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 June 30, 2021

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 Number: 001-35814

Harrow Health, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**45-0567010**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
102 Woodmont Blvd., Suite 610 Nashville, Tennessee	**37205**
(Address of principal executive offices)	(Zip code)

(615) 733-4730
(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 on exchange on which registered
Common Stock, $0.001 par value per share	HROW	The NASDAQ Global Market
8.625% Senior Notes due 2026	HROWL	The NASDAQ Global Market

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

As of August 9, 2021, there were 26,893,896 shares of the registrant's common stock, $0.001 par value, outstanding.

HARROW HEALTH, INC.

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PART I
FINANCIAL INFORMATION

Item 1. Financial Statements

HARROW HEALTH, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)

	June 30, 2021	December 31, 2020
	(unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents, including restricted cash of $200	$ 72,851	$ 4,301
Investment in Eton Pharmaceuticals	12,209	28,455
Accounts receivable, net	3,710	2,662
Inventories	3,903	3,962
Prepaid expenses and other current assets	801	751
Total current assets	93,474	40,131
Property, plant and equipment, net	4,937	4,453
Operating lease right-of-use assets	4,747	6,799
Intangible assets, net	1,882	1,939
Investment in Surface Ophthalmics	-	1,314
Investment in Melt Pharmaceuticals	1,594	2,506
Goodwill	332	332
TOTAL ASSETS	$ 106,966	$ 57,474
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 5,207	$ 3,932
Accrued payroll and related liabilities	2,388	2,315
Deferred revenue and customer deposits	56	66
Current portion of paycheck protection program loan payable	-	1,259
Current portion of loan payable, net of unamortized debt discount	-	2,639
Current portion of operating lease liabilities	485	580
Current portion of finance lease obligations	8	8
Total current liabilities	8,144	10,799
Operating lease liabilities, net of current portion	4,695	6,652
Finance lease obligations	14	17
Accrued expenses, net of current portion	-	800
Paycheck protection program loan payable, net of current portion	-	708
Loan payable, net of current portion and unamortized debt discount	71,265	11,670
TOTAL LIABILITIES	84,118	30,646
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Common stock, $0.001 par value, 50,000,000 shares authorized, 26,893,896 and 25,749,875 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	27	26
Additional paid-in capital	102,837	104,557
Accumulated deficit	(79,661)	(77,400)
TOTAL HARROW HEALTH STOCKHOLDERS' EQUITY	23,203	27,183
Noncontrolling interests	(355)	(355)
TOTAL EQUITY	22,848	26,828
TOTAL LIABILITIES AND EQUITY	$ 106,966	$ 57,474

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements

HARROW HEALTH, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except for share and per share data)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Revenues:				
Sales, net	$ 17,297	$ 8,049	$ 32,245	$ 19,859
Other revenues	837	11	1,332	18
Total revenues	18,134	8,060	33,577	19,877
Cost of sales	(4,417)	(3,204)	(8,187)	(6,830)
Gross profit	13,717	4,856	25,390	13,047
Operating expenses:				
Selling, general and administrative	9,123	6,954	17,287	15,370
Research and development	425	749	1,017	1,152
Impairment of intangible assets	-	363	-	363
Total operating expenses	9,548	8,066	18,304	16,885
Income (loss) from operations	4,169	(3,210)	7,086	(3,838)
Other (expense) income:				
Interest expense, net	(1,314)	(505)	(1,827)	(1,065)
Investment loss from Melt Pharmaceuticals, net	(477)	(690)	(947)	(1,236)
Investment loss from Surface Pharmaceuticals, net	(465)	(599)	(1,314)	(938)
Investment (loss) gain from Eton Pharmaceuticals, net	(3,584)	4,725	(6,419)	(6,125)
Loss from early extinguishment of loan	(756)	-	(756)	-
Gain on forgiveness of PPP loan	-	-	1,967	-
Other (expense) income, net	(51)	19	(51)	19
Total other (expense) income, net	(6,647)	2,950	(9,347)	(9,345)
Total net loss including noncontrolling interests	(2,478)	(260)	(2,261)	(13,183)
Net loss attributable to noncontrolling interests	-	23	-	39
Net loss attributable to Harrow Health, Inc.	(2,478)	(237)	(2,261)	(13,144)
Preferred dividends and accretion of preferred stock discount	(472)	-	(472)	-
Net loss attributable to common stockholders	$ (2,950)	$ (237)	$ (2,733)	$ (13,144)
Basic and diluted net loss per share of common stock	$ (0.11)	$ (0.01)	$ (0.10)	$ (0.51)
Weighted average number of shares of common stock outstanding, basic and diluted	26,736,970	25,893,629	26,379,943	25,867,478

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements

HARROW HEALTH, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the three and six months ended June 30, 2021 and 2020
(In thousands, except for share data)

	Preferred Stock		Common Stock		Additional		Total Harrow Health, Inc.	Total Noncontrolling	Total
	Shares	Par Value	Shares	Par Value	Paid-in Capital	Accumulated Deficit	Stockholders' Equity	Interests Equity	Stockholders' Equity
Balance at March 31, 2020	-	$ -	25,618,918	$ 26	$ 102,261	$ (86,950)	$ 15,337	$ (309)	$ 15,028
Issuance of common stock in connection with:									
Exercise of employee stock options	-	-	253	-	-	-	-	-	-
Stock-based payment for services provided	-	-	30,000	-	83	-	83	-	83
Stock-based compensation expense	-	-	-	-	545	-	545	-	545
Net loss	-	-	-	-	-	(237)	(237)	(23)	(260)
Balance at June 30, 2020	-	$ -	25,649,171	$ 26	$ 102,889	$ (87,187)	$ 15,728	$ (332)	$ 15,396

	Preferred Stock		Common Stock		Additional		Total Harrow Health, Inc.	Total Noncontrolling	Total
	Shares	Par Value	Shares	Par Value	Paid-in Capital	Accumulated Deficit	Stockholders' Equity	Interests Equity	Stockholders' Equity
Balance at March 31, 2021	-	$ -	25,983,676	$ 26	$ 105,382	$ (77,183)	$ 28,225	$ (355)	$ 27,870
Issuance of common stock in connection with:									
Exercise of employee stock options	-	-	5,312	-	21	-	21	-	21
Exercise of warrants	-	-	311,369	-	-	-	-	-	-
Vesting of RSUs	-	-	977,500	1	(1)	-	-	-	-
Shares withheld related to net share settlement of equity awards	-	-	(383,961)	-	(3,171)	-	(3,171)	-	(3,171)
Issuance of preferred shares, net of discount and issuance costs	440,000	-	-	-	10,655	-	10,655	-	10,655
Redemption of preferred shares	(440,000)	-	-	-	(11,000)	-	(11,000)	-	(11,000)
Payment of preferred dividends	-	-	-	-	(127)	-	(127)	-	(127)
Stock-based compensation expense	-	-	-	-	1,078	-	1,078	-	1,078
Net loss	-	-	-	-	-	(2,478)	(2,478)	-	(2,478)
Balance at June 30, 2021	-	$ -	26,893,896	$ 27	$ 102,837	$ (79,661)	$ 23,203	$ (355)	$ 22,848

	Preferred Stock		Common Stock		Additional		Total Harrow Health, Inc.	Total Noncontrolling	Total
	Shares	Par Value	Shares	Par Value	Paid-in Capital	Accumulated Deficit	Stockholders' Equity	Interests Equity	Stockholders' Equity
Balance at	-	$ -	25,526,931	$ 26	$ 101,728	$ (74,043)	$ 27,711	$ (293)	$ 27,418

December 31, 2019									
Issuance of common stock in connection with:									
Exercise of employee stock options	-	-	253	-	-	-	-	-	-
Vesting of RSUs			91,987	-	-	-	-	-	-
Stock-based payment for services provided	-	-	30,000	-	83	-	83	-	83
Stock-based compensation expense	-	-	-	-	1,078	-	1,078	-	1,078
Net loss	-	-	-	-	-	(13,144)	(13,144)	(39)	(13,183)
Balance at June 30, 2020	-	$ -	25,649,171	$ 26	$ 102,889	$ (87,187)	$ 15,728	$ (332)	$ 15,396

	Preferred Stock		Common Stock		Additional		Total Harrow Health, Inc.	Total Noncontrolling	Total
	Shares	Par Value	Shares	Par Value	Paid-in Capital	Accumulated Deficit	Stockholders' Equity	Interests Equity	Stockholders' Equity
Balance at December 31, 2020	-	$ -	25,749,875	$ 26	$ 104,557	$ (77,400)	$ 27,183	$ (355)	$ 26,828
Issuance of common stock in connection with:									
Exercise of employee stock options	-	-	16,613	-	48	-	48	-	48
Exercise of warrants	-	-	311,369	-	-	-	-	-	-
Vesting of RSUs	-	-	1,207,500	1	(1)	-	-	-	-
Shares withheld related to net share settlement of equity awards	-	-	(391,461)	-	(3,228)	-	(3,228)	-	(3,228)
Issuance of preferred shares, net of discount and issuance costs	440,000	-	-	-	10,655	-	10,655	-	10,655
Redemption of preferred shares	(440,000)	-	-	-	(11,000)	-	(11,000)	-	(11,000)
Payment of preferred dividends	-	-	-	-	(127)	-	(127)	-	(127)
Stock-based compensation expense	-	-	-	-	1,933	-	1,933	-	1,933
Net loss	-	-	-	-	-	(2,261)	(2,261)	-	(2,261)
Balance at June 30, 2021	-	$ -	26,893,896	$ 27	$ 102,837	$ (79,661)	$ 23,203	$ (355)	$ 22,848

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements

HARROW HEALTH, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	For the Six Months Ended June 30, 2021	For the Six Months Ended June 30, 2020
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss (including noncontrolling interests)	$ (2,261)	$ (13,183)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization of property, plant and equipment	876	913
Amortization of intangible assets	79	88
Amortization of operating lease right-of-use assets	299	341
Provision for bad debt expense	36	302
Amortization of debt issuance costs and discount	288	243
Gain on forgiveness of PPP loan	(1,967)	-
Investment loss from Eton Pharmaceuticals, net	6,419	6,125
Investment loss from Surface Opthalmics, net	1,314	938
Investment loss from Melt Pharmaceuticals, net	947	1,236
Loss on sale and disposal of assets	-	5
Interest paid-in-kind on loan payable	-	348
Impairment of long-lived assets	-	363
Loss on early extinguishment of loan	706	-
Stock-based payment of consulting services	-	83
Stock-based compensation	1,933	1,078
Changes in assets and liabilities:		
Accounts receivable	(1,084)	(311)
Inventories	59	(540)
Prepaid expenses and other current assets	(85)	(25)
Accounts payable and accrued expenses	1,026	(2,253)
Accrued payroll and related liabilities	73	1,052
Deferred revenue and customer deposits	(10)	(4)
NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES	8,648	(3,201)
CASH FLOWS FROM INVESTING ACTIVITIES		
Net proceeds on sale investments	9,827	-
Investment in patent and trademark assets	(22)	(74)
Purchases of property, plant and equipment	(1,360)	(536)
NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES	8,445	(610)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payments on finance lease obligations	(3)	(3)
Net proceeds from 8.625% notes payable, net of costs	71,073	-
Principal and exit fee payments on SWK loan	(15,961)	-
Net proceeds from PPP loan	-	1,967
Proceeds from SWK debt, net of costs	-	1,000
Payment of taxes for vesting of RSUs	(3,228)	-
Proceeds from exercise of stock options	48	-
Sale of preferred stock, net of discount and issuance costs	10,655	-
Redemption of preferred stock	(11,000)	-
Payment of preferred stock dividends	(127)	-
NET CASH PROVIDED BY FINANCING ACTIVITIES	51,457	2,964
NET CHANGE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	68,550	(847)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, beginning of period	4,301	4,949
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, end of period	$ 72,851	$ 4,102
RECONCILIATION OF CASH, CASH EQUIVALENTS AND RESTRICTED CASH		
Cash and cash equivalents	$ 72,651	$ 3,902
Restricted cash	200	200
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD	$ 72,851	$ 4,102
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for income taxes	$ -	$ -
Cash paid for interest	$ 788	$ 408
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Right-of-use asset obtained in exchange for lease obligation	$ -	$ 41
Net reduction in right-of-use assets and lease liabilities in connection with lease modifications	$ 1,753	$ -

The accompanying notes are an integral part of these condensed consolidated financial statements

NOTE 1. DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION

Company and Background

Harrow Health, Inc. (together with its subsidiaries, partially owned companies and royalty arrangements unless the context indicates or otherwise requires, the "Company" or "Harrow") specializes in the development, production and sale of innovative medications that offer unique competitive advantages and serve unmet needs in the marketplace through its subsidiaries and deconsolidated companies. The Company owns one of the nation's leading ophthalmology-focused pharmaceutical businesses, ImprimisRx. In addition to wholly owning ImprimisRx, the Company also has non-controlling equity positions in Surface Ophthalmics, Inc. ("Surface") and Melt Pharmaceuticals, Inc. ("Melt"), both companies that began as subsidiaries of Harrow. In 2020, Harrow created Visionology, Inc. ("Visionology"), which recently launched an online eye health platform business. Harrow also owns royalty rights in various drug candidates being developed by Surface and Melt.

Basis of Presentation

The Company has prepared the accompanying unaudited condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and in accordance with the rules and regulations of the U.S. Securities and Exchange Commission. Accordingly, they do not include all of the information and footnotes required by GAAP for audited financial statements. In the opinion of management, all adjustments (consisting of only normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the three and six months ended June 30, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021 or for any other period. For further information, refer to the Company's audited consolidated financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly owned and majority-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Harrow consolidates entities in which it has a controlling financial interest. The Company consolidates subsidiaries in which it holds and/or controls, directly or indirectly, more than 50% of the voting rights. All intercompany accounts and transactions have been eliminated in consolidation.

The condensed consolidated balance sheets at June 30, 2021 and December 31, 2020 and the condensed consolidated statements of operations, stockholders' equity and cash flows for the periods ended June 30, 2021 and 2020 include our accounts and those of our wholly owned subsidiaries, as well as our majority owned subsidiaries Mayfield Pharmaceuticals, Inc. and Stowe Pharmaceuticals, Inc.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The following represents an update for the six months ended June 30, 2021 to the significant accounting policies described in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

Risks, Uncertainties and Liquidity

The Company is subject to certain regulatory standards, approvals, guidelines and inspections which could impact the Company's ability to make, dispense, and sell certain products. If the Company was required to cease compounding and selling certain products as a result of regulatory guidelines or inspections, this may have a material impact on the Company's financial condition, liquidity and results of operations.

Segments

The Company's chief operating decision-maker is its Chief Executive Officer who makes resource allocation decisions and assesses performance based on financial information of our operating segments. The Company has identified two operating segments as reportable segments. See Note 16 for more information regarding the Company's reportable segments.

Noncontrolling Interests

The Company recognizes any noncontrolling interest as a separate line item in equity in the condensed consolidated financial statements. A noncontrolling interest represents the portion of equity ownership in a less-than-wholly-owned subsidiary not attributable to the Company. Generally, any interest that holds less than 50% of the outstanding voting shares is deemed to be a noncontrolling interest; however, there are other factors, such as decision-making rights, that are considered as well. The Company includes the amount of net loss attributable to noncontrolling interests in consolidated net loss on the face of the condensed consolidated statements of operations.

The Company provides in the condensed consolidated statements of stockholders' equity a reconciliation at the beginning and the end of the period of the carrying amount of total equity, equity attributable to the parent, and equity attributable to the noncontrolling interest that separately discloses:

(1) Net income or loss;
(2) transactions with owners acting in their capacity as owners, showing separately contributions from and distributions to owners; and
(3) each component of other income or loss.

Basic and Diluted Net Loss per Common Share

Basic net loss per common share is computed by dividing net loss attributable to common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders for the period by the weighted average number of common and common equivalent shares, such as stock options and warrants, outstanding during the period. Basic and diluted net loss per share is computed using the weighted average number of shares of common stock outstanding during the period. Common equivalent shares (using the treasury stock or "if converted" method) from stock options, unvested restricted stock units ("RSUs") and warrants were 4,121,398 and 5,414,504 at June 30, 2021 and 2020, respectively. For the three and six months ended June 30, 2021 and 2020, the common equivalent shares are excluded in the calculation of diluted net loss per share because the effect is anti-dilutive. Included in the basic and diluted net loss per share calculation were RSUs awarded to directors that had vested, but the issuance and delivery of the shares are deferred until the director resigns. The number of shares underlying vested RSUs at June 30, 2021 and 2020 was 235,973 and 251,746, respectively.

The following table shows the computation of basic and diluted net loss per share of common stock for the three and six months ended June 30, 2021 and 2020:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Numerator – net loss attributable to Harrow Health, Inc. common stockholders	$ (2,950)	$ (237)	$ (2,733)	$ (13,144)
Denominator - weighted average number of shares outstanding, basic and diluted	26,736,970	25,893,629	26,379,943	25,867,478
Net loss per share, basic and diluted	$ (0.11)	$ (0.01)	$ (0.10)	$ (0.51)

Investment in Eton Pharmaceuticals, Inc.

During the three and six months ended June 30, 2021, the Company sold 1,518,000 shares of its Eton Pharmaceuticals, Inc. ("Eton") common stock through an underwritten public offering at a public offering price of $7.00 per share (the "Eton Stock Sale"). The gross proceeds to the Company from the Eton Stock Sale were $10,626, before deducting underwriting discounts and commissions and other offering expenses payable by the Company of $799. During the three and six months ended June 30, 2021, the Company recorded a realized loss of $1,406 related to the sale of 1,518,000 shares of its Eton common stock.

Following the Eton Stock Sale and as of June 30, 2021, the Company owns 1,982,000 shares of Eton common stock, which represents less than 10% of the equity interests of Eton. At June 30, 2021, the fair market value of Eton's common stock was $6.16 per share. In accordance with the Accounting Standards Update ("ASU") 2016-01, *Financial Instruments-Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*, the Company recorded an unrealized investment gain (loss) from its Eton common stock position of $(2,178) and $(5,013) and $4,725 and $(6,125) during the three and six months ended June 30, 2021 and 2020, respectively, related to the change in fair market value of its investment in Eton during the measurement period. As of June 30, 2021, the fair market value of the Company's investment in Eton was $12,209.

As part of the Eton Stock Sale, the Company also agreed, for a period of 180 days, not to conduct any further sales of shares of its common stock of Eton or otherwise dispose of, directly or indirectly, any common stock of Eton (or any securities convertible into, or exercisable or exchangeable for, the common stock of Eton).

Investment in Melt Pharmaceuticals, Inc. – Related Party

The Company owns 3,500,000 common shares (which is approximately 44% of the equity interests as of June 30, 2021) of Melt and uses the equity method of accounting for this investment, as management has determined that the Company has the ability to exercise significant influence over the operating and financial decisions of Melt. Under this method, the Company recognizes earnings and losses in Melt in its condensed consolidated financial statements and adjusts the carrying amount of its investment in Melt accordingly. The Company's share of earnings and losses are based on the Company's ownership interest of Melt. Any intra-entity profits and losses are eliminated. During the three months ended June 30, 2021 and 2020, the Company recorded equity in the net losses of Melt of $477 and $690, and $947 and $1,236 during the six months ended June 30, 2021 and 2020, respectively. As of June 30, 2021 and December 31, 2020, the Company's investment in Melt was $1,594 and $2,506, respectively, which includes $885 and $851, respectively, due from Melt for reimbursable expenses and amounts due under a Management Services Agreement between the Company and Melt (the "Melt MSA").

See Note 4 for more information and related party disclosure regarding Melt.

Investment in Surface Ophthalmics, Inc. – Related Party

The Company owns 3,500,000 common shares (which is approximately 20% of the equity interests following the close of a round of financing completed by Surface at various dates from May 2021 to July 2021) of Surface and uses the equity method of accounting for this investment, as management has determined that the Company has the ability to exercise significant influence over the operating and financial decisions of Surface. Under this method, the Company recognizes earnings and losses in Surface in its condensed consolidated financial statements and adjusts the carrying amount of its investment in Surface accordingly. The Company's share of earnings and losses are based on the Company's ownership interest of Surface. Any intra-entity profits and losses are eliminated. The Company recorded equity in the net losses of Surface of $465 and $599 during the three months and $1,314 and $938 during the six months ended June 30, 2021 and 2020, respectively. As of June 30, 2021 and December 31, 2020, the Company's investment in Surface was $0 and $1,314, respectively.

See Notes 5 for more information and related party disclosure regarding Surface.

Property, Plant and Equipment

Property, plant and equipment is stated at cost less accumulated depreciation and amortization. Depreciation and amortization is calculated using the straight-line method over the estimated useful life of the asset. Leasehold improvements and capital lease equipment are amortized over the estimated useful life or remaining lease term, whichever is shorter. Software costs during the application development stage used to meet the Company's internal needs are generally capitalized. Computer software and hardware and furniture and equipment are depreciated over three to five years.

Recently Adopted Accounting Pronouncements

In December 2019, the FASB issued ASU 2019-12, *Income Taxes: Simplifying the Accounting for Income Taxes*, which simplifies the accounting for income taxes. This guidance became effective for the Company on January 1, 2021 on a prospective basis. Adoption of this ASU did not have a material impact on the Company's condensed consolidated financial statements.

NOTE 3. REVENUES

The Company accounts for contracts with customers in accordance with ASC 606, *Revenues from Contracts with Customers*. The Company has three primary streams of revenue: (1) revenue recognized from our sale of products within our pharmacy services, (2) revenue recognized from a commission agreement with a third party and (3) revenue recognized from intellectual property license and asset purchase agreements.

Product Revenues from Pharmacy Services

The Company sells prescription drugs directly through our pharmacy and outsourcing facility network. Revenue from our pharmacy services division includes: (i) the portion of the price the client pays directly to us, net of any volume-related or other discounts paid back to the client, (ii) the price paid to us by individuals, and (iii) customer copayments made directly to the pharmacy network. Sales taxes are not included in revenue. Following the core principles of ASC 606, we have identified the following:

1. Identify the contract(s) with a customer: A contract exists with a customer at the time the prescription or order is received by the Company.

2. Identify the performance obligations in the contract: The order received contains the performance obligations to be met, in almost all cases the product the customer is wishing to receive. If we are unable to meet the performance obligation, the customer is notified.

3. Determine the transaction price: the transaction price is based on the product being sold to the customer and any related customer discounts. These amounts are pre-determined and built into our order management software.

4. Allocate the transaction price to the performance obligations in the contract: The transaction price associated with the product(s) being ordered is allocated according to the pre-determined amounts.

5. Recognize revenue when (or as) the entity satisfies a performance obligation: At the time of shipment from the pharmacy or outsourcing facility, the performance obligation has been met.

The following revenue recognition policy has been established for the pharmacy services division:

Revenues generated from prescription or office use drugs sold by our pharmacies and outsourcing facility are recognized when the prescription is shipped. At the time of shipment, the pharmacy services division has performed substantially all of its obligations under its client contracts and does not experience a significant level of returns or reshipments. Determination of criteria (3) and (4) is based on management's judgments regarding the fixed nature of the selling prices of the products delivered and the collectability of those amounts. The Company records reductions to revenue for discounts at the time of the initial sale. Estimated returns and allowances and other adjustments are provided for in the same period during which the related sales are recorded and are based on actual returns history. The rate of returns is analyzed annually to determine historical returns experience. If the historical data we use to calculate these estimates do not properly reflect future returns, then a change in the allowance would be made in the period in which such a determination is made and revenues in that period could be materially affected. The Company will defer any revenues received for a product that has not been delivered or is subject to refund until such time that the Company and the customer jointly determine that the product has been delivered and no refund will be required.

Commission Revenues

During the year ended December 31, 2020, the Company entered into an agreement whereby it is paid a fee calculated based on sales it generates from a pharmaceutical product that is owned by a third party. The revenue earned from this arrangement is recognized at the time a customer has ordered the pharmaceutical product and it has shipped from the third party (or one of its distributors or affiliates), at which point there is no future performance obligation required by the Company and no consequential continuing involvement on the part of the Company to recognize the associated revenue.

Intellectual Property License Revenues

As of June 30, 2021, we are party to four intellectual property licenses and asset purchase agreements in which we have agreed to grant a license and which provide a customer with the right to access the Company's intellectual property. License arrangements may consist of non-refundable upfront license fees, data transfer fees, research reimbursement payments, exclusive license rights to patented or patent pending compounds, technology access fees, and various performance or sales milestones. These arrangements can be multiple-element arrangements, the revenue of which is recognized at the point in time at which the performance obligation is met.

