperate to achieve the allocation of rights to Inventions anticipated herein. Each Party shall be solely responsible for the costs of filing, prosecution and maintenance of patents and patent applications on, and otherwise protecting, its Inventions.

12.3. **Licenses**.

(a) To Halo. Client hereby grants to Halo and its Affiliates a non-exclusive, paid-up, royalty-free, non-transferable, sublicensable (solely to Halo's subcontractors) right and license during the Term to use Client's Intellectual Property (including Client Inventions) solely in connection with the Services.

(b) To Client. Halo hereby grants to Client a non-exclusive, non-transferable, sublicensable (solely to Client's subcontractors) right and license to use Halo Inventions solely to develop and manufacture Client's Product.

(c) No Other Rights. Neither Party has, nor shall it acquire, any interest in any Intellectual Property of the other Party, and neither Party shall use any Intellectual Property of the other Party, except to the extent expressly permitted by this Section 12.3.

12.4. **Ownership of Data**. Except as set forth in Section 12.2(b) (Halo Inventions), all data and information resulting from the conduct of the Services shall be the sole property of Client and shall be subject to Client's exclusive use, commercial or otherwise.

ARTICLE 13
DISPUTE RESOLUTION

13.1. **Escalation**. The Parties shall try to resolve any dispute arising out of or in connection with this Agreement other than a dispute determined in accordance with Section 6.1(b) (Evaluation) (a "**Dispute**") amicably between themselves before resorting to any formal dispute resolution proceeding. To this end, either Party may send a notice of Dispute to the other. Within [***] following the date of the Dispute notice, each Party shall appoint a single, senior representative with the full power and authority to resolve the Dispute (a "**Facilitator**"). The Facilitators shall meet and discuss as necessary to try to resolve the Dispute as quickly as practicable. If a Dispute relates exclusively to technical aspects of the Services, the Facilitators shall be competent to address the technical nature of the issues in question and may elect to engage an independent laboratory or expert to assist them in their discussions; however, the input of such laboratory or expert shall not be binding on either Party. If a Party fails to timely appoint a Facilitator or if, despite their reasonable efforts, the Facilitators have not resolved a Dispute within [***] from the date of the Dispute notice, either Party may resort to a court of competent jurisdiction, subject to Section 13.3 (Jurisdiction), or any other method of binding dispute resolution on which the Parties may agree.

13.2. **Governing Law**. This Agreement shall be construed and enforced in accordance with the laws of the State of New York and the laws of the United States applicable therein, without regard to any conflicts of law principles. The UN Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.

13.3. **Jurisdiction**. The Parties irrevocably agree that the state and federal courts sitting in the State of New York shall have exclusive jurisdiction to deal with any Dispute and that venue is proper in such courts. Each Party hereby expressly consents and submits to the personal jurisdiction of such courts, waives any objection to the laying of venue in such courts, and waives any claim that such courts constitute an inconvenient forum. Each Party, to the extent permitted by law, knowingly, voluntarily, and intentionally waives its right to a trial by jury in any Dispute, regardless of the legal theory of the claims asserted in such Dispute. All documents and proceedings in connection with any Dispute shall be in the English language.

13.4. [*Intentionally Omitted*.]

ARTICLE 14
MISCELLANEOUS

14.1. **Further Assurances**. The Parties agree to execute, acknowledge, and deliver such further instruments and to take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.

14.2. **Right to Dispose and Settle**. If Halo requests in writing Client's direction with respect to disposal of any Inventory, Product, work-in-process, API, equipment, Records, samples or other items belonging to Client and is unable to obtain a response from Client within [***] of providing written notice to Client, Halo shall have the right to dispose of such items at Client's expense (which may be by set off against any credit on Client's account).