Non-refundable fees that are not contingent on any future performance by the Company and require no consequential continuing involvement on the part of the Company are recognized as revenue when the license term commences and the licensed data, technology, compounded drug preparation and/or other deliverable is delivered. Such deliverables may include physical quantities of compounded drug preparations, design of the compounded drug preparations and structure-activity relationships, the conceptual framework and mechanism of action, and rights to the patents or patent applications for such compounded drug preparations. The Company defers recognition of non-refundable fees if it has continuing performance obligations without which the technology, right, product or service conveyed in conjunction with the non-refundable fee has no utility to the licensee and that are separate and independent of the Company's performance under the other elements of the arrangement. In addition, if the Company's continued involvement is required, through research and development services that are related to its proprietary know-how and expertise of the delivered technology or can only be performed by the Company, then such non-refundable fees are deferred and recognized over the period of continuing involvement. Guaranteed minimum annual royalties are recognized on a straight-line basis over the applicable term.

Revenue disaggregated by revenue source for the three and six months ended June 30, 2021 and 2020, consists of the following:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Product sales, net	$ 17,297	$ 8,049	$ 32,245	$ 19,859
Commission revenues	827	-	1,312	-
License revenues	10	11	20	18
Total revenues	$ 18,134	$ 8,060	$ 33,577	$ 19,877

Deferred revenue and customer deposits at June 30, 2021 and December 31, 2020, were $56 and $66, respectively. All deferred revenue and customer deposit amounts at December 31, 2020 were recognized as revenue during the six months ended June 30, 2021.

NOTE 4. INVESTMENT IN MELT PHARMACEUTICALS, INC. RELATED PARTY TRANSACTIONS

In December 2018, the Company entered into an asset purchase agreement with Melt (the “Melt Asset Purchase Agreement”). Pursuant to the terms of the Melt Asset Purchase Agreement, Melt was assigned certain intellectual property and related rights from the Company to develop, formulate, make, sell, and sub-license certain Company conscious sedation and analgesia related formulations (collectively, the “Melt Products”). Under the terms of the Melt Asset Purchase Agreement, Melt is required to make mid-single-digit royalty payments to the Company on net sales of the Melt Products while any patent rights remain outstanding, as well as other conditions. In January and March 2019, the Company entered into the Melt Series A Preferred Stock Agreement. See also Note 2, under the subheading

Investment in Melt Pharmaceuticals, Inc.

In February 2019, the Company and Melt entered into the Melt MSA, whereby the Company provides to Melt certain administrative services and support, including bookkeeping, web services and human resources related activities, and Melt is required to pay the Company a monthly amount of $10.

As of June 30, 2021 and December 31, 2020, the Company was due $885 and $851, respectively, from Melt for reimbursable expenses and amounts due under the Melt MSA. Melt did not make any payments to the Company during the three and six months ended June 30, 2021.

The Company’s Chief Executive Officer, Mark L. Baum is a member of the Melt board of directors, and several employees of the Company (including Mr. Baum and the Company’s Chief Financial Officer, Andrew R. Boll) entered into consulting agreements and provide consulting services to Melt.

The unaudited condensed results of operations information of Melt is summarized below:

	For the Six Months Ended June 30,	
	2021	2020
Revenues, net	$ -	$ -
Loss from operations	2,177	2,574
Net loss	$ (2,177)	$ (2,574)

The unaudited condensed balance sheet information of Melt is summarized below:

	At June 30, 2021	At December 31, 2020
Current assets	$ 927	$ 2,947
Non current assets	98	11
Total assets	1,025	2,958
Total liabilities	1,784	1,778
Total stockholders’ (deficit) equity	(759)	1,180
Total liabilities and stockholders’ equity	$ 1,025	$ 2,958

NOTE 5. INVESTMENT IN SURFACE OPHTHALMICS, INC. - RELATED PARTY TRANSACTIONS

The Company entered into an asset purchase and license agreement with Surface in 2017 and amended it in April 2018 (the "Surface License Agreements"). Pursuant to the terms of the Surface License Agreements, the Company assigned and licensed to Surface certain intellectual property and related rights associated with Surface's drug candidates (collectively, the "Surface Products"). Surface is required to make mid-single-digit royalty payments to the Company on net sales of the Surface Products while any patent rights remain outstanding.

As of June 30, 2021, the Company owned 3,500,000 shares of Surface common stock. A Company director, Richard L. Lindstrom, and the Company's Chief Executive Officer, Mark L. Baum, are directors of Surface. Surface is required to make royalty payments to Dr. Lindstrom of net sales of certain Surface products while certain patent rights remain outstanding. Dr. Lindstrom is also a minority owner of Flying L Partners, an affiliate of the funding investor who purchased the Surface Series A Preferred Stock. Several employees and a director of the Company (including Mr. Baum and Dr. Lindstrom) entered into consulting agreements and provide consulting services to Surface.

The unaudited condensed results of operations information of Surface is summarized below:

	For the Six Months Ended June 30,	
	2021	**2020**
Revenues, net	$ -	$ -
Loss from operations	4,712	3,127
Net loss	$ (4,712)	$ (3,127)

The unaudited condensed balance sheet information of Surface is summarized below:

	At June 30, 2021	At December 31, 2020
Current assets	$ 25,786	$ 9,074
Non current assets	43	45
Total assets	25,829	9,119
Total liabilities	1,771	1,666
Total stockholders' equity	24,058	7,453
Total liabilities and stockholders' equity	$ 25,829	$ 9,119

NOTE 6. RESTRICTED CASH

The restricted cash at June 30, 2021 and December 31, 2020 consisted of funds held in a money market account. At June 30, 2021 and December 31, 2020, the restricted cash was recorded at amortized cost, which approximates fair value.

At June 30, 2021 and December 31, 2020, the funds held in a money market account of $200 were classified as a current asset. The money market account funds are required as collateral as additional security for the Company's New Jersey facility lease.

NOTE 7. INVENTORIES

Inventories are comprised of finished compounded formulations, over-the-counter and prescription retail pharmacy products, commercial pharmaceutical products, related laboratory supplies and active pharmaceutical ingredients. The composition of inventories as of June 30, 2021 and December 31, 2020 was as follows:

	June 30, 2021	December 31, 2020
Raw materials	$ 1,990	$ 2,501
Work in progress	17	17
Finished goods	1,896	1,444
Total inventories	$ 3,903	$ 3,962

NOTE 8. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets at June 30, 2021 and December 31, 2020, consisted of the following:

	June 30, 2021	December 31, 2020
Prepaid insurance	$ 120	$ 160
Other prepaid expenses	607	401
Deposits and other current assets	74	190
Total prepaid expenses and other current assets	$ 801	$ 751

NOTE 9. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment at June 30, 2021 and December 31, 2020, consisted of the following:

	June 30, 2021	December 31, 2020
Property, plant and equipment, net:		
Computer software and hardware	$ 1,427	$ 1,370
Internal use software costs in development	803	337
Furniture and equipment	441	418
Lab and pharmacy equipment	4,225	3,426
Leasehold improvements	5,735	5,720
	12,631	11,271
Accumulated depreciation and amortization	(7,694)	(6,818)
	$ 4,937	$ 4,453

For the three and six months ended June 30, 2021, depreciation and amortization related to the property, plant and equipment was $412 and $876, respectively. For the three and six months ended June 30, 2020, depreciation and amortization related to the property, plant and equipment was $465 and $913, respectively.

NOTE 10. INTANGIBLE ASSETS AND GOODWILL

The Company's intangible assets at June 30, 2021 consisted of the following:

	Amortization periods (in years)	Cost	Accumulated amortization	Impairment	Net carrying value
Patents	17-19	$ 540	$ (60)	$ -	$ 480
Licenses	20	50	(6)	-	44
Trademarks	Indefinite	358	-	-	358
Customer relationships	3-15	1,519	(520)	-	999
Trade name	5	5	(5)	-	-
Non-competition clause	3-4	50	(50)	-	-
State pharmacy licenses	25	8	(7)	-	1
		$ 2,530	$ (648)	$ -	$ 1,882

Amortization expense for intangible assets for the three and six months ended June 30, 2021 and 2020 was as follows:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Patents	$ 6	$ 8	$ 12	$ 19
Licenses	-	-	1	1
Customer relationships	33	35	66	68
	$ 39	$ 43	$ 79	$ 88

Estimated future amortization expense for the Company's intangible assets at June 30, 2021 is as follows:

Remainder of 2021	$ 110
2022	188
2023	188
2024	161
2025	148
Thereafter	729
	$ 1,524

NOTE 11. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	June 30, 2021	December 31, 2020
Accounts payable	$ 3,882	$ 3,645
Other accrued expenses	49	49
Accrued interest	1,276	238
Accrued exit fee for loan payable	-	800
Total accounts payable and accrued expenses	5,207	4,732
Less: Current portion	(5,207)	(3,932)
Non-current total accrued expenses	$ -	$ 800

NOTE 12. DEBT

8.625% Senior Notes Due 2026

In April 2021, the Company closed an offering of $50,000 aggregate principal amount of 8.625% senior notes due in April 2026 and in May 2021 issued an additional $5,000 of such notes pursuant to the full exercise of the underwriters' option to purchase additional notes (collectively, the "April Notes"). The April Notes were sold to investors at a par value of $25.00 per April Note and the offering resulted in net proceeds to the Company of approximately $51,909 after deducting underwriting discounts and commissions and expenses of $3,091. In June 2021, in a further issuance of the April Notes, the Company sold an additional $20,000 aggregate principal amount of such notes (the "June Notes," and together with the April Notes, the "Notes"), at a price of $25.75 per June Note, with interest of $278 on the June Notes being accrued from April 20, 2021 as of the date of issuance. The June offering resulted in net proceeds to the Company of approximately $19,164 after deducting underwriting discounts and commissions and expenses of $1,158 and a premium on note issuance of $322. The June Notes are treated as a single series with the April Notes under the indenture governing the April Notes, dated as of April 20, 2021, and have the same terms as the April Notes (other than the initial offering price and issue date). The Notes are senior unsecured obligations of the Company and rank equally in right of payment with all of our other existing and future senior unsecured and unsubordinated indebtedness. The Notes are effectively subordinated in right of payment to all of the Company's existing and future secured indebtedness and structurally subordinated to all existing and future indebtedness of the Company's subsidiaries, including trade payables. The Notes bear interest at a rate of 8.625% per annum. Interest on the Notes is payable quarterly in arrears on January 31, April 30, July 31 and October 31 of each year, commencing on July 31, 2021. The Notes will mature on April 30, 2026. The issuance costs were recorded as a debt discount and are being amortized as interest expense, net of the amortization of the premium on note issuance, over the term of the Notes using the effective interest rate method.

Prior to February 1, 2026, the Company may, at its option, redeem the Notes, in whole at any time or in part from time to time, at a redemption price equal to 100% of the principal amount of the Notes to be redeemed, plus a make-whole amount, if any, plus accrued and unpaid interest to, but excluding, the date of redemption. The Company may redeem the Notes for cash in whole or in part at any time at our option on or after February 1, 2026 and prior to maturity, at a price equal to 100% of their principal amount, plus accrued and unpaid interest to, but excluding, the date of redemption. On and after any redemption date, interest will cease to accrue on the redeemed Notes.

Interest expense related to the Notes totaled $1,466 for the three and six months ended June 30, 2021, and included amortization of debt issuance costs and discount of $192 for the three and six months ended June 30, 2021.

SWK Senior Note – Paid in April 2021

In July 2017, the Company and several of its wholly owned subsidiaries entered into a term loan and security agreement in the principal amount of $16,000 (the "SWK Loan Agreement" or "SWK Loan") with SWK Funding LLC and its partners (collectively, "SWK"), as lender and collateral agent. The SWK Loan Agreement was fully funded at closing with a five-year term; however, such term could be reduced to four years if certain revenue requirements were not achieved. The SWK Loan was secured by substantially all of the Company's assets, including its intellectual property rights. The SWK Loan was subsequently amended in May 2019 and again in April 2020. The SWK Loan bore an interest rate equal to the three-month London Inter-Bank Offered Rate (subject to a minimum of 2.00%), plus an applicable margin of 10.00% (the "Margin Rate"); provided that, if, two days prior to a payment date, the Company provided SWK evidence that the Company has achieved a leverage ratio as of such date of less than 4.00:1:00, the Margin Rate shall equal 9.00%; and if the Company had achieved a leverage ratio as of such date of less than 3.00:1:00, the Margin Rate shall equal 7.00%. The leverage ratio means, as of any date of determination, the ratio of: (a) indebtedness as of such date to (b) EBITDA (as defined in the SWK Loan), of the Company for the immediately preceding 12 month period, adding-back (i) actual litigation expenses for the immediately preceding 12 month period, minus (ii) actual litigation expenses for the immediately preceding 3 month period multiplied by 4.

A summary of the material changes contained in the amendment entered into with SWK in April 2020 was as follows:

- SWK agreed to make available to the Company, and the Company drew down on, an additional principal amount of $1,000;
- The definition of the first amortization date was changed to August 14, 2020, permitting the Company to pay interest only on the principal amount loaned for the next payment (payments are due on a quarterly basis) following the SWK Second Amendment; and
- The interest payment of $358 due May 14, 2020 was paid in-kind by increasing the principal amount of the term loans by an amount equal to the interest accrued as of such date.

Interest expense related to the SWK Loan Agreement, as amended, amounted to $138 and $647 for the three and six months ended June 30, 2021, respectively, and $505 and $1,065 for the three and six months ended June 30, 2020, respectively, and included amortization of debt issuance costs and discount of $0 and $96 for the three and six months ended June 30, 2021, respectively, and $83 and $243 for the three and six months ended June 30, 2020, respectively.

In April 2021, the Company paid $15,540 related to all outstanding obligations to SWK under the SWK Loan, including outstanding principal, accrued interest, accrued exit fee and related expenses and recorded a loss from early extinguishment of $756 related to the SWK Loan during the three and six months ended June 30, 2021.

Paycheck Protection Program Loan – Forgiven in March 2021

In April 2020, the Company entered into an unsecured promissory note and related Business Loan Agreement with Renasant Bank, as lender, for a loan (the "PPP Loan") in the principal amount of $1,967 and received cash proceeds of the same amount, pursuant to the Paycheck Protection Program (the "PPP") under the Federal Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), which was enacted March 27, 2020. The PPP is administered by the U.S. Small Business Administration (the "SBA"). On March 30, 2021, the Company received a notice of forgiveness of the full balance of the PPP Loan, including all accrued interest, in accordance with the terms and conditions of the CARES Act. Related to the forgiveness, the Company recorded a gain on the forgiveness of the PPP Loan for the loan balance of $1,967 in the accompanying condensed consolidated statement of operations for the six months ended June 30, 2021.

At June 30, 2021, future minimum payments under the Company's debt were as follows:

	Amount
Remainder of 2021	$ 3,308
2022	6,562
2023	6,562
2024	6,580
2025	6,562
2026	77,158
Total minimum payments	106,732
Less: amount representing interest payments	(31,732)
Notes payable, gross	75,000
Less: unamortized discount, net of premium	(3,735)
Notes payable, net of unamortized discount	$ 71,265

NOTE 13. LEASES

The Company leases office and laboratory space under non-cancelable operating leases listed below. These lease agreements have remaining terms between one to four years and contain various clauses for renewal at the Company's option.

- An operating lease for 10,200 square feet of office space in San Diego, California that expires in December 2021;
- An operating lease for 26,400 square feet of lab, warehouse and office space in Ledgewood, New Jersey that expires in July 2026, with an option to extend the term for two additional five-year periods. This includes an amendment that was made effective July 2020 that extended the term of the original lease and added 1,400 of additional square footage to the lease and another amendment entered into in May 2021 that extended the term of the lease to July 2027; and
- An operating lease for 5,500 square feet of office space in Nashville, Tennessee that expires in December 2024, with an option to extend the term for two additional five-year periods.

In May 2021, the Company amended its New Jersey lease to include the addition of 8,926 square feet of space (the "May Lease Amendment"), which will expire in July 2027. The Company expects to take possession of this additional space in September 2021, which will trigger the commencement of the May Lease Amendment. Since the commencement date of the May Lease Amendment is expected to occur after June 30, 2021, right-of-use assets and operating lease liabilities associated with the May Lease Amendment are not included in the Company's condensed consolidated balance sheets as of June 30, 2021.

At June 30, 2021, the weighted average incremental borrowing rate and the weighted average remaining lease term for the operating leases held by the Company were 6.32% and 14.08 years, respectively.

During the three and six months ended June 30, 2021, cash paid for amounts included for the operating lease liabilities was $251 and $502, respectively, and the Company recorded operating lease expense of $241 and $502 included in selling, general and administrative expenses, respectively.

Future lease payments under operating leases as of June 30, 2021 were as follows**:**

	Operating Leases
Remainder of 2021	$ 502
2022	585
2023	600
2024	617
2025	433
Thereafter	5,146
Total minimum lease payments	7,883
Less: amount representing interest payments	(2,703)
Total operating lease liabilities	5,180
Less: current portion, operating lease liabilities	(485)
Operating lease liabilities, net of current portion	$ 4,695

The Company also has a finance lease that is included in its lease accounting but is not considered significant.
Future lease payments under the non-cancelable finance lease as of June 30, 2021 were as follows**:**

	Finance Leases
Remainder of 2021	$ 5
2022	9
2023	9
2024	1
Total minimum lease payments	24
Less: amount representing interest payments	(2)
Present value of future minimum lease payments	22
Less: current portion, finance lease obligation	(8)
Finance lease obligation, net of current portion	$ 14

At June 30, 2021, the weighted average incremental borrowing rate and the weighted average remaining lease term for the finance lease held by the Company were 6.36% and 2.58 years, respectively.

For the three and six months ended June 30, 2021, depreciation expense related to the equipment held under the finance lease obligation was $2 and $4, respectively.

For the three and six months ended June 30, 2021, cash paid and expense recognized for interest expense related to the finance lease obligation was $0 and $1, respectively.

NOTE 14. STOCKHOLDERS' EQUITY AND STOCK-BASED COMPENSATION

Preferred Stock

At June 30, 2021 and 2020, the Company had 5,000,000 shares of preferred stock, $0.001 par value, authorized and no shares of preferred stock issued and outstanding.

Series B Cumulative Preferred Stock – Redeemed

In May 2021, the Company sold 440,000 shares of the Company's Series B Cumulative Preferred Stock, par value $0.001 per share and liquidation preference of $25.00 per share (the "Series B Preferred Stock"), for a net purchase price of approximately $10,655. The Series B Preferred Stock was not convertible into our common stock, had no voting rights, except as required by Delaware law, and was redeemable by the Company at any time. Holders of Series B Preferred Stock were entitled to cumulative cash dividends at the rate of 9.50% of the $25.00 liquidation preference per year; provided, however, that for each thirty (30) day period following May 5, 2021, the dividend rate increased at various rates, except as otherwise limited by applicable law. Dividends were payable quarterly in arrears, on or about the 15th of January, April, July and October, beginning on or about July 15, 2021.

In June 2021, the Company redeemed all of the outstanding shares of the Company's Series B Preferred Stock, par value $0.001 per share. The redemption price for the 440,000 shares of Series B Preferred Stock outstanding was equal to $25.00 per share, plus accrued and unpaid dividends, which in aggregate totaled $11,127. During the three and six months ended June 30, 2021, the Company recorded preferred stock cash dividends and deemed dividends equal to $472.

Common Stock

During the six months ended June 30, 2021, the Company issued 311,369 shares of its common stock upon the cashless exercise of warrants to purchase 406,539 shares of common stock with exercise prices between $1.79 and $3.75 per share.

During the six months ended June 30, 2021, the Company issued 16,613 shares of its common stock upon the exercise of options to purchase 16,613 shares of common stock with exercise prices between $1.70 and $4.29 per share and received net proceeds of $48.

During the six months ended June 30, 2021, the Company issued 715,871 shares of its common stock to Mark L. Baum, its CEO, related to the vesting of 1,050,000 performance-based restricted stock units. The Company withheld issuance of 334,129 shares of common stock valued at $2,760 for payroll tax purposes.

During the six months ended June 30, 2021, the Company issued 100,168 shares of common stock to Andrew R. Boll, its CFO, related to the vesting of 157,500 performance-based restricted stock units. The Company withheld issuance of 57,332 shares of common stock to Mr. Boll for payroll tax purposes valued at $468.

During the six months ended June 30, 2021, 35,510 shares of the Company's common stock underlying RSUs issued to directors vested, but the issuance and delivery of these shares are deferred until the director resigns.

Stock Option Plan

On September 17, 2007, the Company's Board of Directors and stockholders adopted the Company's 2007 Incentive Stock and Awards Plan, which was subsequently amended on November 5, 2008, February 26, 2012, July 18, 2012, May 2, 2013 and September 27, 2013 (as amended, the "2007 Plan"). The 2007 Plan reached its term in September 2017, and we can no longer issue additional awards under this plan, however, options previously issued under the 2007 Plan will remain outstanding until they are exercised, reach their maturity or are otherwise cancelled/forfeited. On June 13, 2017, the Company's Board of Directors and stockholders adopted the Company's 2017 Incentive Stock and Awards Plan which was subsequently amended on June 3, 2021 (as amended, the "2017 Plan" together with the 2007 Plan, the "Plans"). As of June 30, 2021, the 2017 Plan provides for the issuance of a maximum of 6,000,000 shares of the Company's common stock. The purpose of the Plans are to attract and retain directors, officers, consultants, advisors and employees whose services are considered valuable, to encourage a sense of proprietorship and to stimulate an active interest of such persons in the Company's development and financial success. Under the Plans, the Company is authorized to issue incentive stock options intended to qualify under Section 422 of the Internal Revenue Code, non-qualified stock options, restricted stock units and restricted stock. The Plans are administered by the Compensation Committee of the Company's Board of Directors. The Company had 3,967,251 shares available for future issuances under the 2017 Plan at June 30, 2021.

Stock Options

A summary of stock option activity under the Plans for the six months ended June 30, 2021 is as follows:

	Number of Shares	Weighted Avg. Exercise Price	Weighted Avg. Remaining Contractual Life	Aggregate Intrinsic Value
Options outstanding - January 1, 2021	3,030,033	$ 5.43		
Options granted	67,000	$ 8.07		
Options exercised	(16,613)	$ 2.99		
Options cancelled/forfeited	(29,945)	$ 5.32		
Options outstanding - June 30, 2021	3,050,475	$ 5.50	5.28	$ 11,555
Options exercisable	2,333,132	$ 5.01	4.85	$ 9,985
Options vested and expected to vest	2,978,866	$ 5.46	5.25	$ 11,399

The aggregate intrinsic value in the table above represents the total pre-tax amount of the proceeds, net of exercise price, which would have been received by option holders if all option holders had exercised and immediately sold all options with an exercise price lower than the market price on June 30, 2021, based on the closing price of the Company's common stock of $9.29 on that date.

During the six months ended June 30, 2021, the Company granted stock options to certain employees and a consultant. The stock options were granted with an exercise price equal to the current market price of the Company's common stock, as reported by the securities exchange on which the common stock was then listed, at the grant date and have contractual terms of 10 years. Vesting terms for options granted to employees and consultants during the six months ended June 30, 2021 included the following vesting schedules: 25% of the shares subject to the option vest and become exercisable on the first anniversary of the grant date and the remaining 75% of the shares subject to the option vest and become exercisable quarterly in equal installments thereafter over three years. Certain option awards provide for accelerated vesting if there is a change in control (as defined in the Plans) and in the event of certain modifications to the option award agreement.

The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton option pricing model. The expected term of options granted to employees and directors was determined in accordance with the "simplified approach," as the Company has limited, relevant, historical data on employee exercises and post-vesting employment termination behavior. The expected risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The financial statement effect of forfeitures is estimated at the time of grant and revised, if necessary, if the actual effect differs from those estimates. For option grants to employees and directors, the Company assigns a forfeiture factor of 10%. These factors could change in the future, which would affect the determination of stock-based compensation expense in future periods. Utilizing these assumptions, the fair value is determined at the date of grant.

The table below illustrates the fair value per share determined using the Black-Scholes-Merton option pricing model with the following assumptions used for valuing options granted to employees:

	2021
Weighted-average fair value of options granted	$ 4.96
Expected terms (in years)	6.11
Expected volatility	69%
Risk-free interest rate	0.39-0.45%
Dividend yield	-

The following table summarizes information about stock options outstanding and exercisable at June 30, 2021:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$1.47 - $2.60	760,318	5.13	$ 2.06	755,208	$ 2.06
$2.76 - $4.66	506,566	5.22	$ 3.98	449,872	$ 3.98
$5.49 - $6.36	470,350	6.59	$ 6.12	348,128	$ 6.14
$6.64 - $8.99	1,313,241	4.93	$ 7.86	779,924	$ 7.96
$1.47 - $8.99	3,050,475	5.28	$ 5.50	2,333,132	$ 5.01

As of June 30, 2021, there was approximately $2,012 of total unrecognized compensation expense related to unvested stock options granted under the Plans. That expense is expected to be recognized over the weighted-average remaining vesting period of 5.17 years. The stock-based compensation for all stock options was $569 and $1,021 during the three and six months ended June 30, 2021, respectively.

The intrinsic value of options exercised during the three and six months ended June 30, 2021 was $14 and $77, respectively.

Restricted Stock Units

RSU awards are granted subject to certain vesting requirements and other restrictions, including performance and market-based vesting criteria. The grant date fair value of the RSUs, which has been determined based upon the market value of the Company's common stock on the grant date, is expensed over the vesting period of the RSUs.

During the six months ended June 30, 2021, 300,000 RSUs with a fair market value of $2,670 were issued to certain employees; the RSUs vest in full on the third anniversary of the grant date.

During the six months ended June 30, 2021, the Company's board of directors were granted 38,576 RSUs with a fair market value of $400 which vest in equal quarterly installments over one year.

A summary of the Company's RSU activity and related information for the six months ended June 30, 2021 is as follows:

	Number of RSUs		Weighted Average Grant Date Fair Value
RSUs unvested - January 1, 2021	1,601,509	$	3.14
RSUs granted	338,576	$	9.07
RSUs vested	(1,243,009)	$	2.24
RSUs cancelled/forfeited	-		-
RSUs unvested at June 30, 2021	697,076	$	7.61

As of June 30, 2021, the total unrecognized compensation expense related to unvested RSUs was approximately $3,606, which is expected to be recognized over a weighted-average period of 1.74 years, based on estimated and actual vesting schedules of the applicable RSUs. The stock-based compensation for RSUs during the three and six months ended June 30, 2021 was $481 and $827, respectively.

Warrants

From time to time, the Company issues warrants to purchase shares of the Company's common stock to investors, lenders, underwriters and other non-employees for services rendered or to be rendered in the future, or pursuant to settlement agreements.

A summary of warrant activity for the six months ended June 30, 2021 is as follows:

	Number of Shares Subject to Warrants Outstanding		Weighted Avg. Exercise Price
Warrants outstanding - January 1, 2021	780,386	$	2.12
Granted	-		
Exercised	(406,539)		2.16
Expired	-		
Warrants outstanding and exercisable - June 30, 2021	373,847	$	2.08
Weighted average remaining contractual life of the outstanding warrants in years - June 30, 2021	3.05		

Warrants outstanding and exercisable as of June 30, 2021 are as follows:

Warrant Series	Issue Date	Warrants Outstanding	Exercise Price	Expiration Date
Lender warrants	7/19/2017	373,847	$ 2.08	7/19/2024

Subsidiary Stock-Based Transactions

The Company recognized $28 and $85 in stock-based compensation expense related to subsidiary stock options during the three and six months ended June 30, 2021, respectively.

Stock-Based Compensation Summary

The Company recorded stock-based compensation related to equity instruments granted to employees, directors and consultants as follows:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Employees - selling, general and administrative	923	436	1,678	872
Employees - R&D	55	-	55	-
Directors - selling, general and administrative	100	96	200	193
Consultants - selling, general and administrative	-	96	-	96
Total	$ 1,078	$ 628	$ 1,933	$ 1,161

NOTE 15. COMMITMENTS AND CONTINGENCIES

Legal

Novel Drug Solutions et al.

In April 2018, Novel Drug Solutions, LLC and Eyecare Northwest, PA (collectively “NDS”) filed a lawsuit against the Company in the U.S. District Court of Delaware asserting various claims, including breach of contract. The claims stem from an asset purchase agreement between the Company and NDS entered into in 2013. In July 2019, NDS filed a second amended complaint which added claims related to its purported termination of the APA. In October 2019, NDS voluntarily dismissed all but two claims, leaving only claims related to the scope and performance of the post-termination obligations to be litigated. Trial is currently set to begin in November 2021. NDS is seeking damages, interest, attorneys’ fees and other costs. The Company believes the claims are meritless and has previously and will continue to dispute all claims asserted against it and intends to vigorously defend against these allegations. Nonetheless, the Company cannot predict the eventual outcome of this litigation and it could result in substantial costs, losses and a diversion of management’s resources and attention, which could harm the Company’s business and the value of its common stock.

Product and Professional Liability

Product and professional liability litigation represents an inherent risk to all firms in the pharmaceutical and pharmacy industry. We utilize traditional third-party insurance policies with regard to our product and professional liability claims. Such insurance coverage at any given time reflects current market conditions, including cost and availability, when the policy is written.

John Erick et al.

In January 2018, John Erick and Deborah Ferrell, successors-in-interest and heirs of Jade Erick, (collectively “Erick”) filed a lawsuit in the San Diego County Superior against Kim Kelly, ND, MPH asserting claims related to the death of Jade Erick. In April 2018, Erick filed an amendment to the lawsuit, naming the Company as a co-defendant. In September 2018, co-defendant Dr. Kelly filed a cross-complaint against the Company and various entities affiliated with Spectrum Laboratory Products, Inc., Spectrum Chemical Manufacturing Corp. and Spectrum Pharmacy Products, Inc. (collectively “Spectrum”). The cross-complaint seeks indemnity and contribution from the Company and Spectrum. The Company answered the claims filed by Dr. Kelly in October 2018. The case is currently in the discovery phase. Trial is currently set to begin October 2021. Erick is seeking unspecified damages, interest, attorneys’ fees and other costs. The Company believes the claims are meritless and has previously and will continue to dispute all claims asserted against it and intends to vigorously defend against these allegations. The Company’s insurance carrier has reserved its rights to seek contribution from the Company if the plaintiffs prevail on certain claims which the carrier alleges are uncovered. The Company believes the policy covers all claims. Nonetheless, the Company cannot predict the eventual outcome of this litigation, it could result in substantial costs, losses and a diversion of management’s resources and attention, which could harm the Company’s business and the value of its common stock.

General and Other

In the ordinary course of business, the Company may face various claims brought by third parties and it may, from time to time, make claims or take legal actions to assert its rights, including intellectual property disputes, contractual disputes and other commercial disputes. Any of these claims could subject the Company to litigation.

Indemnities

In addition to the indemnification provisions contained in the Company's governing documents, the Company generally enters into separate indemnification agreements with each of the Company's directors and officers. These agreements require the Company, among other things, to indemnify the director or officer against specified expenses and liabilities, such as attorneys' fees, judgments, fines and settlements, paid by the individual in connection with any action, suit or proceeding arising out of the individual's status or service as the Company's director or officer, other than liabilities arising from willful misconduct or conduct that is knowingly fraudulent or deliberately dishonest, and to advance expenses incurred by the individual in connection with any proceeding against the individual with respect to which the individual may be entitled to indemnification by the Company. The Company also indemnifies its lessors in connection with its facility leases for certain claims arising from the use of the facilities. These indemnities do not provide for any limitation of the maximum potential future payments the Company could be obligated to make. Historically, the Company has not incurred any payments for these obligations and, therefore, no liabilities have been recorded for these indemnities in the accompanying condensed consolidated balance sheets.

Klarity License Agreement – Related Party

The Company entered into a license agreement in April 2017 and as amended in April 2018, (the "Klarity License Agreement") with Richard L. Lindstrom, M.D., a member of its Board of Directors. Pursuant to the terms of the Klarity License Agreement, the Company licensed certain intellectual property and related rights from Dr. Lindstrom to develop, formulate, make, sell, and sub-license the topical ophthalmic solution Klarity designed to protect and rehabilitate the ocular surface (the "Klarity Product").

Under the terms of the Klarity License Agreement, the Company is required to make royalty payments to Dr. Lindstrom ranging from 3% - 6% of net sales, dependent upon the final formulation of the Klarity Product sold. In addition, the Company is required to make certain milestone payments to Dr. Lindstrom including: (i) an initial payment of $50 upon execution of the Klarity License Agreement, (ii) a second payment of $50 following the first $50 in net sales of the Klarity Product; and (iii) a final payment of $50 following the first $100 in net sales of the Klarity Product. All of the above referenced milestone payments are payable at the Company's election in cash or shares of the Company's restricted common stock. Payments totaling $35 and $70 were made during the three and six months ended June 30, 2021, respectively. Payments totaling $0 and $55 were made during the three and six months ended June 30, 2020, respectively. Royalty expense of $44 and $79 was incurred during the three and six months ended June 30, 2021, respectively, and $44 is included in accounts payable to Dr. Lindstrom as of June 30, 2021. Royalty expense of $27 and $56 was incurred during the three and six months ended June 30, 2020, respectively.

Injectable Asset Purchase Agreement – Related Party

In December 2019, the Company entered into an asset purchase agreement (the "Lindstrom APA") with Dr. Lindstrom, a member of its Board of Directors. Pursuant to the terms of the Lindstrom APA, the Company acquired certain intellectual property and related rights from Dr. Lindstrom to develop, formulate, make, sell, and sub-license an ophthalmic injectable product (the "Lindstrom Product").

Under the terms of the Lindstrom APA, the Company is required to make royalty payments to Dr. Lindstrom ranging from 2% to 3% of net sales, dependent upon the final formulation and patent protection of the Lindstrom Product sold. In addition, the Company is required to make certain milestone payments to Dr. Lindstrom including an initial payment of $33 upon execution of the Lindstrom APA. Dr. Lindstrom was paid $7 and $14 in cash during the three and six months ended June 30, 2021, respectively. Dr. Lindstrom was paid $0 and $7 in cash during the three and six months ended June 30, 2020, respectively. The Company incurred royalty expense of $7 and $14 and $4 and $42 related to the Lindstrom APA during the three and six months ended June 30, 2021, and 2020, respectively.

Eyepoint Commercial Alliance Agreement

In August 2020, the Company, through its wholly owned subsidiary ImprimisRx, LLC, entered into a Commercial Alliance Agreement (the "Dexycu Agreement") with Eyepoint Pharmaceuticals, Inc. ("Eyepoint"), pursuant to which Eyepoint granted the Company the non-exclusive right to co-promote DEXYCU® (dexamethasone intraocular suspension) 9% for the treatment of post-operative inflammation following ocular surgery in the United States. Pursuant to the Dexycu Agreement, Eyepoint will pay the Company a fee calculated based on the quarterly sales of DEXYCU in excess of predefined volumes to specific customers of the Company in the U.S. Under the terms of the Dexycu Agreement, the Company shall use commercially reasonable efforts to promote and market DEXYCU in the U.S.

Subject to early termination, the Dexycu Agreement expires on August 1, 2025, subject to specified notice periods and specified limitations, either party may terminate the Dexycu Agreement in the event of (i) uncured material breach by the other party or (ii) if DEXYCU ceases to have "pass-through" payment status. In addition, subject to certain limitations, the Company may terminate the Dexycu Agreement (i) for convenience subject to an extended specified notice period or (ii) in the event Eyepoint undergoes a change of control. Eyepoint may terminate the Dexycu Agreement, subject to specified notice periods and specified limitations, if the Company fails to achieve certain minimum sales levels during specified periods. During the three and six months ended June 30, 2021, the Company recorded $827 and $1,312, respectively, in commission revenues related to the Dexycu Agreement.

Sales and Marketing Agreements

The Company has entered various sales and marketing agreements with certain organizations to provide exclusive and non-exclusive sales and marketing representation services to Harrow in select geographies in the U.S. in connection with the Company's ophthalmic pharmaceutical compounded formulations or related products.

Under the terms of the sales and marketing agreements, the Company is generally required to make commission payments equal to 10% - 14% of net sales for products above and beyond the initial existing sales amounts. In addition, the Company is required to make periodic milestone payments to certain organizations in shares of the Company's restricted common stock if net sales in the assigned territory reach certain future levels by the end of their terms. Commission expenses of $1,032 and $1,836 and $318 and $921 were incurred under these agreements during the three and six months ended June 30, 2021, and 2020, respectively.

Asset Purchase, License and Related Agreements

The Company has acquired and sourced intellectual property rights related to certain proprietary innovations from certain inventors and related parties (the "Inventors") through multiple asset purchase agreements, license agreements, strategic agreements and commission agreements. In general, these agreements provide that the Inventors will cooperate with the Company in obtaining patent protection for the acquired intellectual property and that the Company will use commercially reasonable efforts to research, develop and commercialize a product based on the acquired intellectual property. In addition, the Company has acquired a right of first refusal on additional intellectual property and drug development opportunities presented by these Inventors.

In consideration for the acquisition of the intellectual property rights, the Company is obligated to make payments to the Inventors based on the completion of certain milestones, generally consisting of: (1) a payment payable within 30 days after the issuance of the first patent in the United States arising from the acquired intellectual property (if any); (2) a payment payable within 30 days after the Company files the first investigational new drug application ("IND") with the U.S. Food and Drug Administration ("FDA") for the first product arising from the acquired intellectual property (if any); (3) for certain of the Inventors, a payment payable within 30 days after the Company files the first new drug application with the FDA for the first product arising from the acquired intellectual property (if any); and (4) certain royalty payments based on the net receipts received by the Company in connection with the sale or licensing of any product based on the acquired intellectual property (if any), after deducting (among other things) the Company's development costs associated with such product. If, following five years after the date of the applicable asset purchase agreement, the Company either (a) for certain of the Inventors, has not filed an IND or, for the remaining Inventors, has not initiated a study where data is derived, or (b) has failed to generate royalty payments to the Inventors for any product based on the acquired intellectual property, the Inventors may terminate the applicable asset purchase agreement and request that the Company re-assign the acquired technology to the Inventors. Royalty expenses of $261 and $493 and $117 and $261 were incurred under these agreements for the three and six months ended June 30, 2021 and 2020, respectively, and $272 and $431 are included in accounts payable at June 30, 2021 and 2020, respectively.

Mayfield Pharmaceuticals MAY-66 License Termination

In May 2021, Mayfield terminated the License Agreement (the "TGV License") with TGV-Health, LLC and affiliated entities (collectively, "TGV"), pursuant to which it acquired intellectual property rights for use in the women's health field, related to Mayfield's proprietary drug candidate MAY-66. Concurrent with the termination, TGV returned to Mayfield 300,000 shares of Mayfield's common stock, constituting all of the equity held by TGV. Mayfield has no outstanding or remaining obligations under the TGV License.

Mayfield Pharmaceuticals MAY-44 APA Termination

In May 2021, Mayfield and Harrow terminated their asset purchase agreement dated January 2020 for intellectual property rights associated with Mayfield's drug candidate MAY-44 with Elle Pharmaceutical LLC (the "MAY-44 APA"). As part of the termination, Mayfield re-acquired 350,000 shares of its common stock from Elle. Mayfield has no outstanding or remaining obligations related to the MAY-44 APA.

Stowe License Termination

In May 2021, Stowe terminated the License Agreement (the "Stowe License") with TGV, pursuant to which it acquired intellectual property rights for use in the ophthalmic field, related to Stowe's proprietary drug candidate STE-006. Concurrent with the termination, TGV returned to Stowe 1,750,000 shares of Stowe's common stock, constituting all of the equity held by TGV. Stowe has no outstanding or remaining obligations under the Stowe License.

NOTE 16. SEGMENT INFORMATION AND CONCENTRATIONS

Management evaluates performance of the Company based on operating segments. Segment performance for its two operating segments is based on segment contribution. The Company's reportable segments consist of (i) its commercial stage pharmaceutical business known as ImprimisRx; and (ii) its start-up operations associated with pharmaceutical drug development business (Pharmaceutical Drug Development). Segment contribution for the segments represents net revenues less cost of sales, research and development, selling and marketing expenses, and select general and administrative expenses. The Company does not evaluate the following items at the segment level:

- Selling, general and administrative expenses that result from shared infrastructure, including certain expenses associated with legal matters, public company costs (e.g. investor relations), board of directors and principal executive officers and other like shared expenses.

- Operating expenses within selling, general and administrative expenses that result from the impact of corporate initiatives. Corporate initiatives primarily include integration, restructuring, acquisition and other shared costs.

- Other select revenues and operating expenses including R&D expenses, amortization, and asset sales and impairments, net as not all such information has been accounted for at the segment level, or such information has not been used by all segments.

- Total assets including capital expenditures.

The Company defines segment net revenues as pharmaceutical compounded drug sales, licenses, commissions and other revenue derived from related agreements.

Cost of sales within segment contribution includes direct and indirect costs to manufacture formulations and sell products, including active pharmaceutical ingredients, personnel costs, packaging, storage, royalties, shipping and handling costs, manufacturing equipment and tenant improvements depreciation, the write-off of obsolete inventory and other related expenses.

Selling, general and administrative expenses consist mainly of personnel-related costs, marketing and promotion costs, distribution costs, professional service costs, insurance, depreciation, facilities costs, transaction costs, and professional services costs which are general in nature and attributable to the segment.

Segment net revenues, segment operating expenses and segment contribution information consisted of the following for the three and six months ended June 30, 2021:

	For the Three Months Ended June 30, 2021		
	ImprimisRx	Pharmaceutical Drug Development	Total
Net revenues	$ 18,134	$ -	$ 18,134
Cost of sales	(4,417)	-	(4,417)
Gross profit	13,717	-	13,717
Operating expenses:			
Selling, general and administrative	6,422	-	6,422
Research and development	112	104	216
Segment contribution	$ 7,183	$ (104)	7,079
Corporate			2,662
Research and development			209
Amortization			39
Operating income			$ 4,169

	For the Six Months Ended June 30, 2021		
	ImprimisRx	Pharmaceutical Drug Development	Total
Net revenues	$ 33,577	$ -	$ 33,577
Cost of sales	(8,187)	-	(8,187)
Gross profit	25,390	-	25,390
Operating expenses:			
Selling, general and administrative	12,193	-	12,193
Research and development	322	117	439
Segment contribution	$ 12,875	$ (117)	12,758
Corporate			5,015
Research and development			578
Amortization			79
Operating income			$ 7,086

	For the Three Months Ended June 30, 2020		
	ImprimisRx	Pharmaceutical Drug Development	Total
Net revenues	$ 8,060	$ -	$ 8,060
Cost of sales	(3,204)	-	(3,204)
Gross profit	4,856	-	4,856
Operating expenses:			
Selling, general and administrative	4,598	43	4,641
Research and development	497	46	543
Segment contribution	$ (239)	$ (89)	(328)
Corporate			2,270
Research and development			206
Amortization			43
Asset sales and impairments, net			363
Operating loss			$ (3,210)

	For the Six Months Ended June 30, 2020		
	Pharmaceutical Compounding	Pharmaceutical Drug Development	Total
Net revenues	$ 19,877	$ -	$ 19,877
Cost of sales	(6,830)	-	(6,830)
Gross profit	13,047	-	13,047
Operating expenses:			
Selling, general and administrative	11,238	87	11,325
Research and development	540	57	597
Segment contribution	$ 1,269	$ (144)	1,125
Corporate			3,957
Research and development			555
Amortization			88
Asset sales and impairments, net			363
Operating loss			$ (3,838)

The Company categorizes revenues by geographic area based on selling location. All operations are currently located in the U.S.; therefore, total revenues are attributed to the U.S. All long-lived assets at June 30, 2021 and December 31, 2020 were located in the U.S.

Concentrations

The Company has two products that each comprised more than 10% of total revenues during the quarter. These products collectively accounted for 36% of revenues during each of the three and six months ended June 30, 2021.

The Company sells its compounded formulations to a large number of customers. There were no customers who comprised more than 10% of the Company's total pharmacy sales for the three and six months ended June 30, 2021 and 2020.

The Company receives its active pharmaceutical ingredients from three main suppliers. These suppliers collectively accounted for 85% and 79% of active pharmaceutical ingredient purchases during the three and six months ended June 30, 2021, respectively, and 60% and 70% of active pharmaceutical ingredient purchases during the three and six months ended June 30, 2020, respectively.

NOTE 17. SUBSEQUENT EVENTS

The Company has performed an evaluation of events occurring subsequent to June 30, 2021 through the filing date of this Quarterly Report. Based on its evaluation, no events other than those described below need to be disclosed.

Sintetica Agreement

In July 2021, the Company entered into a License and Supply Agreement (the "Sintetica Agreement") with Sintetica S.A. ("Sintetica"), pursuant to which Sintetica granted the Company the exclusive license and marketing rights to its patented ophthalmic drug candidate ("AMP-100") in the U.S. and Canada.

Pursuant to the Sintetica Agreement, the Company will pay Sintetica a per unit transfer price to supply AMP-100, along with a per unit royalty for units sold. The Company is required to pay Sintetica up to $18,000 in one-time milestone payments including a $5,000 payment due within 30 days of signing the Sintetica Agreement and the balance of payments due upon achievement of certain regulatory and commercial milestones. Under the terms of the Sintetica Agreement, Sintetica will be responsible for regulatory filings for AMP-100 in the U.S.

Subject to certain limitations, the term of the Sintetica Agreement is ten years, and allows for a ten-year extension if certain sales thresholds are met.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and the related notes thereto contained in Part I, Item 1 of this Quarterly Report on Form 10-Q (this "Quarterly Report"). Our condensed consolidated financial statements have been prepared and, unless otherwise stated, the information derived therefrom as presented in this discussion and analysis is presented, in accordance with accounting principles generally accepted in the United States of America ("GAAP").

The information contained in this Quarterly Report is not a complete description of our business or the risks associated with an investment in our common stock. We urge you to carefully review and consider the various disclosures made by us in this Quarterly Report and in our other reports filed with the U.S. Securities and Exchange Commission (the "SEC"), including our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and subsequent reports, which discuss our business in greater detail. As used in this discussion and analysis, unless the context indicates otherwise, the terms the "Company," "Harrow," "we," "us" and "our" refer to Harrow Health, Inc. and its consolidated subsidiaries, consisting of Park Compounding, Inc., ImprimisRx, LLC, ImprimisRx NJ, LLC dba ImprimisRx, Imprimis NJOF, LLC, Radley Pharmaceuticals, Inc., Mayfield Pharmaceuticals, Inc., and Stowe Pharmaceuticals, Inc. In this discussion and analysis, we refer to our consolidated subsidiaries ImprimisRx, LLC, ImprimisRx NJ, LLC and Imprimis NJOF, LLC collectively as "ImprimisRx."

In addition to historical information, the following discussion contains forward-looking statements regarding future events and our future performance. In some cases, you can identify forward-looking statements by terminology such as "will," "may," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "forecasts," "potential" or "continue" or the negative of these terms or other comparable terminology. All statements made in this Quarterly Report other than statements of historical fact are forward-looking statements. These forward-looking statements involve risks and uncertainties and reflect only our current views, expectations and assumptions with respect to future events and our future performance. If risks or uncertainties materialize or assumptions prove incorrect, actual results or events could differ materially from those expressed or implied by such forward-looking statements. Risks that could cause actual results to differ from those expressed or implied by the forward-looking statements we make include, among others, risks related to: the impact of the COVID-19 pandemic on our financial condition, liquidity or results of operations; our ability to successfully implement our business plan, develop and commercialize our proprietary formulations in a timely manner or at all, identify and acquire additional proprietary formulations, manage our pharmacy operations, service our debt, obtain financing necessary to operate our business, recruit and retain qualified personnel, manage any growth we may experience and successfully realize the benefits of our previous acquisitions and any other acquisitions and collaborative arrangements we may pursue; competition from pharmaceutical companies, outsourcing facilities and pharmacies; general economic and business conditions; regulatory and legal risks and uncertainties related to our pharmacy operations and the pharmacy and pharmaceutical business in general; physician interest in and market acceptance of our current and any future formulations and compounding pharmacies generally; our limited operating history; and the other risks and uncertainties described under the heading "Risk Factors" in Part II, Item 1A of this Quarterly Report and in our other filings with the SEC. You should not place undue reliance on forward-looking statements. Forward-looking statements speak only as of the date they are made and, except as required by law, we undertake no obligation to revise or publicly update any forward-looking statement for any reason.

Overview

Our business specializes in the development, production and sale of innovative medications that offer unique competitive advantages and serve unmet needs in the marketplace through our subsidiaries and deconsolidated companies. We own and operate one of the nation's leading ophthalmology pharmaceutical businesses, ImprimisRx. In addition to wholly owning ImprimisRx, we also have non-controlling equity positions in Surface Ophthalmics, Inc. ("Surface") and Melt Pharmaceuticals, Inc. ("Melt"), both companies that began as subsidiaries of Harrow. In 2020, Harrow created Visionology, Inc. ("Visionology") and recently launched an online eye health platform business in certain regions. We also own royalty rights in various drug candidates being developed by Surface and Melt.

ImprimisRx

ImprimisRx is our ophthalmology focused prescription pharmaceutical business. We offer to over 10,000 physician customers and their patients critical medicines to meet their needs that are unmet by commercially available drugs. We make our formulations available at prices that are, in most cases, lower than non-customized commercial drugs. Our current ophthalmology formulary includes over twenty compounded formulations, many of which are patented or patent-pending, and are customizable for the specific needs of a patient. Some examples of our compounded medications are various combinations of drugs formulated into one bottle and numerous preservative free formulations. Depending on the formulation, the regulations of a specific state and ultimately the needs of the patient, ImprimisRx products may be dispensed as patient-specific medications from our 503A pharmacy, or for in-office use, made according to current good manufacturing practices (or cGMPs) or other FDA-guidance documents, in our FDA-registered New Jersey outsourcing facility ("NJOF").