14.3. **Force Majeure**. Neither Party shall be liable for the failure to perform its obligations under this Agreement if such failure is occasioned by a cause or contingency beyond such Party's reasonable control, whether or not foreseeable, including strikes or other labor disturbances, lockouts, riots, quarantines, communicable disease outbreaks (including pandemics and epidemics), wars, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, lack of or inability to obtain fuel, power, materials or components, or compliance with any order or regulation of any Authority acting within color of right. A Party claiming a right to excused performance under this Section 14.3 shall promptly, and within [***], notify the other Party in writing of the extent of its inability to perform and the nature of the force majeure event. Such excuse shall continue as long as the force majeure event continues. Upon cessation of such force majeure event, the affected Party shall promptly, and within [***], resume performance under this Agreement. Neither Party shall be entitled to rely on a force majeure event to relieve it from an obligation to pay money (including any interest for delayed payment) that would otherwise be due and payable under this Agreement. In the event a force majeure event continues for [***], and such force majeure event is solely related to Halo (e.g., is not a circumstance that is generally impacting global trade, the pharmaceutical industry, the U.S. economy, etc.), [***].

14.4. **Notices**. Any notice or other communication required or permitted by this Agreement shall be in writing and deemed given to the other Party (a) upon receipt if delivered personally, (b) upon receipt or refusal if sent by reputable overnight courier service or registered/certified mail with tracking capability, postage prepaid, or (c) on the next Business Day if sent by email with electronic verification of delivery, in each case to the mailing address or email address set forth below (or to such other contact information provided to the other Party in accordance with the terms of this Section 14.4):

To Client: Aytu BioPharma, Inc.
7900 East Union Avenue, Suite 920
Denver, CO 80237
Attention: Legal Department
Email: legal@aytubio.com

To Halo: Halo Whippany
30 North Jefferson Rd.
Whippany NJ 07981 USA
Attention: VP, GM

With copy to: Noramco
500 Swedes Landing Road
Wilmington, DE 19801 USA
Attention: General Counsel

14.5. **Assignment; No Third-Party Beneficiaries**. This Agreement shall be binding upon and inure to the benefit of the Parties, their successors and permitted assigns. Neither Party may assign this Agreement, in whole or in part, without the prior written consent of the other Party, which consent may be withheld in the other Party's sole discretion except that either Party may, without the other Party's consent (but subject to prior written notice), assign this Agreement in its entirety to an Affiliate or to a successor to all or substantially all of the business or assets of the assigning Party or the assigning Party's business unit responsible for performance under this Agreement. This Agreement shall not confer any rights or remedies upon any Person other than the Parties named herein and their respective successors and permitted assigns.

14.6. **Entire Agreement; Amendments; Waivers**. This Agreement, together with the Quality Agreement and the Confidentiality Agreement, constitutes the entire and integrated agreement between the Parties relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions, or understandings with respect to the subject matter hereof. Any modification, amendment or supplement to this Agreement must be in writing and signed by both Parties to be effective, except to the extent otherwise expressly provided in this Agreement. Either Party's failure to require the other Party to comply with any provision of this Agreement shall not be deemed a waiver of such provision or any other provision of this Agreement, or of any other breach of such provision.

14.7. **Conflicts**. No terms, provisions or conditions of any purchase order, order acknowledgement, quote, proposal, invoice, or other business form or written authorization used by Client or Halo will have any effect on the rights, duties or obligations of the Parties under, or otherwise modify, this Agreement, regardless of any failure of Client or Halo to object to such terms, provisions, or conditions, except to the extent such document specifically refers to this Agreement, sets forth an express intent to override it, and is signed by both Parties.

14.8. **Construction**.

(a) Independent Contractors. The Parties are independent contractors to one another, and this Agreement shall not be construed to create between Halo and Client any other relationship such as, by way of example only, that of employer-employee, principal-agent, joint-venturers, partners or any similar relationship, the existence of which is expressly denied by the Parties. Neither Party shall have the power or authority to bind the other Party or to assume or create any obligation, express or implied, on the other Party's behalf or in the other Party's name, and it will not represent to any Person that it has such power or authority.