On August 1, 2020, ImprimisRx entered into a Commercial Alliance Agreement (the "Dexycu Agreement") with Eyepoint Pharmaceuticals, Inc. ("Eyepoint"), pursuant to which Eyepoint granted ImprimisRx the non-exclusive right to co-promote DEXYCU® (dexamethasone intraocular suspension) 9% for the treatment of post-operative inflammation following ocular surgery in the United States. Pursuant to the Dexycu Agreement, Eyepoint pays ImprimisRx a fee that is calculated based on the quarterly sales of DEXCYU in excess of predefined volumes to specific customers of ImprimisRx in the U.S.

AMP-100

Sintetica has granted the Company the exclusive license and marketing rights to AMP-100 in the U.S. and Canada. AMP-100 is a patented, ophthalmic topical anesthetic drug candidate. If FDA-approved, the active ingredient used in AMP-100 will be the first approved use of this active ingredient in the U.S. ophthalmic market.

The safety and efficacy of AMP-100 was demonstrated in various clinical trials including a Phase 2/3 randomized, double-masked, vehicle-controlled, efficacy, safety and tolerability study in healthy volunteers and a non-inferiority Phase 3 study of 342 patients undergoing cataract surgeries comparing AMP-100 to an active comparator. Ultimately, these studies demonstrated:

- AMP-100 is safe, and the most common adverse event was mydrasis (dilation of pupil) in about 20% of patients which is an effect most ophthalmologists may consider beneficial;
- AMP-100 has rapid onset, and no inferiority to the active comparator (Phase 3);
- Anesthesia success of patients receiving AMP-100 was 95% vs. 20% with placebo (Phase 2/3 study);
- Single administration of AMP-100 provides roughly 20 minutes of sensory loss; and
- AMP-100 has predictable offset (end of anesthesia) within a narrow bell curve (i.e. no wide variance).

We expect a new drug application ("NDA") for AMP-100 to be submitted by Sintetica to the FDA in the fourth quarter of 2021 and, if approved, we plan to commercially launch AMP-100 in the fourth quarter of 2022.

If approved, we expect our initial commercial focus of AMP-100 to be on ophthalmic procedures that traditionally require the eye to be anesthetized. According to a 2019 MarketScope report, there are over four million cataract surgeries performed in the U.S. annually. In addition to cataract procedures, according to Ophthalmologica, there were about 5.9 million intravitreal injections performed in the U.S. in 2018. Most of these intravitreal injections, which are typically treatments for variety of conditions, including, age-related macular degeneration, diabetic macular edema, and uveitis, often require the ocular surface to be anesthetized during the procedure.

AMP-100 is protected by one issued patent and another patent-pending. The issued patent includes composition of matter and method of use claims and could provide protection for AMP-100 into 2037.

In addition to AMP-100, we expect to acquire and/or develop additional FDA-approved/approvable ophthalmic products and product candidates that will allow us to leverage the commercial infrastructure of ImprimisRx to promote, sell, and ultimately bring these products to market.

Visionology

Visionology, a direct-to-consumer online eye health platform, leverages our experience in the ophthalmic pharmaceutical business as well as our relationships with eyecare professionals across the United States. We recently launched a proof-of-concept model for Visionology within a certain region of the U.S., and if successful, will expand the launch on a nationwide basis later in 2021.

Pharmaceutical Compounding Businesses

Pharmaceutical Compounding

Pharmaceutical compounding is the science of combining different active pharmaceutical ingredients (APIs), all of which are approved by the FDA (either as a finished form product or as a bulk drug ingredient) and excipients, to create specialized pharmaceutical preparations. Physicians and healthcare institutions use compounded drugs when commercially available drugs do not optimally treat a patient's needs. In many cases, compounded drugs, such as ours, have wide market utility and may be clinically appropriate for large patient populations. Examples of compounded formulations include medications with alternative dosage strengths or unique dosage forms, such as topical creams or gels, suspensions, or solutions with more tolerable drug delivery vehicles.

Almost all of our sales revenue is derived from making, selling and dispensing our compounded prescription drug formulations as cash pay transactions between us and our end-user customer. As such, the majority of our commercial transactions do not involve distributors, wholesalers, insurance companies, pharmacy benefit managers or other middle parties. By not being reliant on insurance company formulary inclusion and pharmacy benefit manager payment clawbacks, we are able to simplify the prescription transaction process. We believe the outcome of our business model is a simple transaction, involving a patient-in-need, a physician's diagnosis, a fair price and great service for a quality pharmaceutical product. We sell our products through a network of employees and independent contractors and we dispense our formulations in all 50 states, Puerto Rico and in selected markets outside the United States.

Our Compounding Facilities

Pharmaceutical compounding businesses are governed by Sections 503A and 503B of the Federal Food Drug and Cosmetic Act (the "FDCA"). Section 503A of the FDCA provides that a pharmacy is only permitted to compound a drug for an individually identified patient based on a prescription for a patient, and is only permitted to distribute the drug interstate if the pharmacy is licensed to do so in the states where it is compounded and where the medication is received.

Section 503B of the FDCA provides that a pharmacy engaged in preparing sterile compounded drug formulations may voluntarily elect to register as an "outsourcing facility." Outsourcing facilities are permitted to compound large quantities of drugs without a prescription and distribute them out of state with certain limitations such as the formulation appearing on the FDA's drug shortage list or the bulk drug substances contained in the formulations appearing on the FDA's "clinical need" list. Entities voluntarily registering with FDA as outsourcing facilities are subject to additional requirements that do not apply to compounding pharmacies (operating under Section 503A of the FDCA), including adhering to standards such as current good manufacturing practices (cGMP) or other FDA guidance documents and being subject to regular FDA inspection.

We operate two compounding facilities located in Ledgewood, New Jersey. Our New Jersey operations are comprised of two separate entities and facilities, one of which is registered with the FDA as an outsourcing facility ("NJOF") under Section 503B of the FDCA. The other New Jersey facility ("RxNJ"), is a licensed pharmacy operating under Section 503A of the FDCA. All products that we sell, produce and dispense are made in the United States.

We believe that, with our current compounding pharmacy facilities and licenses and FDA registration of NJOF, we have the infrastructure to scale our business appropriately under the current regulatory landscape and meet the potential growth in demand we are targeting. We plan to invest in one or both of our facilities to further their capacity and efficiencies. Also, we may seek to access greater pharmacy and production related redundancy and markets through acquisitions, partnerships or other strategic transactions.

Pharmaceutical Development Carve-Out Businesses

We have ownership interests in Eton Pharmaceuticals, Inc. ("Eton"), Surface and Melt and hold royalty interests in some of the drug candidates of Surface and Melt. These companies are pursuing market approval for their drug candidates under the FDCA, including in some instances under the abbreviated pathway described in Section 505(b)(2) which permits the submission of a new drug application ("NDA") where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference.

In 2018 and 2019, we formed and created subsidiaries named Radley Pharmaceuticals, Inc. ("Radley"), Mayfield Pharmaceuticals, Inc. ("Mayfield"), and Stowe Pharmaceuticals, Inc. ("Stowe"). In 2020, we halted nearly all operating activities related to these subsidiaries to invest resources in other areas and may not restart any or all activities related to these businesses. In addition, we terminated license and acquisition agreements for Mayfield's MAY-66 and MAY-44 drug candidates, and Stowe's STE-006 drug candidate.

De-Consolidated Businesses (Noncontrolling Equity Interests)

Surface Ophthalmics, Inc.

Surface is a clinical-stage pharmaceutical company focused on development and commercialization of innovative therapeutics for ocular surface diseases.

In January 2021, Surface announced positive top-line results from a phase 2 trial of its drug candidate SURF-201, a 0.2% betamethasone, preservative-free ophthalmic solution in the Klarity delivery vehicle for the treatment of post cataract surgery pain and inflammation. According to the Surface results, SURF-201 was dosed twice daily, met its primary endpoints of absence of inflammation at both Day 8 and Day 15 and was found to be safe and well-tolerated by the patient group. In addition, a secondary endpoint showed almost 90% of patients given SURF-201 were pain free at Day 15. SURF-201 marks the first ophthalmic therapeutic in the United States to utilize betamethasone as well as being the first preservative-free unit dose therapy for the treatment of post-operative pain and inflammation.

Also in January 2021, Surface announced the first patient dosed in a head-to-head phase 2 trial for its drug candidate SURF-100 (mycophenolate sodium and betamethasone in Klarity vehicle) for the treatment of chronic dry eye disease. The head-to-head study will compare SURF-100 against leading on-market competitors lifitegrast ophthalmic solution 5% (marketed as Xiidra®) and cyclosporine ophthalmic emulsion 0.05% (marketed as Restasis®).

In February 2021, Surface announced the first patient dosed in a phase 2 trial for its drug candidate SURF-200 (betamethasone in Klarity vehicle) for the treatment of episodic dry eye flares. The dose ranging study for SURF-200 will be administered in two different low concentration formulations of betamethasone in the Klarity vehicle. The trial will enroll 120 to 140 patients with a primary endpoint of Symptom Improvement of one unit based on the University of North Carolina Dry Eye Management Scale by the eighth day.

In 2018, Surface closed an offering of its Series A Preferred Stock. At that time, we lost our controlling interest and deconsolidated Surface from our consolidated financial statements. During May, June and July of 2021, Surface closed an offering of its preferred stock at a purchase price of $4.50 per share resulting in gross proceeds to Surface of approximately $25,000,000 (the “Surface Series B Offering”). We own 3,500,000 shares of Surface common stock which was approximately 20% of the equity and voting interests following the final close of the Surface Series B Offering. Harrow owns mid-single digit royalty rights on net sales of SURF-100, SURF-200 and SURF-201.

Melt Pharmaceuticals, Inc.

Melt is a clinical-stage pharmaceutical company focused on the development and commercialization of proprietary non-intravenous, sedation and anesthesia therapeutics for human medical procedures in hospital, outpatient, and in-office settings. Melt intends to seek regulatory approval for its proprietary technologies, where possible. In December 2018, we entered into an Asset Purchase Agreement with Melt (the “Melt Asset Purchase Agreement”), and Harrow assigned to Melt the underlying intellectual property for Melt’s current pipeline, including its lead drug candidate MELT-100. The core intellectual property Melt owns is a patented series of combination non-opioid sedation drug formulations that we estimate to have multitudinous applications.

MELT-100 is a novel, sublingually delivered, non-IV, opioid-free drug candidate being developed for procedural sedation. Melt filed an investigational new drug application (“IND”) with the FDA in June 2020 and began its clinical program for MELT-100. In February 2021, Melt announced data from, and the successful completion of, its phase 1 study. Melt expects to begin its phase 2 study for MELT-100 in the second half of 2021.

In January 2019, Melt closed an offering of its Series A Preferred Stock. At that time, we lost our controlling interest and deconsolidated Melt from our consolidated financial statements. We own 3,500,000 shares of Melt common stock, which was approximately 44% of the equity and voting interests issued and outstanding of as of June 30, 2021. We expect Melt to complete another round of financing within the next six months. Pursuant to the terms of the Melt Asset Purchase Agreement, Melt is required to make mid-single digit royalty payments to the Company on net sales of MELT-100, while any patent rights remain outstanding, subject to other conditions. Melt can require the Company to cease compounding like products at the time of FDA approval of MELT-100. If approved, we do not expect a cessation of compounding like products to have a material impact on our operations and financial performance.

Eton Pharmaceuticals, Inc.

Eton is a commercial-stage pharmaceutical company focused on developing and commercializing innovative drug products. Its pipeline includes several products and drug candidates in various stages of development across a variety of dosage forms. In May 2017, Eton closed an offering of its Series A Preferred Stock and we lost our controlling interest in it. In November 2018, Eton completed an initial public offering of its common stock. At that time, we gave up our controlling interest and deconsolidated Eton from our consolidated financial statements. As of the date of this Quarterly Report and following our April 2021 sale, we own 1,982,000 shares of Eton common stock. We owned less than 10% of the equity and voting interests issued and outstanding of Eton as of June 30, 2021.

Factors Affecting Our Performance

We believe the primary factors affecting our performance are our ability to increase revenues of our proprietary compounded formulations and certain non-proprietary products, grow and gain operating efficiencies in our pharmacy operations, potential regulatory-related restrictions, optimize pricing and obtain reimbursement options for our proprietary compounded formulations, and continue to pursue development and commercialization opportunities for certain of our ophthalmology and other assets that we have not yet made commercially available as compounded formulations. We believe we have built a tangible and intangible infrastructure that will allow us to scale revenues efficiently in the near and long-term. All of these activities will require significant costs and other resources, which we may not have or be able to obtain from operations or other sources. See “Liquidity and Capital Resources” below.

Reimbursement Options

Our proprietary ophthalmic compounded formulations are currently primarily available on a cash-pay basis. However, we work with third-party insurers, pharmacy benefit managers and buying groups to offer patient-specific customizable compounded formulations at accessible prices. We may devote time and other resources to seek reimbursement and patient pay opportunities for these and other compounded formulations and we have hired pharmacy billers to process certain existing reimbursement opportunities for certain formulations. However, we may be unsuccessful in achieving these goals, as many third-party payors have imposed significant restrictions on reimbursement for compounded formulations in recent years. Moreover, third-party payors, including Medicare, are increasingly attempting to contain health care costs by limiting coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has not granted labeling approval. Further, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the “Health Care Reform Law”), may have a considerable impact on the existing U.S. system for the delivery and financing of health care and could conceivable have a material effect on our business. As a result, reimbursement from Medicare, Medicaid and other third-party payors may never be available for any of our products or, if available, may not be sufficient to allow us to sell the products on a competitive basis and at desirable price points. We are communicating with government and third-party payors in order to make our formulations available to more patients and at optimized pricing levels. However, if government and other third-party payors do not provide adequate coverage and reimbursement levels for our formulations, the market acceptance and opportunity for our formulations may be limited.

COVID-19 Pandemic

A novel strain of coronavirus was first identified in Wuhan, China in December 2019. The disease caused by it, COVID-19, was declared a global pandemic by the World Health Organization in March 2020. On March 18, 2020, CMS released guidance for U.S. healthcare providers to limit all elective medical procedures in order to conserve personal protective equipment and limit exposure to COVID-19 during the pendency of the pandemic. In addition to limiting elective medical procedures, many hospitals and other healthcare providers have strictly limited access to their facilities during the pandemic. The COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains and healthcare delivery, led to social distancing recommendation, and created significant volatility in financial markets. In May 2020 and the following months, U.S. states and geographies began easing restrictions associated with the COVID-19 pandemic including those restrictions related to elective procedures. We have since seen sales of our products return to near historical norms and trends as restrictions associated with elective procedures and the COVID-19 pandemic have continued to ease.

However, given the unprecedented and dynamic nature of the COVID-19 pandemic virus, including any mutations/variants, we may not be able to reasonably estimate the impacts it may have on our financial condition, results of operations or cash flows in the future, especially if there are new restrictions in elective procedures in the future which would have an adverse impact, which may be material, on our future revenues, profitability and cash flows.

Recent Developments

The following describes certain developments in 2021 to date that are important to understand our financial condition and results of operations. See the notes to our condensed consolidated financial statements included in this report for additional information about each of these developments.

PPP Loan

In April 2020, we entered into an unsecured promissory note and related Business Loan Agreement with Renasant Bank, as lender, for a loan (the "PPP Loan") in the principal amount of $1,967,000 and received cash proceeds of the same amount, pursuant to the Paycheck Protection Program (the "PPP") under the Federal Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), which was enacted March 27, 2020. The PPP is administered by the U.S. Small Business Administration. On March 30, 2021, the Company received a notice of forgiveness of the full balance of the PPP Loan, including all accrued interest, in accordance with the terms and conditions of the CARES Act and accordingly recognized a gain on forgiveness of debt of $1,967,000.

Eton Stock Sale

In April 2021, we closed an underwritten public offering of 1,518,000 shares of our Eton common stock at a public offering price of $7.00 per share (the "Eton Stock Sale"). The gross proceeds to us from the Eton Stock Sale were $10,626,000 before deducting underwriting discounts and commissions and other offering expenses payable by the Company. Following such sale, we own 1,982,000 shares of Eton common stock, which represented less than 10% of the equity interests issued and outstanding of Eton as of June 30, 2021.

As part of the Eton Stock Sale, we also agreed, for a period of 180 days, not to conduct any further sales of shares of its common stock of Eton or otherwise dispose of, directly or indirectly, any common stock of Eton (or any securities convertible into, or exercisable or exchangeable for, the common stock of Eton).

8.625% Senior Notes Due 2026

During April, May and June 2021, we closed offerings totaling $75,000,000 aggregate principal amount of 8.625% senior notes due 2026 (the "Notes"). The Notes are senior unsecured obligations of the Company and rank equally in right of payment with all of our other existing and future senior unsecured and unsubordinated indebtedness. The Notes are effectively subordinated in right of payment to all of our existing and future secured indebtedness and structurally subordinated to all existing and future indebtedness of the Company's subsidiaries, including trade payables. The Notes bear interest at the rate of 8.625% per annum. Interest on the Notes is payable quarterly in arrears on January 31, April 30, July 31 and October 31 of each year, commencing on July 31, 2021. The Notes will mature on April 30, 2026.

Prior to February 1, 2026, we may, at our option, redeem the Notes, in whole at any time or in part from time to time, at a redemption price equal to 100% of the principal amount of the Notes to be redeemed, plus a make-whole amount, if any, plus accrued and unpaid interest to, but excluding, the date of redemption. We may redeem the Notes for cash in whole or in part at any time at our option on or after February 1, 2026 and prior to maturity, at a price equal to 100% of their principal amount, plus accrued and unpaid interest to, but excluding, the date of redemption. On and after any redemption date, interest will cease to accrue on the redeemed Notes.

Series B Cumulative Preferred Stock

On May 5, 2021, we sold 440,000 shares of Series B Cumulative Preferred Stock (the "Series B Preferred Stock") for net proceeds of $10,670,000. On June 17, 2021, the Company redeemed all of the outstanding shares of the Series B Preferred Stock. The redemption price for the 440,000 shares of the Series B Preferred Stock outstanding was equal to $25.00 per share, plus accrued and unpaid dividends, which in aggregate totaled $11,127,000.

Sintetica Agreement

In July 2021, we entered into a License and Supply Agreement (the "Sintetica Agreement") with Sintetica S.A. ("Sintetica"), pursuant to which Sintetica granted the Company the exclusive license and marketing rights to its patented ophthalmic drug candidate ("AMP-100") in the U.S. and Canada.

Pursuant to the Sintetica Agreement, the Company will pay Sintetica a per unit transfer price to supply AMP-100, along with a per unit royalty for units sold. The Company is required to pay Sintetica up to $18,000 in one-time milestone payments including a $5,000 payment due within 30 days of signing the Sintetica Agreement and the balance of payments due upon achievement of certain regulatory and commercial milestones. Under the terms of the Sintetica Agreement, Sintetica will be responsible for regulatory filings for AMP-100 in the U.S.

Subject to certain limitations, the term of the Sintetica Agreement is ten years, and allows for a ten-year extension if certain sales thresholds are met.

Results of Operations

The following period-to-period comparisons of our financial results for the three and six months ended June 30, 2021 and 2020, are not necessarily indicative of results for the current period or any future period.

Revenues

Our revenues include amounts recorded from sales of proprietary compounded formulations, commissions from third parties and revenues received from royalty payments owed to us pursuant to out-license arrangements.

The following presents our revenues for the three and six months ended June 30, 2021 and 2020:

	For the Three Months Ended June 30,			For the Six Months Ended June 30,		
	2021	2020	$ Variance	2021	2020	$ Variance
Product sales, net	$ 17,297	$ 8,049	$ 9,248	$ 32,245	$ 19,859	$ 12,386
Commission revenues	827	-	827	1,312	-	1,312
License revenues	10	11	(1)	20	18	2
Total revenues	$ 18,134	$ 8,060	$ 10,074	$ 33,577	$ 19,877	$ 13,700

The increase in revenues between periods was related to an increase in sales volumes of our ophthalmology products and commissions attributable to sales of Dexycu®.

Cost of Sales

Our cost of sales includes direct and indirect costs to manufacture formulations and sell products, including active pharmaceutical ingredients, personnel costs, packaging, storage, royalties, shipping and handling costs, manufacturing equipment and tenant improvements depreciation, the write-off of obsolete inventory and other related expenses.

The following presents our cost of sales for the three and six months ended June 30, 2021 and 2020:

	For the Three Months Ended June 30,		$	For the Six Months Ended June 30,		$
	2021	2020	Variance	2021	2020	Variance
Cost of sales	$ 4,417	$ 3,204	$ 1,213	$ 8,187	$ 6,830	$ 1,357

The increase in our cost of sales between periods was largely attributable to an increase in unit volumes sold.

Gross Profit and Margin

	For the Three Months Ended June 30,		$	For the Six Months Ended June 30,		$
	2021	2020	Variance	2021	2020	Variance
Gross profit	$ 13,717	$ 4,856	$ 8,861	$ 25,390	$ 13,047	$ 12,343
Gross margin	75.6%	60.2%	15.4%	75.6%	65.6%	10.0%

The increase in gross margin between periods is largely attributable to increased unit volumes sold, efficiencies in our production process, including increased batch sizes, and improved utilization of capacities as a result of increased output.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses include personnel costs, including wages and stock-based compensation, corporate facility expenses, and investor relations, consulting, insurance, filing, legal and accounting fees and expenses as well as costs associated with our marketing activities and sales of our proprietary compounded formulations and other non-proprietary pharmacy products and formulations.

The following presents our selling, general and administrative expenses for the three and six months ended June 30, 2021 and 2020:

	For the Three Months Ended June 30,		$	For the Six Months Ended June 30,		$
	2021	2020	Variance	2021	2020	Variance
Selling, general and administrative	$ 9,123	$ 6,954	$ 2,169	$ 17,287	$ 15,370	$ 1,917

The increase in selling, general and administrative expenses between periods was primarily attributable to an increase in commissions and other expenses related to increased sales, and as well as an increase in our sales and marketing expenses related to in-person conferences and new employee costs to support sales growth.

Research and Development Expenses

Our research and development expenses primarily include personnel costs, including wages and stock-based compensation, expenses related to the development of intellectual property, investigator-initiated research and evaluations, formulation development, and other costs related to the clinical development of our assets.

The following presents our research and development expenses for the three and six months ended June 30, 2021 and 2020:

	For the Three Months Ended June 30,		$	For the Six Months Ended June 30,		$
	2021	2020	Variance	2021	2020	Variance
Research and development	$ 425	$ 749	$ (324)	$ 1,017	$ 1,152	$ (135)

Research and development expenses between periods was primarily attributable to formulation development studies for new ophthalmic formulations and clinical programs related to our drug development segment during the three and six months ended June 30, 2021.

Interest Expense, net

Interest expense, net was $1,314,000 and $1,827,000 for the three and six months ended June 30, 2021, respectively, compared to $505,000 and $1,065,000 for the same periods last year, respectively. The increase during the period ended June 30, 2021 compared to the same period in 2020 was primarily due to an increase in the outstanding principal amount of our debt obligations.

Investment Loss from Melt

During the three and six months ended June 30, 2021, we recorded a net loss of $477,000 and $947,000, respectively, related to our share of losses in Melt. During the three and six months ended June 30, 2020, we recorded a loss of $690,000 and $1,236,000, respectively, for our share of losses based on our ownership of Melt.

Investment Loss from Surface

During the three and six months ended June 30, 2021, we recorded a loss of $465,000 and $1,314,000, respectively, for our share of losses based on our ownership of Surface. During the three and six months ended June 30, 2020, we recorded a loss of $599,000 and $938,000, respectively, for our share of losses based on our ownership of Surface.

Investment Loss from Eton

We recorded a loss of $3,584 ,000 and $6,419,000 related to the change in fair market value of Eton's common stock and the sale of a portion of our Eton stock during the three and six months ended June 30, 2021, respectively. We recorded a gain of $4,725,000 and loss of $6,125 related to the change in fair market value of Eton's common stock during the three and six months ended June 30, 2020, respectively.

Loss From Early Extinguishment of Loan

During the three and six months ended June 30, 2021, we recorded a loss from the early extinguishment of loan of $756,000 related to the early payoff of the SWK Loan.

Gain on Forgiveness of PPP Loan

During the six months ended June 30, 2021, we recorded gain on forgiveness of PPP loan of $1,967,000 related to the forgiveness of our PPP Loan.

Net loss

The following table presents our net loss and per share net loss for the three and six months ended June 30, 2021 and 2020:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Numerator – net loss attributable to Harrow Health, Inc. common stockholders	$ (2,950,000)	$ (237,000)	$ (2,733,000)	$ (13,144,000)
Net loss per share, basic and diluted	$ (0.11)	$ (0.01)	$ (0.10)	$ (0.51)

Financial Information About Segments and Geographic Areas

Management evaluates performance of the Company based on operating segments. Segment performance for our two operating segments are based on segment contribution. Our reportable segments consist of (i) our commercial stage pharmaceutical business ImprimisRx; and (ii) the start-up operations associated with our pharmaceutical drug development business (Pharmaceutical Drug Development). Segment contribution for the segments represents net revenues less cost of sales, research and development, selling and marketing expenses, and select general and administrative expenses. We do not evaluate the following items at the segment level:

- Selling, general and administrative expenses that result from shared infrastructure, including certain expenses associated with litigation and other legal matters, public company costs (e.g. investor relations), board of directors and principal executive officers, and other like shared expenses.

- Operating expenses within selling, general and administrative expenses that result from the impact of corporate initiatives. Corporate initiatives primarily include integration, restructuring, acquisition and other shared costs.

- Other select revenues and operating expenses including R&D expenses, amortization, and asset sales and impairments, net as not all such information has been accounted for at the segment level, or such information has not been used by all segments.

- Total assets including capital expenditures.

The Company defines segment net revenues as pharmaceutical compounded drug sales, licenses and other revenue derived from related agreements.

Cost of sales within segment contribution includes direct and indirect costs to manufacture formulations and sell products, including active pharmaceutical ingredients, personnel costs, packaging, storage, royalties, shipping and handling costs, manufacturing equipment and tenant improvements depreciation, the write-off of obsolete inventory and other related expenses.

Selling, general and administrative expenses consist mainly of personnel-related costs, marketing and promotion costs, distribution costs, professional service costs, insurance, depreciation, facilities costs, transaction costs, and professional services costs which are general in nature and attributable to the segment.

See Note 16 to our condensed consolidated financial statements included in this Quarterly Report for more information about our reportable segments.

Liquidity and Capital Resources

Liquidity

Our cash on hand (including restricted cash) at June 30, 2021 was $72,851,000, compared to $4,301,000 at December 31, 2020.

As of the date of this Quarterly Report, we believe that cash and cash equivalents of $72,651,000 and restricted cash of $200,000, totaling approximately $72,851,000 at June 30, 2021, will be sufficient to sustain our planned level of operations and capital expenditures for at least the next 12 months. In addition, we may consider the sale of certain assets including, but not limited to, part of, or all of, our ownership interest in Eton, Surface, Melt, and/or any of our consolidated subsidiaries. However, we may pursue acquisitions of pharmacies, revenue generating products, drug candidates or other strategic transactions that involve large expenditures or we may experience growth more quickly or on a larger scale than we expect, any of which could result in the depletion of capital resources more rapidly than anticipated and could require us to seek additional financing to support our operations.

We expect to use our current cash position and funds generated from our operations and any financing to pursue our business plan, which includes developing and commercializing drug candidates, compounded formulations and technologies, integrating and developing our operations, pursuing potential future strategic transactions as opportunities arise, including potential acquisitions of additional pharmacy, outsourcing facilities, drug company and manufacturers, drug products, drug candidates, and/or assets or technologies, and otherwise fund our operations. We may also use our resources to conduct clinical trials or other studies in support of our formulations or any drug candidate for which we pursue FDA approval, to pursue additional development programs or to explore other development opportunities.

Net Cash Flow

The following provides detailed information about our net cash flows:

	For the Six Months Ended June 30,	
	2021	**2020**
Net cash provided by (used in):		
Operating activities	$ 8,648,000	$ (3,201,000)
Investing activities	8,445,000	(610,000)
Financing activities	51,457,000	2,964,000
Net change in cash and cash equivalents	68,550,000	(847,000)
Cash, cash equivalents and restricted cash at beginning of the period	4,301,000	4,949,000
Cash, cash equivalents and restricted cash at end of the period	$ 72,851,000	$ 4,102,000

Operating Activities

Net cash provided by operating activities during the six months ended June 30, 2021 was $8,648,000 compared to net cash used in operating activities of $3,201,000 during the same period in the prior year. The increase in net cash provided by operating activities during the periods was mainly attributed to the increase in revenues.

Investing Activities

Net cash provided by investing activities during the six months ended June 30, 2021 was $8,445,000 compared to net cash used in investing activities of $610,000, respectively. Cash provided by investing activities in 2021 was primarily associated with the sale of a portion of our investment in Eton. Cash used in investing activities in 2020 was primarily associated with equipment and software purchases and upgrades along with investments in our intellectual property portfolio.

Financing Activities

Net cash provided by financing activities during the six months ended June 30, 2021 was $51,457,000 and $2,964,000, respectively. Cash provided by financing activities during the six months ended June 30, 2021 was primarily related to proceeds received from the sale of Notes, net of the payment of all outstanding obligations to the Company's previous senior lender, SWK Funding, LLC and its partners.

Sources of Capital

Our principal sources of cash consist of cash provided by operating activities from our ImprimisRx business, and recently, proceeds from the sale of the Notes and sale of Eton Stock. We may also sell some or all of our ownership interests in Surface, Melt or our other subsidiaries, along with the some or all of the remaining portion of our Eton common stock.

The changing trends and overall economic outlook in light of the COVID-19 pandemic, including the historic interim stay-at-home orders and bans on elective surgeries, created uncertainty surrounding our operating outlook and may impact our future operating results if there is a rise in COVID-19 related cases in the U.S. In addition, we may acquire new products, product candidates and/or businesses, as a result, we may need significant additional capital to support our business plan and fund our proposed business operations. We may receive additional proceeds from the exercise of stock purchase warrants that are currently outstanding. We may also seek additional financing from a variety of sources, including other equity or debt financings, funding from corporate partnerships or licensing arrangements, sales of assets or any other financing transaction. If we issue equity or convertible debt securities to raise additional funds, our existing stockholders may experience substantial dilution, and the newly issued equity or debt securities may have more favorable terms or rights, preferences and privileges senior to those of our existing stockholders. If we raise additional funds through collaboration or licensing arrangements or sales of assets, we may be required to relinquish potentially valuable rights to our product candidates or proprietary technologies or formulations, or grant licenses on terms that are not favorable to us. If we raise funds by incurring additional debt, we may be required to pay significant interest expenses and our leverage relative to our earnings or to our equity capitalization may increase. Obtaining commercial loans, assuming they would be available, would increase our liabilities and future cash commitments and may impose restrictions on our activities, such as the financial and operating covenants. Further, we may incur substantial costs in pursuing future capital and/or financing transactions, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we may issue, such as convertible notes and warrants, which would adversely impact our financial results.

We may be unable to obtain financing when necessary as a result of, among other things, our performance, general economic conditions, conditions in the pharmaceuticals and pharmacy industries, or our operating history, including our past bankruptcy proceedings. In addition, the fact that we have a limited history of profitability could further impact the availability or cost to us of future financings. As a result, sufficient funds may not be available when needed from any source or, if available, such funds may not be available on terms that are acceptable to us. If we are unable to raise funds to satisfy our capital needs when needed, then we may need to forego pursuit of potentially valuable development or acquisition opportunities, we may not be able to continue to operate our business pursuant to our business plan, which would require us to modify our operations to reduce spending to a sustainable level by, among other things, delaying, scaling back or eliminating some or all of our ongoing or planned investments in corporate infrastructure, business development, sales and marketing and other activities, or we may be forced to discontinue our operations entirely.

Recently Issued and Adopted Accounting Pronouncements

See Note 2 to our condensed consolidated financial statements included in this Quarterly Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted pursuant to the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure.

Under the supervision and with the participation of our principal executive officer and principal financial officer, our management conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Exchange Act, as they existed on June 30, 2021. Based on this evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective to achieve their stated purpose as of June 30, 2021, the end of the period covered by this report.

Changes in Internal Controls over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the quarter ended June 30, 2021, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact to our internal control over financial reporting due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 pandemic on our internal controls to minimize the impact on their design and operating effectiveness.

PART II
OTHER INFORMATION

Item 1. Legal Proceedings

See Note 15 to our condensed consolidated financial statements included in this Quarterly Report for information on various legal proceedings, which is incorporated into this Item by reference.

Item 1A. Risk Factors

You should carefully consider the following risk factors in addition to the other information contained in this Quarterly Report. Our business, financial condition, results of operations and stock price could be materially adversely affected by any of these risks. You should consider all of the factors described in this section when evaluating our business as well as the risk factors and the other information in our Quarterly Report on Form 10-Q for the three months ended March 31, 2021 and in our Annual Report on Form 10-K for the year ended December 31, 2020, including our audited financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline and you may lose all or part of your investments. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to the Senior Notes

We have incurred significant indebtedness, which will require substantial cash to service and which subjects us to certain financial requirements and business restrictions.

In April, May and June 2021, we issued $75,000,000 aggregate principal amount of 8.625% senior notes due 2026 (the "Notes"). We may incur additional indebtedness in the future. Our ability to make scheduled payments on our indebtedness depends on our future performance and ability to raise additional capital, which is subject to economic, financial, competitive and other factors, some of which are beyond our control. If we are unable to generate sufficient cash to service our debt, we may be required to adopt one or more alternatives, such as selling assets, restructuring our debt or obtaining additional capital through equity sales or incurrence of additional debt on terms that may be onerous or highly dilutive to our stockholders. Our ability to engage in any of these activities would depend on the capital markets and our financial condition at such time, and we may not be able to do so when needed, on desirable terms or at all, which could result in a default on our debt obligations. Additionally, our debt instruments contain or, from time to time, may contain various restrictive covenants, including, among others, our obligation to deliver certain financial and other information, our obligation to comply with certain notice and insurance requirements, and our inability, without prior consent, to dispose of certain of our assets, incur certain additional indebtedness, enter into certain merger, acquisition or change of control transactions, pay certain dividends or distributions on or repurchase any of our capital stock or incur any lien or other encumbrance on our assets, subject to certain permitted exceptions. Any failure by us to comply with any of these covenants, subject to certain cure periods, or to make all payments under the debt instruments when due, would cause us to be in default under the applicable debt instrument. In the event of any such default, lenders may be able to foreclose on our assets that secure the debt or declare all borrowed funds, together with accrued and unpaid interest, immediately due and payable, thereby potentially causing all of our available cash to be used to pay our indebtedness or forcing us into bankruptcy or liquidation if we do not then have sufficient cash available. Any such event or occurrence could severely and negatively impact our operations and prospects.

We may need additional capital in order to continue operating our business, and such additional funds may not be available when needed, on acceptable terms, or at all.

We only recently started generating cash from operations, but we do not currently earn sufficient revenues to support our operations. We may need significant additional capital to execute our business plan and fund our proposed business operations. Additionally, our plans may change or the estimates of our operating expenses and working capital requirements could be inaccurate, we may pursue acquisitions of pharmacies or other strategic transactions that involve large expenditures, or we may experience growth more quickly or on a larger scale than we expect, any of which may result in the depletion of capital resources more rapidly than anticipated and could require us to seek additional financing earlier than we expect to support our operations.

We have raised over $85,000,000 in funds through equity and debt financings in April, May and June 2021. We may seek to obtain additional capital through equity or debt financings, funding from corporate partnerships or licensing arrangements, sales of assets or other financing transactions. If we issue additional equity or debt securities to raise funds, our existing stockholders may experience substantial dilution, and the newly issued equity or debt securities may have more favorable terms or rights, preferences and privileges senior to those of our existing stockholders. If we raise additional funds through collaboration and licensing arrangements or sales of assets, we may have to relinquish potentially valuable rights to our drug candidates or proprietary technologies, or grant licenses on terms that are not favorable to us. If we raise funds by incurring additional debt, we may be required to pay significant interest expenses and our leverage relative to our earnings or to our equity capitalization may increase. Obtaining commercial loans, assuming those loans would be available, would increase our liabilities and future cash commitments and may impose restrictions on our activities. Further, we may incur substantial costs in pursuing future capital and/or financing transactions, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we may issue, such as options, convertible notes and warrants, which would adversely impact our financial results.

The Notes are unsecured and therefore are effectively subordinated to any secured indebtedness that we currently have or that we may incur in the future.

The Notes are not secured by any of our assets or any of the assets of our subsidiaries. As a result, the Notes are effectively subordinated to any secured indebtedness that we or our subsidiaries have currently outstanding or may incur in the future (or any indebtedness that is initially unsecured to which we subsequently grant security) to the extent of the value of the assets securing such indebtedness. The indenture governing the Notes does not prohibit us or our subsidiaries from incurring additional secured (or unsecured) indebtedness in the future. In any liquidation, dissolution, bankruptcy or other similar proceeding, the holders of any of our existing or future secured indebtedness and the secured indebtedness of our subsidiaries may assert rights against the assets pledged to secure that indebtedness and may consequently receive payment from these assets before they may be used to pay other creditors, including the holders of the Notes.

The indenture under which the Notes were issued contains limited protection for holders of the Notes.

The indenture under which the Notes were issued offers limited protection to holders of the Notes. The terms of the indenture and the Notes do not restrict our or any of our subsidiaries' ability to engage in, or otherwise be a party to, a variety of corporate transactions, circumstances or events that could have an adverse impact on the holders of the Notes. In particular, the terms of the indenture and the Notes do not place any restrictions on our or our subsidiaries' ability to:

- issue debt securities or otherwise incur additional indebtedness or other obligations, including (1) any indebtedness or other obligations that would be equal in right of payment to the Notes, (2) any indebtedness or other obligations that would be secured and therefore rank effectively senior in right of payment to the Notes to the extent of the values of the assets securing such debt, (3) indebtedness of ours that is guaranteed by one or more of our subsidiaries and which therefore is structurally senior to the Notes and (4) securities, indebtedness or obligations issued or incurred by our subsidiaries that would be senior to our equity interests in our subsidiaries and therefore rank structurally senior to the Notes with respect to the assets of our subsidiaries;

- pay dividends on, or purchase or redeem or make any payments in respect of, capital stock or other securities subordinated in right of payment to the Notes;

- sell assets (other than certain limited restrictions on our ability to consolidate, merge or sell all or substantially all of our assets);

- enter into transactions with affiliates;

- create liens (including liens on the shares of our subsidiaries) or enter into sale and leaseback transactions;

- make investments; or

- create restrictions on the payment of dividends or other amounts to us from our subsidiaries.

In addition, the indenture does not include any protection against certain events, such as a change of control, leveraged recapitalization, "going private" transaction (which may result in a significant increase of our indebtedness), restructuring or similar transactions. Furthermore, the terms of the indenture and the Notes do not protect holders of the Notes in the event that we experience changes (including significant adverse changes) in our financial condition, results of operations or credit ratings, as they do not require that we or our subsidiaries adhere to any financial tests or ratios or specified levels of net worth, revenues, income, cash flow, or liquidity. Also, an event of default or acceleration under our other indebtedness would not necessarily result in an event of default under the Notes.

Our ability to recapitalize, incur additional debt and take a number of other actions that are not limited by the terms of the Notes may have important consequences for the holders of the Notes, including making it more difficult for us to satisfy our obligations with respect to the Notes or negatively affecting the trading value of the Notes.

Other debt we issue or incur in the future could contain more protections for its holders than the indenture and the Notes, including additional covenants and events of default. The issuance or incurrence of any such debt with incremental protections could affect the market for and trading levels and prices of the Notes.

An increase in market interest rates could result in a decrease in the value of the Notes.

In general, as market interest rates rise, notes bearing interest at a fixed rate decline in value. Consequently, if the market interest rates increase, the market value of the Notes may decline. We cannot predict the future level of market interest rates.

An active trading market for the Notes may not develop, which could adversely affect the market price of the Notes or limit a holder's ability to sell them.

The Notes are quoted on Nasdaq under the symbol "HROWL." We cannot provide any assurances that an active trading market will develop for the Notes or that a holder will be able to sell the Notes. If the Notes are traded, they may trade at a discount from their initial offering price depending on prevailing interest rates, the market for similar securities, our credit ratings, general economic conditions, our financial condition, performance and prospects and other factors. The underwriters of the Notes may make a market in the Notes, but they are not obligated to do so. The underwriters may discontinue any market-making in the Notes at any time at their sole discretion. Accordingly, we cannot assure a holder that a liquid trading market will develop for the Notes, that a holder will be able to sell the Notes at a particular time or that the price received will be favorable. To the extent an active trading market does not develop, the liquidity and trading price for the Notes may be harmed. Accordingly, a holder may be required to bear the financial risk of an investment in the Notes for an indefinite period of time.

We may issue additional notes.

Under the terms of the indenture governing the Notes, we may from time to time without notice to, or the consent of, the holders of the Notes, create and issue additional notes which will be equal in rank to the Notes.

The rating for the Notes could at any time be revised downward or withdrawn entirely at the discretion of the issuing rating agency.

We have obtained a rating for the Notes. Ratings only reflect the views of the issuing rating agency or agencies and such ratings could at any time be revised downward or withdrawn entirely at the discretion of the issuing rating agency. A rating is not a recommendation to purchase, sell or hold the Notes. Ratings do not reflect market prices or suitability of a security for a particular investor and the rating of the Notes may not reflect all risks related to us and our business, or the structure or market value of the Notes. We may elect to issue other securities for which we may seek to obtain a rating in the future. If we issue other securities with ratings lower than market expectations or that are subsequently lowered or withdrawn, the market for or the market value of the Notes could be adversely affected.

We could enter into various transactions that could increase the amount of our outstanding debt, or adversely affect our capital structure or credit rating.

Subject to certain limited exceptions, the terms of the Notes do not prevent us from entering into a variety of acquisition, divestiture, refinancing, recapitalization or other highly leveraged transactions. As a result, we could enter into any such transaction even though the transaction could increase the total amount of our outstanding indebtedness, adversely affect our capital structure or credit rating or otherwise adversely affect the holders of the Notes.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Description
3.1	Certificate of Designation designating the Series B Cumulative Preferred Stock of the Company (incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K of the Company filed with the SEC on May 5, 2021).
4.1	Indenture, dated as of April 20, 2021, by and between the Company and U.S. Bank National Association, as Trustee (incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company filed with the SEC on April 20, 2021).
4.2	First Supplemental Indenture, dated as of April 20, 2021, by and between the Company and U.S. Bank National Association, as Trustee (incorporated herein by reference to Exhibit 4.2 to the Current Report on Form 8-K of the Company filed with the SEC on April 20, 2021).
4.3	Form of 8.625% Senior Note due 2026 (included in Exhibit 4.2).
10.1	Securities Purchase Agreement, dated as of May 5, 2021, by and between the Company and B. Riley Securities, Inc. (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed with the SEC on May 5, 2021).
10.2*#	License and Supply Agreement, dated as of July 25, 2021, by and between the Company and Sintetica, S.A.
10.3	First Amendment to the Harrow Health, Inc. 2017 Incentive Stock and Awards Plan (incorporated herein by reference to Appendix A to the Company's Definitive Proxy Statement filed with the SEC on April 23, 2021).
31.1*	Certification of Mark L. Baum, principal executive officer, pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes- Oxley Act of 2002.
31.2*	Certification of Andrew R. Boll, principal financial and accounting officer, pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes- Oxley Act of 2002.
32.1**	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, executed by Mark L. Baum, principal executive officer, and Andrew R. Boll, principal financial and accounting officer.
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 Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, has been formatted in Inline XBRL.

* Filed herewith.
** Furnished herewith.
# Portions of this exhibit have been omitted in compliance with Item 601 of Regulation S-K.

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, thereunto duly authorized.

Harrow Health, Inc.

Dated: August 10, 2021

By: */s/ Mark L. Baum*

Mark L. Baum
Chief Executive Officer and Director
(Principal Executive Officer)

By: */s/ Andrew R. Boll*

Andrew R. Boll
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 10.2

Portions of this exhibit indicated by bracketed asterisks have been omitted because they are not material and would likely cause competitive harm to Harrow Health, Inc. if publicly disclosed.

LICENSE AND SUPPLY AGREEMENT

This License and Supply Agreement (this "Agreement") is made effective as of the last date of signature below (the "Effective Date") by and between Sintetica S.A., a Swiss corporation having its principal place of business at Via Penate 5, 6850 Mendrisio, Switzerland, ("Sintetica"), and Harrow IP LLC, a Delaware limited liability company having its principal place of business at 102 Woodmont Blvd., Suite 610, Nashville, TN 37205 USA, ("Harrow"). Sintetica and Harrow are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

RECITALS

Whereas, Harrow is a pharmaceutical company engaged in the research, development and commercialization of products useful in the amelioration, treatment or prevention of ophthalmic diseases and conditions.

Whereas, Sintetica is a pharmaceutical company that has developed a 3% chloroprocaine gel for ophthalmic anesthesia use in 1 ml single use plastic ampoules (the "Product").

Whereas, Sintetica has completed a pivotal efficacy study for the Product, which is needed for marketing approval in the United States of America ("USA") and the Parties believe that no other studies are required to obtain marketing approval of the Product in the USA, while Harrow believes it may be worthwhile to have additional development work done to enhance the commercial appeal of the Product.

Whereas, Sintetica intends to compile NDAs (as defined below) for the Product in the Territory (as defined below).

Whereas, Sintetica's contract manufacturing partner is capable of commercially manufacturing the Product and supplying it to Harrow.

Whereas, Harrow wishes to be granted, and Sintetica is willing to grant, subject to the terms and conditions of this Agreement, an exclusive license under the Product, its formulation, and associated intellectual property in order to obtain regulatory approval and to carry out commercialization of the Product in the Territory (as defined below) for the Licensed Indication (as defined below).

Now, therefore, in consideration of the foregoing and the mutual agreements set forth below, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1.
DEFINITIONS

1.1 "Accepted" is defined in Section 6.9.

1.2 "Accounting Standards" means United States Generally Accepted Accounting Principles ("GAAP"); provided, that, to the extent that a Party adopts International Financial Reporting Standards ("IFRS"), Accounting Standards shall mean IFRS in either case, consistently applied.

1.3 "Affiliate" means, with respect to a particular Party, a Person that controls, is controlled by, or is under common control with, such Party. For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one or more other Affiliates, to direct or cause the direction of the management and policies of such entity, whether by the ownership of fifty percent (50%) or more of the voting stock of such entity, by contract, as a general partner or manager or otherwise.

1.4 "Applicable Law" means all applicable statutes, ordinances, regulations, rules, or orders of any kind whatsoever of any Governmental Authority, including the U.S. Food, Drug and Cosmetic Act, (21 U.S.C. §301 et seq.) ("FFDCA"), Public Health Service Act, (42 U.S.C. §201 et seq) ("PHSA"), Prescription Drug Marketing Act, the Generic Drug Enforcement Act of 1992 (21 U.S.C. §335a et seq.), U.S. Patent Act (35 U.S.C. §1 et seq.), Federal Civil False Claims Act (31 U.S.C. §3729 et seq.), and the Anti-Kickback Statute (42 U.S.C. §1320a-7b et seq.), GCP, GLP, and GMP, all as amended from time to time, together with any rules, regulations, and compliance guidance promulgated thereunder and including any applicable foreign equivalents of any of the foregoing.

1.5 "Applicable Transfer Price" is defined in Section 6.13(d).

1.6 "Bankruptcy Laws" is defined in Section 11.6(b).

1.7 "Breaching Party" is defined in Section 11.3.

1.8 "Business Day" means a day other than Saturday, Sunday or any other day on which commercial banks located in New York City, New York, U.S., or Mendrisio, Switzerland, are obligated by Applicable Law to close.

1.9 "Calendar Year" means the twelve (12) month period ending on December 31; provided, however, that (a) the first Calendar Year of the Term, shall begin on the Effective Date and end on December 31, 2021; and (b) the last Calendar Year of the Term shall end on the effective date of expiration or termination of this Agreement.

1.10 "Change of Control" means, with respect to a Party (an "Acquired Party"), the occurrence of any of the following events from and after the Effective Date: (a) any Person or group of Persons becomes the beneficial owner (directly or indirectly) of voting securities representing more than fifty percent (50%) of the total voting power of all of the then-outstanding voting securities of such Acquired Party; (b) the consummation of a merger, consolidation, recapitalization, or reorganization of such Acquired Party, other than any such transaction, which results in stockholders or equity holders of such Acquired Party, or an Affiliate of such Acquired Party, immediately prior to such transaction owning at least fifty percent (50%) of the outstanding securities of the surviving entity (or its parent entity) immediately following such transaction; or (c) the sale or other transfer to a Third Party of all or substantially all of such Acquired Party's assets which relate to this Agreement. Notwithstanding the foregoing, an investment transaction by venture capital or other financial investors not engaged in the pharmaceutical or biotechnology business and not otherwise affiliated with a pharmaceutical or biotechnology company, the purpose of which is to raise capital for a Party for working capital purposes only, shall not be deemed to be a Change of Control for purposes of this Agreement.