(b) Drafting Party. The language in this Agreement is to be construed in all cases according to its fair meaning. Halo and Client acknowledge that each Party and its counsel have reviewed and revised this Agreement and that any rule of construction, to the effect that any ambiguities are to be resolved against the drafting Party, is not to be employed in the interpretation of this Agreement.

(c) Severability. If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, such determination shall not impair or affect the validity, legality, or enforceability of the remaining provisions hereof, and each provision is hereby declared to be separate, severable, and distinct.

(d) Divisions. The division of this Agreement into Articles, Sections, subsections, clauses and Schedules and the insertion of headings are for convenience of reference only and shall not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to an Article, Section, subsection, clause, or Schedule refers to the specified Article, Section subsection, clause, or Schedule to this Agreement. In this Agreement, the terms "this Agreement", "hereof", "herein", "hereunder" and similar expressions refer to this Agreement as a whole (including any Schedules hereto) and not to any particular Article, Section, subsection, clause, Schedule or other provision hereof.

(e) Conventions. Whenever used in this Agreement, unless otherwise specified: (a) all monetary amounts are expressed in, and all references to "$" or "dollars" mean, the lawful currency of the United States; (b) the word "including" (with its grammatical variations) means "including without limitation," "including but not limited to", or words of similar import; (c) the words "agree" or "written agreement" will not impose any obligation on either Party to agree to any terms or to engage in discussions relating to such terms, except as such Party may elect in such Party's sole discretion; (d) the word "Client" includes its Affiliates whenever the context requires or to the extent applicable; (e) the word "days" means calendar days unless otherwise specified as Business Days; (f) the words "copy" and "copies" include, to the extent available, electronic copies, files or databases containing the information, files, items, documents or materials to which such words apply; and (g) all references to the singular shall include the plural and vice versa.

14.9. **Counterparts**. This Agreement may be executed in counterparts, by original, electronic, or facsimile signature, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be delivered electronically by email of a signed PDF copy.

Signature page follows

IN WITNESS WHEREOF, the duly authorized representatives of the Parties have executed this Agreement as of the Effective Date.

HALO PHARMACEUTICAL, INC.

By /s/ Adam Hopper

Name: Adam Hopper

Title: President

AYTU BIOPHARMA, INC.

By /s/ Joshua R. Disbrow

Name: Joshua R. Disbrow

Title: Chief Executive Officer

SCHEDULES
[***]

Exhibit 31.1

AYTU BIOPHARMA, INC.
Certification by Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Joshua R. Disbrow, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aytu BioPharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a—15(e) and 15d—15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a—15(f) and 15d—15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies or material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 14, 2024

By: /s/ Joshua R. Disbrow
Joshua R. Disbrow
Chairman and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

AYTU BIOPHARMA, INC.
Certification by Chief Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Mark K. Oki, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aytu BioPharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a—15(e) and 15d—15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a—15(f) and 15d—15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies or material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 14, 2024

By: /s/ Mark K. Oki
Mark K. Oki
Chief Financial Officer
(Principal Financial Officer)
(Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S. C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I Joshua R. Disbrow, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, the Quarterly Report on Form 10-Q of Aytu BioPharma, Inc. for the fiscal quarter ended December 31, 2023, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Aytu BioPharma, Inc.

Date: February 14, 2024

By: /s/ Joshua R. Disbrow
Joshua R. Disbrow
Chairman and Chief Executive Officer
(Principal Executive Officer)

I Mark K. Oki, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, the Quarterly Report on Form 10-Q of Aytu BioPharma, Inc. for the fiscal quarter ended December 31, 2023, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Aytu BioPharma, Inc.

Date: February 14, 2024

By: /s/ Mark K. Oki
Mark K. Oki
Chief Financial Officer
(Principal Financial Officer)
(Principal Accounting Officer)