1.11 “Claim” is defined in Section 13.1.

1.12 “Clinical Trial” means any human clinical study, bioequivalence study or trial of Product in the Field in the Territory.

1.13 “Commercial Launch Plan” shall mean any good faith projections as to Harrow’s intended launch plan for Product in each country of the Territory, provided by Harrow to Sintetica in a timely manner with the purpose of facilitating Sintetica’s supply of launch quantities of Product as set forth in this Agreement, including any projected approval dates, forecasting of quantities required and timing for the supply of such quantities and other information useful for such purpose, and, including, in particular, all dates, quantities and other information to be provided by Harrow concerning Product launch, whether in forecasts, the Launch Order, or otherwise, pursuant to Sections 6.5 and 6.6(b), as may be amended from time to time, provided, however, that such amendments do not reduce the terms currently set forth in connection with forecasting and Launch Order leadtime in 6.5 and 6.6.

1.14 “Commercialize” or “Commercialization” means all activities, whether initiated or conducted prior to or following Regulatory Approval for a Product in the Field and in the Territory, undertaken in support of the promotion, marketing, sale and distribution (including importing, exporting, transporting, customs clearance, warehousing, invoicing, handling and delivering Product to customers) of the Product, including: (a) sales force efforts, detailing, advertising, marketing and preparation and use of Promotional Materials, sales and distribution, pricing, contracting managed markets and medical affairs, including activities with respect to medical education and the distribution of medical information, clinical science liaison activities, and the conduct of investigator initiated sponsored research programs and health economics and outcomes research, and (b) product security activities, including enhancing supply chain security, implementing brand protection technologies, intelligence gathering, forensic analysis, customs recordation, and anti-counterfeiting enforcement action, such as taking Internet countermeasures, collaborating with law enforcement and seeking criminal restitution. “Commercialize” means to engage in Commercialization activities.

1.15 “Commercially Reasonable Efforts” means, with respect to the efforts to be expended, or considerations to be undertaken, by a Party or its Affiliate with respect to any objective, activity or decision to be undertaken hereunder, reasonable, good faith efforts to accomplish such objective, activity or decision as used by a company in the industry of a similar size and profile as such Party to accomplish a similar objective, activity or decision, it being understood that with respect to Development and Commercialization of the Product, such efforts shall be consistent with those efforts to develop or commercialize, as the case may be, a product owned by such company or to which it has rights, which product is of similar market potential as the Product, and at a similar stage of its product life, taking into account the establishment of the product in the marketplace, the competitiveness of the marketplace, the proprietary position of the product, the regulatory status involved, and the profitability of the product, in the case of each such factor as in existence and as reasonably projected to be in existence during the Term of this Agreement, as well as other relevant factors including without limitation efficacy and patient safety, which efforts shall correspond at least to the same type (quality and quantity) of channels, methods, investments, time and staff (including, without limitation, sales force) and other resources, which are used by reputable pharmaceutical companies that are engaged in pharmaceutical business in the marketing (in the case of Harrow) or developing and licensing (in the case of Sintetica) of their own products with a similar potential in the Territory.

1.16 “Competing Product” shall mean a product that has the same active ingredient as the Product for use as an anesthetic in ophthalmology.

1.17 “Confidential Information” means, subject to the last paragraph of Section 10.3 or as further defined in Article 10, all non-public or proprietary Information disclosed by a Party to the other Party under this Agreement, which may include ideas, inventions, discoveries, concepts, compositions, formulations, formulas, practices, procedures, processes, methods, knowledge, Know-How, trade secrets, technology, inventories, machines, techniques, development, designs, drawings, computer programs, skill, experience, documents, apparatus, results, clinical and regulatory strategies, regulatory documentation, information and submissions pertaining to, or made in association with, filings with any Governmental Authority, data, including pharmacological, toxicological and clinical data, analytical and quality control data, manufacturing data and descriptions, patent and legal data, market data, financial data or descriptions, devices, assays, chemical formulations, specifications, material, product samples and other samples, physical, chemical and biological materials, and the like, without regard as to whether any of the foregoing is marked “confidential” or “proprietary,” or disclosed in oral, written, graphic, or electronic form. Confidential Information shall include: (a) the terms and conditions of this Agreement, which shall be deemed Confidential Information of both Parties; and (b) Confidential Information disclosed by either Party or its Affiliates to the other Party pursuant to the Prior Confidentiality Agreement.

1.18 “Control” or “Controlled” means, with respect to any Information, Know-How, Patent or other intellectual property right, the possession (including ownership) by a Party or its Affiliates, of the ability (without taking into account any rights granted by one Party to the other Party under the terms of this Agreement) to grant access, a license or a sublicense to such Information, Know-How, Patent or other intellectual property right without violating the terms of any agreement or other arrangement with, or necessitating the consent of, any Third Party, at such time that the Party would be first required under this Agreement to grant the other Party such access, license or sublicense. Notwithstanding the foregoing, a Party and its Affiliates will not be deemed to “Control” any Information, Know-How, Patent or other intellectual property right that, prior to the consummation of a Change of Control of such Party, is owned or in-licensed by a Third Party that becomes an Affiliate of such Acquired Party after the Effective Date as a result of such Change of Control unless (a) prior to the consummation of such Change of Control, such Acquired Party or any of its Affiliates also Controlled such Information, Know-How, Patent or other intellectual property right, or (b) the Information, Know-How, Patent or other intellectual property right owned or in-licensed by such Third Party were not used in the performance of activities under this Agreement prior to the consummation of such Change of Control, but after the consummation of such Change of Control, the Acquired Party or any of its Affiliates determines to use or uses any such Information, Know-How, Patent or other intellectual property right in the performance of its obligations or exercise of its rights under this Agreement, in each of which cases ((a) and (b)), such Information, Know-How, Patent or other intellectual property right will be “Controlled” by such Party for purposes of this Agreement.

1.19 “CRL” is defined in Section 7.1.

1.20 “Cure Period” is defined in Section 11.3.

1.21 “Delivery Date” is defined in Section 6.6(a).

1.22 “Development” means all research, non-clinical and clinical drug development activities, including toxicology, pharmacology, and other non-clinical efforts, statistical analysis, formulation development, delivery system development, statistical analysis, the performance of Clinical Trials, or other activities reasonably necessary in order to obtain Regulatory Approval of Product in the Field in the Territory. “Development” shall exclude all Commercialization activities and Regulatory Activities. When used as a verb, “Develop” means to engage in Development activities.

1.23 “Disclosing Party” is defined in Section 10.1.

1.24 “Dispute” is defined in Section 12.2.

1.25 “Excessive Amount” is defined in Section 6.6(d).

1.26 “Exploit” or “Exploitation” means to Develop, distribute, import, export, use, have used, sell, have sold, or offer for sale, including to Commercialize, register, modify, enhance, improve, or otherwise dispose of or perform Regulatory Activities. When referring to Product, “Exploit” or “Exploitation” means to carry out any such activities in relation to Product used in the Field in the Territory.

1.27 “FDA” means the U.S. Food and Drug Administration, or any successor agency thereto.

1.28 “FFDCA” means the Federal Food, Drug and Cosmetic Act under United States Code, Title 21, as amended.

1.29 “Field” means ophthalmic uses.

1.30 “Firm Orders” is defined in Section 6.6(a).

1.31 “Firm Period” is defined in Section 6.5

1.32 “Force Majeure” means any event beyond the reasonable control of the affected Party including embargoes; war or acts of war, including terrorism, insurrections, riots, or civil unrest; strikes, lockouts or other labor disturbances; epidemics, pandemics, the spread of infectious diseases, and quarantines; fire, floods, earthquakes, tsunami or other acts of nature; or acts, omissions or delays in acting by any Governmental Authority (including the refusal of the competent Governmental Authorities to issue required Regulatory Approvals due to reasons other than the affected Party’s or its Affiliate’s negligence or willful misconduct or breach of any term or condition of this Agreement or any other cause within the reasonable control of the affected Party or its Affiliates, hereafter referred to a “Force Majeure Non-Approval”) and failure of plant or machinery (provided, that, such event or failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). For clarification, any refusal of the competent Governmental Authorities to issue required Regulatory Approvals due to reasons relating solely to the development activities carried out by or for Harrow as contemplated in Section 3.2 shall not be considered a case of Force Majeure, and hence not be case of a Force Majeure Non-Approval.

1.33 “Good Clinical Practices”, “GCP” or “cGCP” means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in the guidelines adopted by the International Conference on Harmonization (“ICH”), titled “Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance,” (or any successor document) including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices any other Regulatory Authority applicable to the Territory, as they may be updated from time to time.

1.34 “Good Laboratory Practices”, “GLP”, or “cGLP” means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in 21 C.F.R. Part 58 (or any successor statute or regulation), including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by any other Regulatory Authority applicable to the Territory, as they may be updated from time to time, including applicable guidelines promulgated under the ICH.

1.35 “Good Manufacturing Practices”, “GMP”, or “cGMP” means the then-current good manufacturing practices required by the FDA, as set forth in the FFDCA, as amended, and the regulations promulgated thereunder, for the manufacture and testing of pharmaceutical materials, and comparable Applicable Law related to the manufacture and testing of pharmaceutical materials in jurisdictions outside the USA and the regulations promulgated thereunder, in each case as they may be updated from time to time.

1.36 “Governmental Authority” means any multi-national, federal, state, local, municipal or other government authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.37 “Gross Margin” shall mean the Selling Price less the sum of the Royalty in Section 7.4 and the Applicable Transfer Price of the Product divided by the Selling Price.

1.38 “Harrow Indemnitee” is defined in Section 13.2.

1.39 “Harrow Invention” means any Invention that is made solely by Harrow’s own employees, agents, or independent contractors involving or used in the Exploitation of Product, together with all intellectual property rights therein.

1.40 “Harrow Know-How” means all Know-How Controlled by Harrow during the Term that is necessary or useful to Exploit Product . Harrow Know-How includes all Harrow Inventions but excludes any Information contained within a Harrow Patent.

1.41 “Harrow Patents” means all Patents Controlled by Harrow during the Term that are necessary or useful to Exploit Product. As of the Effective Date there are no existing Harrow Patents.

1.42 “Harrow Studies” are defined in Section 3.2.

1.43 “Harrow Technology” means all Harrow Know-How and Harrow Patents.

1.44 “Indemnitee” is defined in Section 13.3(a).

1.45 “Indemnifying Party” is defined in Section 13.3(a).

1.46 “Indication” means a human or animal disease or medical condition which is approved by a Regulatory Authority to be included as a discrete claim (as opposed to a subset of a claim) in the Labeling of a Product based on the results of a separate Clinical Trial sufficient to support Regulatory Approval of such claim.

1.47 “Information” means information, inventions, patent claims, discoveries, compositions, formulations, formulas, practices, procedures, processes, methods, knowledge, know-how, trade secrets, technology, techniques, designs, drawings, correspondence, computer programs, documents, apparatus, results, strategies, regulatory documentation, information and submissions pertaining to, or made in association with, filings with any Governmental Authority or patent office, data, including pharmacological, toxicological, non-clinical and clinical data, analytical and quality control data, manufacturing data and descriptions, market data, financial data or descriptions, devices, assays, chemical formulations, specifications, material, product samples and other samples, physical, chemical and biological materials, and the like, in written, electronic, oral or other tangible or intangible form, now known or hereafter developed, whether or not patentable.

1.48 “Initial Term” is defined in Section 11.1.

1.49 “Inventions” means any and all inventions, discoveries and developments, whether or not patentable, involving or used in the Exploitation of Product, whether made, conceived or reduced to practice solely by, or on behalf of, Sintetica, Harrow or the Parties jointly.

1.50 “Joint Inventions” is defined in Section 8.1(c).

1.51 “Joint Know-How” means all Information and Inventions jointly Controlled by Sintetica and Harrow during the Term that is/are necessary or useful to Exploit the Product. Joint Know-How excludes any Information contained within a Joint Patent.

1.52 “Joint Patents” means all Patents jointly Controlled by Sintetica and Harrow during the Term that are necessary or useful to Exploit the Product. As of the Effective Date there are no existing Joint Patents in the Territory.

1.53 “Joint Technology” means, collectively, all Joint Know-How and Joint Patents.

1.54 “Know-How” means, with respect to a Party, all Information and Inventions Controlled by such Party. Know-How excludes any Information contained within a Party’s Patents.

1.55 “Labeling” means the healthcare professional information or patient information that is part of a Product’s Regulatory Approval Application or Regulatory Approval, including the package insert, medication guides, summary of product characteristics, patient information leaflets, company core safety information and company core data sheet.

1.56 “Launch Order” is defined in Section 6.6(a).

1.57 “LCAI” is defined in Section 12.2.

1.58 “Licensed Indication” means: any Indication for (a) topical ophthalmic anesthesia; or for (b) any other ophthalmic use.

1.59 “Losses” is defined in Section 13.1.

1.60 “Manufacture” means all activities related to the manufacturing the Product including any bulk, semi-finished or finished forms thereof, or any ingredient or material thereof, for Development, Commercialization and Regulatory Activities, including the production, manufacture, processing, filling, finishing, and holding of Product and any intermediate thereof, labeling, packaging, Product testing, release of Product or any ingredient thereof, quality assurance activities related to isolation and manufacturing and release of Product, and any stability tests and regulatory activities related to any of the foregoing. When used as a verb, “Manufacture” means to engage in such manufacturing activities.

1.61 “Material Delivery Delay” is defined in Section 6.11(c).

1.62 “Minimum Annual Quantities” or “MAQs” is defined as in Section 6.15.

1.63 “MOQ” means the minimum quantity of Product to be set out in any purchase order of Product, as is further described in Section 6.6(f).

1.64 “NDA” means a New Drug Application or supplemental New Drug Application as contemplated by Section 505(b) of the FFDCA, as amended, and the regulations promulgated thereunder, submitted to the FDA pursuant to Part 314 of Title 21 of the U.S. C.F.R., including any amendments thereto. References herein to NDA shall include, to the extent applicable, any comparable applications filed in countries in the Territory outside the U.S.

1.65 “Net Sales” means, with respect to any Product, the gross amounts invoiced or received by Harrow, its Affiliates and its respective sublicensees for sales of such Product to unaffiliated Third Parties, less the following deductions, to the extent reasonable and customary, provided to unaffiliated entities and actually allowed and taken with respect to such sales:

(a) customary cash, trade or quantity discounts, charge-back payments, and rebates actually granted to trade customers, managed health care organizations, pharmaceutical benefit managers, group purchasing organizations and national, state, or local government;

(b) credits, rebates or allowances actually allowed upon prompt payment or on account of claims, damaged goods, rejections or returns of such Product, including in connection with recalls, and the actual amount of any retroactive price reductions;

(c) packaging, freight, postage, shipping, transportation, warehousing, handling and insurance charges, in each case actually allowed or paid for delivery of such Product, and any customary payments with respect to the Product actually made to wholesalers or other distributors, in each case actually allowed or paid for distribution and delivery of Product, to the extent billed or recognized;

(d) taxes (other than income taxes), duties, tariffs, mandated contribution or other governmental charges levied on the sale of such Product, including VAT, excise taxes, sales taxes and that portion of the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended), that Harrow, its Affiliates or (sub)licensees, as applicable, allocate to sales of such Product in accordance with Harrow's, its Affiliates' or (sub)licensees' standard policies and procedures consistently applied across its products, as applicable; and

(e) any sales, credits or allowances given or made with respect to Product for indigent patient, Clinical Trial and any unpaid compassionate or named patient, charitable or humanitarian programs.

Notwithstanding the foregoing, dispositions of any Product by Harrow to its Affiliates or by Harrow or its Affiliates to its respective sublicensees, in each case, for resale shall not be considered to be a sale for purposes of the definition of Net Sales hereunder unless such Affiliate end customer or sublicensee end customer is the last Person in the distribution chain of the Product. In any event, any amounts received or invoiced by Harrow, its Affiliates, or its sublicensees shall be accounted for only once. For purposes of determining Net Sales, a Product shall be deemed to be sold when recorded as a sale by Harrow, its Affiliates or its respective sublicensees in accordance with the applicable Accounting Standards. For clarity, a particular deduction may only be accounted for once in the calculation of Net Sales. Net Sales shall exclude any samples of Product transferred or disposed of at no expense for promotional or educational purposes. For the avoidance of doubt, and for all purposes under this Agreement, Net Sales shall be accounted for in accordance with standard accounting practices, as practiced by Harrow its Affiliates or its respective sublicensees in the relevant country in the Territory, but in any event in accordance with the applicable Accounting Standards, as consistently applied in such country in the Territory.

1.66 "Non-Breaching Party" is defined in Section 11.2.

1.67 "Patents" means all: (a) patents, including any utility or design patent; (b) patent applications, including provisionals, substitutions, divisionals, continuations, continuations in-part or renewals; (c) patents of addition, restorations, extensions, supplementary protection certificates, registration or confirmation patents, patents resulting from post-grant proceedings, re-issues and re-examinations; (d) other patents or patent applications claiming priority directly or indirectly to: (i) any such specified patent or patent application specified in (a) through (c), or (ii) any patent or patent application from which a patent or patent application specified in (a) through (c) claim direct or indirect priority; (e) inventor's certificates; (f) other rights issued from a Governmental Authority similar to any of the foregoing specified in (a) through (e); ***provided that*** in each of (a) through (f), such patent, patent application or other right shall be deemed a "Patent" solely if and to the extent that it is granted, arises and/or is enforceable in the U.S. or any other jurisdiction in the Territory.

1.68 “Patent Term Extension” means any term extensions, supplementary protection certificates and equivalents thereof offering patent protection beyond the initial term with respect to any issued Patents.

1.69 “Payments” is defined in Section 7.3(a).

1.70 “PDUFA” means the USA Prescription Drug User Fee Act of 1992, as reauthorized and renewed every five years.

1.71 “Person” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government.

1.72 “Pricing Approval” means any approval, agreement, determination or decision by a Governmental Authority establishing prices that can be charged and/or reimbursed for a Product in a jurisdiction where the applicable Governmental Authority or Regulatory Authority approves or determines the pricing of pharmaceutical products.

1.73 “Prior Confidentiality Agreement” means that certain Confidentiality Agreement between the Sintetica and Harrow, dated January 17th, 2020.

1.74 “Product” is defined in the preamble of this Agreement, including all modifications to the current Product formulation made by Sintetica for Exploitation in the Field in the Territory.

1.75 “Product Complaint” means any Information that comes to the attention of either Party, its Affiliates or its sublicensees, concerning any dissatisfaction regarding a Product of such a nature and magnitude that it is required under the Applicable Law to be collected, maintained and reported to a Regulatory Authority, including reports of actual or suspected product tampering, contamination, mislabeling or inclusion of improper ingredients.

1.76 “Product Labelling and Packaging” is defined in Section 6.1(a).

1.77 “Product Liabilities” means all losses, damages, fees, expenses and other liabilities asserted by any Third Parties against a Party and resulting from or relating to human use of Product, including use in Clinical Trials or Commercialization of the Product or Regulatory Activities, in the Territory during the Term, but excluding all losses, damages, fees, expenses and other liabilities that are a result of a Party’s, its Affiliates’ or its sublicensee’s gross negligence, willful misconduct or breach of such Party’s obligations under this Agreement, including its representations and warranties made hereunder. For the avoidance of doubt, Product Liabilities include reasonable attorneys’ and experts’ fees and expenses relating to any claim or potential claim against a Party, its Affiliate, or its sublicensee. Product Liabilities shall not include any losses, damages, fees, expenses and other liabilities associated with recalls and/or the voluntary or involuntary withdrawal of Product.

1.78 “Promotional Materials” means all written, printed, graphic, electronic, audio or video presentations of information, including journal advertisements, sales visual aids, formulary binders, reprints, direct mail, direct-to-consumer advertising, disease awareness materials, internet postings, broadcast advertisements and sales reminder aides (for example, note pads, pens and other such items, if appropriate) that, in each case, are permitted under Applicable Law, and intended for use or used by or on behalf of Harrow , its Affiliates or its sublicensees in connection with the Commercialization of a Product in the Territory.

1.79 “Purchase Order Confirmations” is defined in Section 6.6(a).

1.80 “Quality Agreement” is defined in Section 6.3(f).

1.81 “Receiving Party” is defined in Section 10.1.

1.82 “Recovery Plan” is defined in Section 6.11(c),

1.83 “Regulatory Activities” means all activities, other than Development and Commercialization activities, that are reasonably necessary in order to obtain and maintain Regulatory Approval of Product in the Field in the Territory, including but not limited to (a) the preparation, filing, and maintenance of Regulatory Materials, including the filing of annual updates, and (b) the conduct of post-marketing Studies.

1.84 “Regulatory Approval” means any approval (including supplement, amendment, pre- and post-approval), Pricing Approvals and reimbursement approvals, licenses, registrations or authorizations of any national, regional, state or local Regulatory Authority, department, bureau, commission, council or other Government Authority, that is necessary for the Commercialization of Product under this Agreement in a particular country in the Territory. “Regulatory Approval of an NDA” means a Regulatory Approval of an NDA when all other Regulatory Approvals necessary for Commercialization of Product in the Territory under such approved NDA have also been obtained.

1.85 “Regulatory Approval Application” means an NDA or any corresponding application for Regulatory Approval in the Territory, including, in each case, all supplements, amendments, variations, extensions and renewals thereof.

1.86 “Regulatory Authority” means any applicable Governmental Authority that holds responsibility for granting of Regulatory Approval for development and commercialization of the Product in a country or jurisdiction in the Territory, including in the U.S., the FDA; and in Canada, Health Canada.

1.87 “Regulatory Documentation” means, with respect to Product, all (a) Regulatory Materials, including all data contained therein and all supporting documents created for, submitted to or received from an applicable governmental agency or Regulatory Authority relating to such Regulatory Materials; and (b) other documentation or Information Controlled by a Party which is reasonably necessary in order to Exploit the Product in the Field in the Territory, including any registrations and licenses, regulatory drug lists, advertising and promotion documents shared with Regulatory Authorities, adverse event files, complaint files and Manufacturing records.

1.88 “Regulatory Materials” means, all documentation, correspondence, submissions and notifications submitted to or received from a Regulatory Authority in order to Exploit a Product in the Field in the Territory. For the avoidance of doubt, Regulatory Materials shall include, with respect to Product, all INDs, Regulatory Approval Applications, Regulatory Approvals (including Pricing Approvals), and amendments and supplements for any of the foregoing, as well as the contents of any minutes from meetings (whether in person or by audio conference or videoconference) with a Regulatory Authority.

1.89 “Renewal Term” is defined in Section 11.1.

1.90 “Rolling Forecast” is defined in Section 6.5.

1.91 “Royalty” or “Royalties” shall mean any of the Royalty payments set forth and described in Section 7.4.

1.92 “Safety Data Exchange Agreement” or “SDEA” means written contracts to define the responsibilities of each party with reference to each pharmacovigilance activity, with the aim of ensuring regulatory compliance and preventing duplication of pharmacovigilance activities by the different parties.

1.93 “Selling Price” shall be the invoice price at which Harrow sells the Product to any Third Party.

1.94 “Sintetica Indemnitee” is defined in Section 13.1.

1.95 “Sintetica Invention” means any Invention that is made solely by Sintetica’s own employees, agents, or independent contractors involving or used in the Exploitation of the Product, together with all intellectual property rights therein.

1.96 “Sintetica Know-How” means all Know-How Controlled by Sintetica during the Term, which is necessary or useful to Exploit Product. Sintetica Know-How includes all Sintetica Inventions but excludes any Information contained within a Sintetica Patent.

1.97 “Sintetica Patents” means all Patents Controlled by Sintetica during the Term that are necessary or useful to Exploit Product. As of the Effective Date the Sintetica Patents are set forth in Schedule 1.97.

1.98 “Sintetica Technology” means, collectively, all Sintetica Know-How and Sintetica Patents.

1.99 “Supply Failure” is defined in Section 6.11(b).

1.100 “Term” is defined in Section 11.1.

1.101 “Territory” means the United States of America and Canada, including their territories and possessions.

1.102 “Third Party” means a Person other than Sintetica and Harrow and their respective Affiliates.

1.103 “Third-Party Manufacturer” or “TPM” is defined in Section 6.3(a).

1.104 “Trademark” means Sintetica’s AMPRES trademark, if registered in the Territory, or, if mutually agreed to by the Parties, any other trademark for the Product registered by Sintetica in the Territory after the Effective Date .

1.105 “Transfer Price” is defined in Section 6.13(a).

ARTICLE 2.
LICENSES

2.1 License from Sintetica to Harrow. Subject to the terms and conditions of this Agreement, Sintetica hereby grants to Harrow, including its Affiliates, for the Term an exclusive (even as to Sintetica) license, solely in the Field and in the Territory, and with the right to grant sublicenses in accordance with Section 2.2, to develop, promote, market, sell and distribute the Product for the Licensed Indication within the Territory. For the avoidance of doubt, the Manufacture of Licensed Product is not included within the scope of the license as Sintetica’s contract manufacturing partner shall be responsible for manufacturing Product for supply to Harrow. The license grant in this Section 2.1 expressly includes: (i) a license of all Sintetica Technology; and (ii) a license of all of Sintetica’s rights in Joint Technology.

2.2 Sublicenses.

(a) Subject to the terms and conditions of this Agreement, Harrow shall have the right to grant sublicenses to sublicensees, through multiple tiers, under the rights granted by Sintetica to Harrow under Section 2.1 to one or more Third Parties.

(b) Each sublicense shall refer to and be subordinate to this Agreement and, except to the extent the Parties otherwise agree in writing, any such sublicense must be consistent in all material respects with the terms and conditions of this Agreement. Harrow shall remain responsible for the performance of this Agreement through any sublicensee and any violation of any sublicense granted by Harrow under this Section.

(c) Upon an early termination of Harrow’s license rights under this Agreement, Harrow shall identify to Sintetica Third Party sublicensees having received a sublicense granted by Harrow or its Affiliates pursuant to this Section 2.2, and Sintetica shall be free to contact and enter into agreements with any such sublicensees. If Sintetica so requests at such time, Harrow agrees to assign its sublicense agreement(s) to Sintetica, without any consideration, effective as of the termination date of this Agreement.

2.3 License from Harrow to Sintetica. Subject to the terms and conditions of this Agreement, Harrow hereby grants to Sintetica and its Affiliates for the Term a non-exclusive license, and with the right to grant sublicenses to sublicensees, solely in the Field and in the Territory to enable Sintetica to perform its obligations and exercise its rights under this Agreement. The license grant in this Section 2.3 expressly includes: (i) a license of all Harrow Technology; and (ii) a license of all of Harrow’s rights in Joint Technology. Sintetica shall remain responsible for the performance of this Agreement through any sublicensee and any violation of any sublicense granted by Sintetica under this Section.

2.4 No Implied Licenses. No license or other right is or shall be created or granted hereunder by implication, estoppel, or otherwise. All licenses and rights are or shall be granted only as expressly provided in this Agreement. All rights not expressly granted by a Party under this Agreement are reserved by the Party and may not be used by the other Party for any purpose.

ARTICLE 3.
DEVELOPMENT

3.1 Sintetica Development. Sintetica shall be responsible for developing the Product suitable for submission in an NDA. The Product will demonstrate clinical non-inferiority (or better) efficacy and safety data as compared to Tetracaine 0.5% and Akten® (lidocaine hydrochloride 3.5%) ophthalmic gel.

3.2 Harrow Development. Notwithstanding Section 3.1, Harrow shall have the unilateral right, at its sole discretion, to demand the delay of the filing of the NDA of the Product for up to thirty (30) months in order to invest in additional product development, including clinical and non-clinical studies, chemistry, manufacturing and control optimization, and the like associated with the Product (the "Harrow Studies"). Sintetica will provide insight and counsel to Harrow regarding the Product and the Harrow Studies, but Harrow will have the final decision authority on whether to initiate Harrow Studies. The actual costs to complete the Harrow Studies will be paid for by Harrow; provided, however, Harrow will be allowed to recover on a dollar for dollar basis up to **** of such costs as a credit against future royalties owed to Sintetica pursuant to Section 7.4. In consideration for receiving such credit, Harrow hereby grants Sintetica an irrevocable, royalty-free license to use any results of the Harrow Studies in any Product registration dossiers, regulatory activities and regulatory approval applications outside of the Territory and for Product marketed, distributed and/or sold by or for Sintetica outside of the Territory.

3.3 Disclosure of Sintetica Know-How. Promptly following the Effective Date, and promptly during the Term upon such Sintetica Know-How being obtained or generated by Sintetica, Sintetica shall provide to Harrow, at no additional expense any Sintetica Know-How as is necessary to enable Harrow to conduct Development activities, Commercialization activities and Regulatory Activities under this Agreement or otherwise to practice the license granted to it under this Agreement, to the extent such Sintetica Know-How has not previously been provided to Harrow.

3.4 Records; Disclosure of Data and Results. In conformity with Applicable Law, standard pharmaceutical industry practices and the terms and conditions of this Agreement, each Party shall prepare and maintain, or shall cause to be prepared and maintained, complete and accurate written records, accounts, notes, reports and data with respect to Development activities conducted pursuant to this Agreement; provided, that, in no instance shall such records be maintained for less than two (2) years following the end of the Calendar Year to which the records pertain.

ARTICLE 4.
REGULATORY

4.1 NDA Preparation. Sintetica will be responsible for the activities required for the preparation and compilation of the NDA for the Product for submission to the FDA and Health Canada, respectively, at its own expense. As time is of the essence for submission of the NDA in the USA, and in Canada subsequently thereafter, subject to Section 3.2, Sintetica shall promptly complete the compilation and submission under Section 4.2 below for the US submission and Harrow shall provide oversight and collaborate in a timely manner for said submission.

4.2 NDA Submission and Transfer of Ownership. For each country in the Territory Sintetica will transfer ownership of the NDA for the Product to Harrow upon its approval by the competent Regulatory Authority (i.e., FDA for the United States and Health Canada for Canada), with Harrow owning registration rights to the NDA. Sintetica will be responsible for payment of the NDA filing fees (i.e., the PDUFA fee for FDA). Harrow will be responsible for payment of any comparable and necessary filing fees for the NDA submitted to Health Canada (whether it is called a New Drug Submission (NDS), an Abbreviated New Drug Submission (ANDS) or otherwise) and including for establishment licensing.

4.3 NDA Review and Approval Process. Sintetica, or Sintetica's designee, shall oversee and manage the NDA approval process at FDA and/or Health Canada and shall be responsible for managing all communications with FDA and/or Health Canada during the NDA approval process. Notwithstanding the above, Sintetica, or its NDA agent designee, shall actively and reasonably keep Harrow informed of any regulatory filings and communications from FDA or Health Canada that would put the NDA at risk or otherwise delay approval of the NDA, and shall consult with Harrow prior to submission of any responses to such communications, who shall provide feedback to Sintetica in a timely manner to avoid any delay in the Regulatory Authority review process. Should any additional fees in addition to those in Section 4.2 be assessed as part of the NDA review and approval process, Sintetica will inform Harrow and shall be responsible for payment of all such fees, with Harrow promptly reimbursing Sintetica for all mutually agreed upon amounts relative thereto. After transfer of Regulatory Approval of each respective NDA, Harrow shall be responsible for all communications with each respective Regulatory Authority and for all fees and costs relative to NDAs and their maintenance, including but not limited to yearly PDUFA Program fee costs, and relative to any post-approval changes (including but not limited to cost and fees regarding Annual Reports, CBE-0, CBE-30, PAS, and addition of foreign sites) submitted to the Regulatory Authorities), and including but not limited to annual fees to Health Canada.

4.4 Regulatory Authority Communications Received by a Party. Prior to Regulatory Approval of an NDA, each Party shall keep the other Party informed in a timely manner, compliant with the reporting requirements of Regulatory Authorities in the Territory, of the notification of any action by, or notification or other information which it receives (directly or indirectly) from any regulatory authority which, in relation to such NDA: (a) relates to the potential approvability of the Product; or (b) raises any material concerns regarding the safety or efficacy of a Product; or (c) which may have a material impact on obtaining Regulatory Approvals. Following Regulatory Approval of an NDA, each Party shall keep the other Party informed in a timely manner, compliant with the reporting requirements of Regulatory Authorities in the Territory, of the notification of any action by, or notification or other information which it receives (directly or indirectly) from any regulatory authority which, in relation to such NDA: (a) indicates or suggests a potential material liability of Harrow to Third Parties in connection with a Product; (b) is reasonably likely to lead to a recall or market withdrawal of a Product; or (c) relates to expedited and periodic reports of adverse events with respect to a Product, or Product Complaints, and which may have a material impact on maintaining Regulatory Approvals or the continued Commercialization of a Product, as then conducted. Once an NDA has been transferred to Harrow, Harrow shall provide to Sintetica copies of all correspondence to or from the FDA or Health Canada, as appropriate, relating to the Product, including without limitation to any post-approval changes (Annual Reports, CBE-0, CBE-30, PAS or similar filings) submitted to the FDA or Health Canada. In particular, all the documentation generated after the approval of the NDA should be shared with Sintetica (e.g., any eCTD sequences filed to FDA), to ensure Sintetica has availability of the complete dossier. Harrow shall fully cooperate with and assist Sintetica in complying with regulatory obligations and communications, including by providing to Sintetica, in a timely manner after a request, such Information and documentation in Harrow's possession as may be necessary or helpful for Sintetica to prepare a response to an inquiry from a Regulatory Authority.

4.5 Adverse Event Reporting and Safety Data Exchange. During the Term, Harrow shall have the sole responsibility for the monitoring of all clinical experiences, safety monitoring and pharmacovigilance surveillance in the Territory, compliance and filing of all required safety reports to Regulatory Authorities in the Territory, including annual safety reports, throughout the Development and Commercialization of the Product. A dedicated Safety Data Exchange Agreement (SDEA) will be prepared and discussed with Harrow.

4.6 Audits. If a Regulatory Authority notifies a Party that it plans to conduct an inspection or audit of its facility or a facility under contract with it with regard to a Product in the Territory, then such Party shall notify the other Party as soon as practicably possible after receipt of such notification of such audit or inspection and provide copies of any materials provided to it by the applicable Regulatory Authority; provided, that either Party shall not be required to notify the other Party of audits or inspections that are of a routine nature or that do not relate to a Product, except where such audits result in communications or actions of such Regulatory Authority which would reasonably be expected to have an impact upon the Product. In addition, if a Regulatory Authority conducts an unannounced inspection or audit of Harrow's facility or a facility under contract with Harrow with regard to a Product in the Territory, then Harrow shall notify Sintetica within twenty-four (24) hours of commencement of such audit or inspection. Harrow shall cooperate with such Regulatory Authority and Sintetica during such inspection or audit. Following receipt of the inspection or audit observations of such Regulatory Authority (a copy of which the Harrow shall promptly provide to Sintetica), Harrow shall also provide Sintetica with copies of any written communications received from Regulatory Authorities with respect to such facilities in a timely manner after receipt, to the extent such written communications relate to Product or the Manufacture thereof, and shall assist Sintetica in preparing the response to any such observations, as requested. Harrow agrees to conform its activities under this Agreement to any commitments made in such a response.

4.7 Confidentiality of Regulatory Materials. All Regulatory Materials prepared by Harrow shall be deemed Harrow Confidential Information and subject to Article 10 of this Agreement.

ARTICLE 5.
COMMERCIALIZATION

5.1 Commercialization Activities. Subject to the terms and conditions of this Agreement, Harrow shall be solely responsible for all aspects of the Commercialization of Product in the Field in the Territory, including: (i) developing and executing a commercial launch and pre-launch plan, (ii) marketing and promotion; (iii) booking sales and distribution and performance of related services, including those described in Section 5.1(a); (iv) handling all aspects of order processing, invoicing and collection, inventory and receivables; (v) publications, (vi) providing customer support, including handling medical queries, and performing other related functions; (vii) conforming its practices and procedures in all respects to the Applicable Law relating to the marketing, detailing and promotion of Product in the Field in the Territory; and (viii) product security activities. Harrow shall be solely responsible for the review and approval of all Promotional Materials for compliance with Applicable Law, including providing to the NDA agent for submission, where appropriate, to the applicable Regulatory Authority. Except as otherwise provided in this Article 5, Harrow shall bear all of the expenses incurred in connection with all such Commercialization activities.

(a) **Sales and Distribution**. Harrow shall have the sole right and responsibility for handling all sales and distribution activities, including returns, order processing, invoicing and collection, distribution (including importing, exporting, transporting, customs clearance, warehousing, invoicing, handling and delivering Product to customers), and inventory and receivables for Product in the Field in the Territory. Sintetica shall not accept orders for the purchase of Product from Third Parties, or make sales of Product to Third Parties in the Field in the Territory for its own account or for Harrow's account. If Sintetica receives any order for Product in the Field in the Territory, it shall refer such order to Harrow for acceptance or rejection.

(b) **Booking Sales and Setting Pricing.** Harrow shall have the sole and exclusive right to book sales and determine all pricing of Product in the Territory, including (i) negotiating, establishing or modifying the terms and conditions regarding the sale of Product in the Field in the Territory, including any terms and conditions relating to or affecting (A) the price at which Product shall be sold, (B) discounts available to any Third Party payers (including managed care providers, indemnity plans, unions, self-insured entities, and government payer, insurance or contracting programs such as Medicare, Medicaid, or the U.S. Department of Veterans Affairs, or similar programs located in other countries of the Territory), (C) discounts attributable to payments on receivables, (D) distribution of Product, and (E) credits, price adjustments, or other discounts and allowances to be granted or refused; and (2) all activities relating to government price reporting with respect to Product in the Field in the Territory. Notwithstanding anything in this Agreement express or implied to the contrary, Sintetica shall not have any right to direct, control, or approve Harrow's pricing of Product for the Territory.

5.2 Trademarks. Except for the Trademark, Harrow shall be solely responsible, at its own expense, for all matters relating to the use of, and shall own, all other trademarks, including all associated goodwill, used in the sale of Product in the Field in the Territory, including the selection, filing, prosecution, maintenance, defense and enforcement thereof. Notwithstanding the above, at Harrow's request, Sintetica shall grant a license to Harrow to use the Trademark, along with all associated goodwill, on an exclusive (even as to Sintetica) and royalty-free basis for use as the brand name of the Product in the Territory. Harrow agrees to use the Trademark consistent with guidelines that shall be provided by Sintetica. Sintetica shall be solely responsible, at its own expense, for the Trademark, including the prosecution, maintenance, defense and enforcement thereof.

5.3 Commercialization Diligence. Harrow shall use Commercially Reasonable Efforts to Commercialize the Product for the Licensed Indication for which Harrow receives Regulatory Approval in the Territory. Notwithstanding the preceding sentence, Harrow shall not be obligated to launch the Product (a) in the event that Sintetica has not supplied to Harrow the amount of Product Harrow has ordered for such launch, *provided that* such Harrow shall not be released from such obligation if (i) it has not provided to Sintetica in a timely manner the appropriate information for such launch in the Commercial Launch Plan Sintetica or (ii) it has not issued the Launch Order in accordance with the applicable provisions of this Agreement, or, (b) in the event that in the opinion of Harrow's external patent counsel, launching the product would involve an unnecessary commercial patent infringement risk to Harrow. Harrow shall promptly notify Sintetica when Harrow has received such opinion.

ARTICLE 6.
MANUFACTURING AND SUPPLY

6.1 Product Labeling and Packaging.

(a) Packaging artworks will be designed by Sintetica, consistent with any input received from Harrow. In accordance with Section 5.2, any proprietary trademark and/or brand name and design artwork to be used shall be selected by Harrow and agreed to by Sintetica, such agreement not to be unreasonably withheld, conditioned or delayed. Sintetica shall design or have the TPM design an industrial application of the packaging, the containers, the labels, the user instructions, warning notices, master shipper, and pallet layout for Product ("Product Labelling and Packaging"), as per FDA approved text, transportation regulations within Applicable Laws, and shall have no liability for the design artwork on any Product Labelling and Packaging approved by Harrow. Sintetica shall be solely responsible for, at its cost and expense, to ensure that the requirements to serialize the Product are met in accordance with Applicable Law. Any deviations or specific request from Harrow that differs from Sintetica's standard protocols shall be evaluated and agreed upon by the parties prior to implementation. Prior to the TPM's commencing the first production of any Product Labeling and Packaging, Sintetica shall submit the intended Product Labelling and Packaging to Harrow for its review for accuracy and approval. Only upon Harrow's approval, which shall not be unreasonably withheld or delayed and which shall not be in contrast with Applicable Law, shall Sintetica cause the TPM to proceed to print the Product Labelling and Packaging. Sintetica shall be responsible or liable towards Harrow for the final content of the Product Labelling and Packaging not conforming to the approved Product Labeling and Packaging.

(b) After Harrow approves the Product Labelling and Packaging as set forth in Section 6.1(a), all Product supplied by Sintetica shall be in finished dosage form and fully packaged and ready for Commercialization by Harrow in the Territory.

(c) Harrow shall distribute the Product exclusively with the Product Labelling and Packaging in which it is supplied to Harrow by Sintetica. For avoidance of doubt, Harrow shall not modify the Product Labelling and Packaging in any way when handling, storing, distributing or otherwise Commercializing the Product in the Territory.

(d) Subsequent to its approval, any modification of the Product Labelling and Packaging shall require prior written approval by both Parties and must comply with all Applicable Laws in the relative country of the Territory.

6.2 Supply of Product.

(a) Sintetica shall be the exclusive supplier of the Product to Harrow for Harrow's Development, Commercialization and Regulatory Activities in the Territory, and Harrow shall exclusively purchase from Sintetica the Product and Commercialize the Product in the Territory, except as otherwise expressly provided in this Agreement.

(b) Sintetica shall use Commercially Reasonable Efforts to supply on a timely basis one hundred percent (100%) of Harrow's requirements for each Product for commercialization in the Territory, subject to the terms and conditions set forth in Sections 6.5 and 6.6 of this Agreement.

(c) Sintetica shall use Commercially Reasonable Efforts to have produced and to supply Harrow with Product with an expiration date that is such that, on the date Product is delivered to Harrow, it has at least seventy-five percent (75%) of the shelf-life for the applicable Product.

(d) Sintetica shall supply the Product to Harrow in accordance with the terms and conditions of this Agreement, the Quality Agreement, the relevant NDAs and Applicable Law. Sintetica shall deliver to Harrow, together with each delivery of each batch of Product, the corresponding certificate of analysis relating to such batch and certification that all Product in such batch was manufactured in accordance with GMP, the Quality Agreement and any Applicable Law in the country of Manufacture. The certificate of analysis shall include the actual result of the testing performed by, or on behalf of, Sintetica on such batch.

6.3 Manufacture of Product

(a) Third Party Manufacturers. Without limiting Sintetica's responsibility under this Agreement, Sintetica shall have the right, upon written notice to Harrow (except for the case already acknowledged and agreed to in the last sentence of this paragraph), to satisfy its supply obligations to Harrow hereunder either in whole or in part through arrangements with one or more Third Parties engaged by Sintetica to perform services or supply facilities or goods in connection with the Manufacture or testing of Product (each, a "Third-Party Manufacturer" or "TPM"). Sintetica shall be responsible for any acts or omissions of such Third-Party Manufacturers in breach of Sintetica's representations, warranties and obligations under this Agreement to the same extent as if Sintetica had committed the breach itself. The Parties acknowledge and agree that as of the Effective Date, Sintetica will obtain Product Manufactured by the TPM, Unither Pharmaceuticals at its manufacturing site in Coutances, France.

- Sintetica shall endeavor to have the contractual arrangements with each TPM be consistent with the relevant Manufacturing provisions of this Agreement, and use Commercially Reasonable Efforts to monitor and enforce the TPM's performance under such arrangements to ensure that such provisions of the are met.

- The performance by Sintetica described in Sections 6.3(d), and in other provisions of this Agreement, have been written in regard to any Manufacturing activities that may be carried out directly by Sintetica, where applicable. For purposes of this Agreement, however, and even where not so indicated expressly, such provisions should be interpreted *mutatis mutandis* so as to regard also performance of (the same) Manufacturing activities by TPMs for Sintetica, and to regard also Sintetica's responsibilities and obligations under the present Section for such TPM performance. As an example for clarification, in Section 6.3(d), to the extent applicable to Manufacturing activities carried out by a TPM for Sintetica, such Section should (also) be read as follows: "Sintetica shall, during the Term, *ensure that each TPM* maintain its relevant Manufacturing sites, and all property, equipment, machinery and systems therein, used in performing *Sintetica* obligations under this Agreement, in the ordinary course of business and in compliance with GMP and Applicable Law (including Drug Security and Supply Chain Act) and free of material defects except for those attributable to wear and tear consistent with age and usage of such assets and except for such defects as do not and will not in the aggregate impair the ability to use such assets in connection with this Agreement.

(b) Sintetica shall ensure that the TPM has an adequate supply of active and other ingredients required to Manufacture the Product in order to meet in a timely manner Harrow's firmly forecasted requirements for the Product in the Territory. In the event that for any reason the TPM may have insufficient supply of active or other ingredients required to meet its obligations under this Section (b), Sintetica, upon Harrow's approval, shall obtain a Third Party source, compliant with the requisite provisions of Regulatory Approvals, for such active and other ingredients agreed to by Harrow.

(c) Sintetica shall have Product Manufactured for Commercialization in the Territory only at sites included in the its approved NDAs, provided that the Applicable Laws require such inclusion for the Manufacturing Activities being carried out. In the event Sintetica desires to transfer the manufacture of any Product to another site other than those designated in the relevant NDA, Sintetica shall require Harrow's written approval. For the avoidance of doubt, the transfer to another site remains subject to the first sentence of this Section.

(d) Sintetica shall, during the Term, maintain its relevant Manufacturing sites, and all property, equipment, machinery and systems therein, used in performing its obligations under this Agreement, in the ordinary course of business and in compliance with GMP and Applicable Law (including Drug Security and Supply Chain Act) and free of material defects except for those attributable to wear and tear consistent with age and usage of such assets and except for such defects as do not and will not in the aggregate impair the ability to use such assets in connection with this Agreement.

(e) Sintetica will properly arrange, and have TPM maintain, samples from each batch of Product as required by applicable regulatory standards in the Territory, country of Manufacture, Applicable Law and as otherwise agreed in writing by the Parties.

(f) Notwithstanding anything to the contrary in this Agreement, all Product sold to Harrow under this Agreement, when delivered by Sintetica to Harrow, shall be Manufactured in accordance with the NDA and all Applicable Law, shall meet the Specifications and the requirements as set forth in a Quality Agreement, to be entered into by the Parties as soon as practicable and which, upon execution, shall become Schedule 6.3(f) to this Agreement (the "Quality Agreement"). For such purpose, the Parties agree to have appropriate personnel discuss the structure of the Quality Agreement, and the allocation of responsibilities therein as soon as reasonably practicable.

6.4 Audits and Inspections. On a regular basis, not to exceed once (1) per calendar year except for good cause, upon Harrow's prior written notice of at least ninety (90) days and at Harrow's own expense, Sintetica shall permit representatives of or selected on behalf of Harrow to inspect the Manufacturing facilities, relevant to the manufacture, testing, packaging, labeling, quality control, storage and transport of any Product.

6.5 Forecasts. No later than one hundred twenty (120) days prior to Sintetica's good faith projected Product approval date for the US NDA, which date shall be timely communicated to Harrow, Harrow shall provide to Sintetica a forecast which shall indicate Harrow's reasonable estimate of its expected requirements for each Product from Sintetica for the twelve (12) month period commencing on the desired initial Delivery Date for such Product. Thereafter, Harrow commits to providing Sintetica with a 12 months rolling forecast no later than the 5th five Business Day of each calendar month (each a "Rolling Forecast"). The first three (3) calendar months of each Rolling Forecast shall be considered binding forecasts for Product (the "Firm Period"). Pursuant to the following Section, the minimum leadtime for supply is considered to be three (3) months.

6.6 Purchase Orders and Minimum Order Requirements.

(a) The purchase of each Product under this Agreement shall be implemented by Harrow's issuance of individual purchase orders to Sintetica for specific quantities of each Product which purchase orders shall reflect the quantities and timing set out in the applicable Firm Periods of previous Rolling Forecasts ("Firm Orders"), and shall specify the delivery date for each Product (the "Delivery Date"). For purposes of this Agreement, unless expressly indicated otherwise, "quantities" of Product shall be considered to be whole number of batches of Product (with a batch to be intended as described in Section 6.14).

(b) The first order of Product ("Launch Order"), which shall regard launch quantities required by Harrow for the US market, shall be placed no later than ten (10) days after approval of the NDA for the Product by the FDA, with the Delivery Date specified in the Launch Order to be that date anticipated by Harrow to coincide with the end of the one hundred twenty (120) day term set forth in the following sentence. Sintetica shall use reasonable efforts to deliver the Launch Order as soon as reasonably possible before such term but, shall have no liability for its failure to deliver Product in less than one hundred twenty (120) days after the date of Harrow's final approval of Product Labeling and Packaging pursuant to Section 6.1(a).

(c) All subsequent orders placed hereunder shall, in any event, be placed at least one hundred fifty (150) days prior to Harrow's requested Delivery Date. Within ten (10) Business Days of its receipt of a purchase order, to the extent that it is able to supply the quantities of Product ordered, Sintetica shall accept in writing such purchase order to the extent that it has been submitted in accordance with Sections 6.5 6.6(a), 6.6(c) and 6.6(e) by delivering a confirmation of the Delivery Date, or an indication of the date that Sintetica actually expects to deliver Product, and of the quantities set forth therein (a "Purchase Order Confirmation"). For clarity, any such "acceptance" of a purchase order shall only be with regard to terms and conditions set forth in this Agreement; any additional terms or conditions in Harrow's purchase order, and any terms or conditions in conflict with those herein, shall not be deemed as accepted by Sintetica is issuing and delivering such Purchasing Order Confirmation, even when the wording or language used therein may indicate otherwise.

(d) If a Harrow purchase order requests quantities of such Product in excess of one hundred twenty five percent (125%) of Harrow's most recent forecast for such month, then Sintetica shall within ten (10) Business Days of its receipt of such a purchase order, notify Harrow whether and to what amount Sintetica believes at such time it can supply some of all of such excess. For any given calendar month, Sintetica may be required to accept purchase orders for quantities of Product up to one hundred twenty-five percent (125%) of Harrow's most recent forecast for such month and shall use commercially reasonable efforts to supply quantities of Product in excess of one hundred twenty-five percent (125%) of the forecasted amounts (the "Excessive Amount").

(e) Harrow shall assign a purchase order number to each order placed with Sintetica and notify such order numbers to Sintetica. Each Party shall use the relevant purchase order number in all subsequent correspondence relating to the order.

(f) The minimum quantity per order (***"MOQ"***) shall be one batch of Product, as described in Section 6.14. The MOQ may be changed at any time in writing under mutually agreeable terms.

6.7 Delaying of Shipments; Cancellation of Confirmed Orders. In the event of any commercial or regulatory issues in the Territory that would adversely affect its sales of a given Product, Harrow shall have the right to delay shipment of Confirmed Orders of Product affected by such issues for a period of up to three (3) months after the relative Delivery Date for such Product. In the event Harrow wishes to delay any such shipments it will notify Sintetica in writing at least sixty (60) days in advance of the applicable Delivery Date. Harrow shall also have the right to cancel any such Confirmed Orders of Product, however, in the event of such cancellation Harrow shall pay for all such applicable Product already manufactured by Sintetica. Any cancellations under this Section 6.7 shall be without prejudice to Harrow's obligation to purchase MAQs.

6.8 Shipment.

Product shall be delivered Ex Works **** manufacturing facility in Coutances, France (Incoterms 2020) , in such TPM's standard packaging and delivery units as may be applicable from time to time. Sintetica will provide reasonable assistance, where necessary, to ensure coordination between the TPM, Sintetica and Harrow and/or Harrow's designated shipping agent for Product shipments. Upon Harrow's reasonable request, Sintetica, as the NDA owner in the USA prior to approval, shall file a Pre-Launch Activities Importation Request (PLAIR) with the FDA to assist Harrow with the importation of Products in the form that may be allowed under the PLAIR in preparation for market launch.

(a) For purposes of this Agreement, delivery within thirty (30) days before or after the Delivery Date shall be deemed as meeting the Delivery Date.

(b) Sintetica will not ship any Product that it reasonably believes will not conform to the relevant Specifications, NDAs, this Agreement or with Applicable Law. If Sintetica reasonably believes any Product would not conform as such, then Sintetica shall, at no cost to Harrow, manufacture and supply an appropriate quantity of Product to replace the non-conforming Product as soon as reasonably possible.

(c) Risk of loss shall pass in accordance with the aforementioned Incoterm directly from the TPM to Harrow as a simultaneous, "flow-through" transfer of risk with regards to Sintetica. With such delivery, Sintetica shall ensure passage to Harrow of good and marketable title to each Product, free and clear of all liens, claims, security interests, pledges, charges, mortgages, deeds of trusts, options, or other encumbrances of any kind.

6.9 Acceptance of Product. Within thirty (30) days of receipt of each shipment of Product to Harrow's warehouse, Harrow shall perform or cause to be performed any physical inspections and testing Harrow deems necessary for each shipment of the Product and notify Sintetica in writing within such thirty (30) day period if Harrow believes that the Product fails to conform to the Specifications, NDAs, this Agreement, or Applicable Law, or if any defect, shortage, or other nonconformance exists. If Harrow does not provide such notice within the thirty (30) day period, the shipment shall be deemed to be accepted ("Accepted"), except as otherwise provided by Section 6.10.

6.10 Non-Conformity; Shortage; Defectiveness. If Harrow believes that (a) any Product has not been manufactured in accordance with the requirements of the Specifications, NDAs, this Agreement or Applicable Law; (b) any defect exists in any Product delivered, or (c) there is a shortage of Product delivered; then in each case Harrow will, within thirty (30) days of the receipt of such Product by Harrow, notify Sintetica in writing setting forth in reasonable detail the alleged nonconformity, defect (in the case of defects that can be discovered by routine inspection) or shortage. In the event of any hidden or latent defects that cannot be discovered by routine inspection, Harrow shall notify Sintetica within five (5) Business Days of discovery of such defects, but in any event no later than the expiry date of the relevant Products' shelf life. Failure by Harrow to notify Sintetica of hidden or latent defects within either of such terms shall exclude any claim or other right or remedy of Harrow with regards to the allegedly defective Product. Upon any such notification, Sintetica shall have the right to inspect the applicable Product itself or appoint, at its expense, a mutually acceptable Third Party to perform such inspection. Sintetica or such Third Party will have thirty (30) days to inspect the affected Product to make an assessment of the alleged nonconformity, defect or shortage. Any dispute between the Parties concerning rejection of all or any part of a shipment of Product which the Parties are unable to resolve as between the Parties within thirty (30) days of the end of the aforementioned thirty (30) day period will be submitted to an agreed-upon, qualified, independent laboratory for testing using the test methods set forth in the applicable NDA or other mutually agreed upon methods. Sintetica shall replace promptly any shipment or portion of a shipment of Product, and the cost of the laboratory will be at Sintetica's expense, if the laboratory finds that the lot in question is non-conforming or otherwise defective. The costs of the laboratory shall be Harrow's expense if the Product in question is found to be conforming or otherwise non-defective. The findings of the laboratory shall be final and binding upon the Parties and not subject to appeal or review by any Third Party. In the event the laboratory finds that the Product in question is nonconforming, then Sintetica shall pay or reimburse Harrow for costs of the destruction of such nonconforming Product.

6.11 Delays; Inability to Supply.

(a) In the event that (i) Sintetica is unable to accept a purchase order submitted by Harrow in accordance with Section 6.6(a) and to supply the Product as ordered therein or (ii) Sintetica is unable for any reason to supply any quantity of Product ordered and accepted by a Purchase Order Confirmation, then Sintetica shall promptly notify Harrow of such inability to supply and if possible, of the date on which such inability is expected to end. In such event, Sintetica and Harrow will for a period up to thirty (30) days discuss in good faith a resolution to such inability to supply. Sintetica shall also immediately prioritize available production capacity, materials and components to the manufacture of the affected Product to minimize the impact of the inability to supply.

(b) In the event (a) that Sintetica is unable to supply Product to Harrow as ordered by Harrow per Purchase Order Confirmations, in the amounts of Product equal to at least that specified in Firm Periods and to any Excessive Amounts accepted by Sintetica for a period within thirty (30) days of the Delivery Date (a "Supply Failure"), and unless (b) Sintetica and Harrow have agreed otherwise under the good faith discussions carried out pursuant to Section 6.11(a), then Harrow shall, in addition to its other rights and remedies available hereunder, including the right to indemnification for any claims made by a Harrow customer as a direct result of such Supply Failure, have the right to cancel the relative purchase order(s) for Product(s) without penalty or liability and to purchase such Product from an alternate source, including a Third Party.

(c) In the event that Sintetica shall have reason to believe it will be unable to supply Product to Harrow for a period of at least three (3) months beyond the Delivery Date (a "Material Delivery Delay"), Sintetica shall promptly notify Harrow thereof. Following Harrow's receipt of such notice the Parties shall promptly meet to discuss in good faith and establish in writing a plan that shall contain all necessary activities to be implemented by the two Parties to avoid or eliminate the interruption in supply and/or to mitigate the possible impact of interruption (the **"**Recovery Plan**"**).

(d) In the event of any Supply Failure or any Material Delivery Delay where the Recovery Plan provides for Manufacture by another Third Party Manufacturer, Sintetica shall use Commercially Reasonable Efforts to effectuate a transfer of any Sintetica Technology to a such new Third Party Manufacturer, who can Manufacture product which meets the requisite quality and Regulatory Standards.

6.12 Inventory. Commencing two years after Harrow has launched the Product, Harrow shall keep an amount of inventory at all times greater than six (6) months of forecasted sales of Product.

6.13 Transfer Price.

(a) The supply price of the Product ("Transfer Price") shall, starting from the Effective Date, be equal to **** per unit of Product with delivery as described in Section 6.8(a). For clarification, where this Agreement refers to a "unit of Product", it shall mean a single dose of Product unless specified otherwise, with the understanding that each such single dose will then be (pouched and) packaged as part of a multidose box (stock-keeping) unit.

(b) Sintetica may invoice Harrow when the Product has been made available for pickup at the TPM as described in Section 6.8(a), at a price per unit that is equal to the Transfer Price for such Product. Except as otherwise provided for in this Agreement, Harrow shall pay to Sintetica the Transfer Price applicable for such Product at such time within sixty (60) days after the date of receipt of an invoice from Sintetica.

(c) If Harrow fails to cure any non-payment of an invoice within thirty (30) days of its due date, then Sintetica may call for immediate payment of all outstanding invoices that are not subject to dispute. Sintetica may also make further deliveries subject to prepayment.

(d) Notwithstanding any of the foregoing, for purposes of determining Royalties due under this Agreement, the sum of the Applicable Transfer Price of Product and the Royalty under Section 7.4 shall not exceed **** per unit of Product. Solely for purposes of such calculation, no matter what the actual Transfer Price is, the "Applicable Transfer Price" shall be deemed to be the then current Transfer Price, but in any event no greater than **** per unit of Product.

6.14 Batch size. Purchases of Product shall be in full batch amounts, with the current full batch amount being approximately 250,000 units of Product, based upon the Product's formulation as of the Effective Date. Said batch size has been agreed to by the Parties regarding final, finished, packaged and labeled Product; it is recognized by Harrow that the batch of Product manufactured by Sintetica's TPM is a larger size, with the intention that the TPM batch will be timely split by Sintetica for the purpose of supply under this Agreement and also for other countries outside of the Territory.

6.15 Minimum Annual Quantities. Harrow undertakes to purchase in each and every calendar year of the Term, starting in the year of the Regulatory Approval of a USA NDA, at least one full batch of Product (the "Minimum Annual Quantities" or "MAQs"). Such requirement is established in relation to the USA market; upon Regulatory Approval of the Canadian NDA, the Parties agree to negotiate in good faith whether or not the MAQs need to be increased for the remainder of the Term.

ARTICLE 7.
PAYMENTS

7.1 Upfront Payment. Within thirty (30) days of the Effective Date, Harrow shall pay Sintetica an amount equal to $5,000,000.00. Fifty percent (50%) of this payment will be refunded by Sintetica to Harrow if, as of October 31, 2022, an NDA for the Product has not been submitted to FDA or Harrow has not received a so-called "Day 74" letter from FDA related to the NDA. In addition, if FDA issues a Complete Response Letter ("CRL") for the Product, $500,000.00 of the above amount will be refunded to Harrow. If the NDA for the Product is not approved within twelve (12) months of Harrow receiving a CRL, an additional $1,000,000.00 will be refunded by Sintetica to Harrow. Notwithstanding the above, in the event that Harrow elects to delay submission of the NDA in accordance with Section 3.2, the date in the second sentence of this Section 7.1 shall be reset to the date that is October 31, 2022 plus the amount of delay on a "day to day" basis. By means of a non-limiting example, if Harrow decides to delay the NDA filing for 270 days in order to complete a study or other activity pursuant to Section 3.2, the date under the second sentence of this Section 7.1 shall be reset from October 31, 2022 to July 28, 2023.

7.2 Regulatory Milestones.

(a) Harrow shall make payments to Sintetica based on achievement of certain milestone events for Product as set forth in the following table.:

Milestone Number	Milestone Event	Milestone Payment (U.S. Dollars)
(i)	The date on which Sintetica submits the filing to the FDA and pays the PDUFA fee.	****[1]
(ii)	The date the FDA approves the United States NDA for the Product for the Licensed Indication	****

[1] This amount shall be increased by the amount of any increase in the cost for the USA NDA (i.e., the full PDUFA filing fee) relative to that which was expected by the Parties in discussions leading up to the signing of the Confidential Terms Sheet of May 14, 2021. Such cost for the USA NDA will be determined only after September 30, 2021, when the new Fiscal Year for FDA will come into force, and the Agreement the amount in Milestone 7.2(a)(i) shall be automatically amended to reflect such actual cost.

(b) Sintetica shall notify Harrow upon achievement of each milestone event and Harrow shall pay to Sintetica the amounts as set forth above within ten (10) Business Days after the date of achievement of the respective milestone events.

(c) Notwithstanding the foregoing, the payment of Milestone Number (ii) above shall be conditioned on Sintetica's having supplied sufficient launch quantities of the Product to Harrow consistent with Harrow's Commercial Launch Plan for that date.

(d) The milestone payments for Milestone Numbers (i) and (ii) by Harrow to Sintetica hereunder shall be payable only once and, except as set forth for Milestone Number (i) in the following Section 7.2(e), shall be non-refundable.

(e) In the event that the FDA refuses to accept the USA NDA filing for review (refuse to file designation) which filing has given rise to payment by Harrow of the Milestone Number (i), any amounts of the PDUFA fee, paid by Sintetica to the FDA with such filing, which are subsequently returned to Sintetica by the FDA will be returned to Harrow on a dollar for dollar basis.

(f) In the event that the Parties agree, after any such FDA refusal to accept the USA NDA filing, to have the USA NDA adapted, as appropriate, and resubmitted by Sintetica, Sintetica will again be the responsible Party for paying the relative PDUFA filing fee , and there shall be no milestone payable in connection with such resubmission.

7.3 Net Sales Milestones.

(a) As further consideration for the rights granted to Harrow, Harrow shall pay to Sintetica the following milestones based upon its achievement of certain annual Net Sales within the Territory for the Product and/or the passage of time from Harrow's first commercial sale of the Product to a Third Party for use within the Field in the Territory. Harrow shall notify Sintetica upon its achievement of each such milestone event and Harrow shall pay to Sintetica the amounts set forth below within sixty (60) days following the end of applicable calendar year upon satisfaction of the relevant annual net sales thresholds for the Licensed Product in the Territory as set forth in the table below. Each milestone payment by Harrow to Sintetica hereunder shall be payable only once and shall be non-refundable. Multiple milestones can be achieved for the same calendar year.

Annual Net Sales of Product in the Territory Milestone	**Milestone Payment (U.S. Dollars)**
Upon the earlier of: (a) reaching $5,000,000.00 in annual Net Sales for all sales of the Product in the Territory; or (b) the 24 month anniversary of the first commercial sale of the Product in the Territory by Harrow	****
Upon the earlier of: (a) reaching $10,000,000.00 in annual Net Sales for all sales of the Product in the Territory; or (b) the 48 month anniversary of the first commercial sale of the Product in the Territory by Harrow	****

7.4 Royalty. Sixty (60) days after the end of each calendar quarter, Harrow shall pay to Sintetica an amount equal to **** per unit of Product for each unit of Product sold in the Territory for the immediately preceding quarter. Notwithstanding the above, in the event that Harrow's Gross Margin for Product sales in the Territory falls below 80%, the amount of the Royalty payable to Sintetica can be reduced to enable Harrow to achieve a Gross Margin of 80%, but under no circumstances shall the Royalty ever be less than **** per unit of Product. The following non-limiting examples demonstrate the royalty adjustment mechanism and assume that the Applicable Transfer Price is not less than ****:

(a) ****If Harrow's Selling Price is **** per unit, the Gross Margin calculated is ****, and no adjustment to the Royalty is to be made as it would remain **** per unit;

(b) If Harrow's Selling Price is ****/unit, the Gross Margin calculated is ****. To achieve a Gross Margin of 80%, the Royalty is reduced to **** per unit ****.

(c) If Harrow's Selling Price is ****, the Gross Margin calculated is ****. To achieve a Gross Margin of 80%, the Royalty would need to be is reduced to **** per unit ****. However since **** is less than ****, the Royalty would only be reduced to **** per unit.

7.5 Audit. Each Party shall maintain complete and accurate records in sufficient detail to permit the other Party to confirm the accuracy of the calculation of milestone and royalty payments under this Agreement. Upon reasonable prior notice, such records shall be available during regular business hours for a period of three (3) years from the end of the Calendar Year to which they pertain for examination at the expense of the requesting Party by an independent certified public accountant selected by the requesting Party and reasonably acceptable to the other Party, for the sole purpose of verifying the accuracy of the financial reports and the correctness of payments furnished by the other Party pursuant to this Agreement. Any such auditor shall not disclose the other Party's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by the other Party or the amount of payments due by the other Party under this Agreement. Any amounts shown to be owed but unpaid shall be paid within thirty (30) days from the accountant's report, plus interest (as set forth in Section 7.6 from the original due date). Any amounts shown to have been overpaid shall be refunded within thirty (30) days from the accountant's report. The requesting Party shall bear the full expense of such audit, unless such audit discloses an underpayment by the other Party of more than five percent (5%) of the amount due, in which case the other Party shall bear the full expense of such audit. The audit rights set forth in this Section 7.5 shall survive the termination or expiration of this Agreement for one (1) year. There shall be no more than two such audits for this Agreement.

7.6 Late Payment**.** All payments due to a Party hereunder shall be made in U.S. Dollars by wire transfer of immediately available funds into an account designated by such Party. If a Party does not receive payment of any sum due to it on or before the due date, simple interest shall thereafter accrue on the sum due to such Party until the date of payment at the per annum rate of two percent (2%) over the then-current prime rate quoted by Citibank in New York City or the maximum rate allowable by Applicable Law, whichever is lower.

ARTICLE 8.
INTELLECTUAL PROPERTY MATTERS

8.1 Ownership of Inventions.

(a) Harrow shall solely own all Harrow Inventions.

(b) Sintetica shall solely own all Sintetica Inventions.

(c) The Parties shall jointly own any Inventions that are made jointly by employees, agents, or independent contractors of each Party in the course of performing activities under this Agreement, or in connection therewith, involving or which can be used in the Exploitation of Product, together with all intellectual property rights therein ("Joint Inventions"). For clarification, Inventions "made jointly by" employees, agents, or independent contractors of each Party shall mean Inventions made by such Persons in work carried out jointly by or for both using Information exchanged by the Parties specifically for such work. For the avoidance of doubt, Joint Inventions shall be subject to the licenses in Article 2 of this Agreement.

(d) Inventorship shall be determined in accordance with U.S. patent laws.

8.2 Disclosure of Inventions. Sintetica shall promptly disclose to Harrow any of its Sintetica Inventions during the Term to the extent that such Inventions can be Exploited in the Territory. With respect to any Joint Inventions, each Party shall promptly disclose to the other Party any invention disclosures, or other similar documents, submitted to it by its employees, agents or independent contractors describing the Joint Inventions, and all Information relating to such inventions to the extent necessary for the use of such Joint Technology and, to the extent patentable, for the preparation, filing and maintenance of any Patent with respect to such Invention.

8.3 Prosecution of Patents.

(a) **Sintetica Patents**. Except as otherwise provided in this Section 8.3(a), Sintetica shall have the right and authority, at its own expense, to prepare, file, prosecute and maintain the Sintetica Patents. If requested by Harrow, Sintetica shall provide Harrow's external patent counsel a reasonable opportunity to review and comment on its efforts to prepare, file, prosecute and maintain Sintetica Patents in the Territory, including by providing Harrow's external patent counsel with a copy of material communications from any patent authority in the Territory regarding any Sintetica Patent, and by providing drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. If Sintetica determines in its discretion to abandon or not maintain any Sintetica Patent listed in Schedule 1.96 that is being prosecuted or maintained by Sintetica in the Territory, then Sintetica shall provide Harrow with written notice of such determination within a period of time reasonably necessary to allow Harrow to determine, in its discretion, its interest in such Sintetica Patent (which notice by Sintetica shall be given no later than sixty (60) days prior to the final deadline for any pending action or response that may be due with respect to such Sintetica Patent with the applicable patent authority). If Harrow provides written notice expressing its interest in obtaining ownership of such Sintetica Patent, (i) Sintetica shall, free of charge, transfer to Harrow the control of such Sintetica Patent in the Territory, (ii) Harrow will thereupon have the right, but not the obligation, to assume the prosecution and maintenance thereof at Harrow's sole cost and expense (each, a "Harrow Assumed Patent"), through patent counsel or agents of its choice; and (b) Sintetica shall promptly deliver to Harrow copies of all necessary files related to any Harrow Assumed Patents with respect to which responsibility has been transferred and shall take all actions and execute all documents reasonably necessary for Harrow to assume such activities, at Harrow's request. Harrow hereby grants to Sintetica an irrevocable , royalty-free license to Harrow Assumed Patents.

(b) **Harrow Patents**. Harrow shall have the sole right and authority, at its own expense, to prepare, file, prosecute and maintain the Harrow Patents.

(c) **Joint Patents**. Except as otherwise provided in this Section 8.3(c), Harrow shall have the primary right and authority, to prepare, file, prosecute and maintain the Joint Patents in the Territory at its own expense and using external patent counsel in the Territory that is reasonably acceptable to Sintetica. Harrow shall provide Harrow with a reasonable opportunity to review and comment on such efforts regarding such Joint Patent, including by providing Sintetica with a copy of material communications from any patent authority in such country(ies) in the Territory regarding such Joint Patent, and by providing drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. Harrow shall consider Sintetica's comments regarding such communications and drafts in good faith. If Harrow determines in its sole discretion to abandon or not maintain any Joint Patent in any country(ies) of the Territory, then Harrow shall provide Sintetica with written notice of such determination within a period of time reasonably necessary to allow Sintetica to determine its interest in such Joint Patent (which notice from Harrow shall be given no later than sixty (60) days prior to any final deadline for any pending action or response that may be due with respect to such Joint Patent with the applicable patent authority). In the event Sintetica provides written notice expressing that it has an interest in obtaining full ownership title to such Joint Patent(s), (a) Harrow shall promptly deliver to Sintetica copies of all necessary files related to such Joint Patent(s), and shall take all actions and execute all documents reasonably necessary to charge, assign and transfer to Sintetica the full ownership of, and interest in, such Joint Patent in the applicable jurisdiction in the Territory so that, for all extents and purposes, such Patent shall become a Sintetica Patent, and Sintetica shall grant to Harrow an irrevocable royalty-free license to such Sintetica Patent. Sintetica shall have the sole right and authority, to prepare, file, prosecute and maintain the Joint Patents outside of the Territory at its own expense.

(d) **Cooperation in Prosecution**.

(i) Each Party shall provide the other Party all reasonable assistance and cooperation in the Patent prosecution efforts in the Territory provided above in Sections 8.3(a) and (c), including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution, as well as further actions as set forth below. Such assistance and cooperation shall include making a Party's inventors and other scientific advisors reasonably available to assist the other Party's Patent preparation, filing, prosecution and maintenance efforts.

(ii) All communications between the Parties relating to the preparation, filing, prosecution or maintenance of Sintetica Patents and Joint Patents, including copies of any draft or final documents or any communications received from or sent to patent offices or patenting authorities with respect to such Patents, shall be considered Confidential Information and subject to the confidentiality provisions of Article 10.

(iii) Assignments in Sintetica Patents and Joint Patents shall be effected as follows: (1) employees or agents of Sintetica that are named as inventors on Sintetica Patents shall assign their interest in such Patents to Sintetica; and (2) employees or agents of Harrow or Sintetica that are named as inventors on Joint Patents shall assign their interest in such Patents to their respective employer.

8.4 Patent Term Extensions in the Territory.

(a) Sintetica shall have the right to decide on which, if any, of the Patents within Sintetica Patents and Joint Patents in the Territory it should seek Patent Term Extensions; provided, that, Sintetica shall reasonably consider in good faith Harrow's position in connection therewith. Subject to the foregoing, Sintetica shall be responsible for applying for the Patent Term Extension. Harrow shall cooperate fully with Sintetica in making such filings or actions, for example and without limitation, making available all required regulatory data and information and executing any required authorizations to apply for such Patent Term Extension. All expenses incurred in connection with activities of each Party with respect to the Patent(s) for which Patent Term Extensions are filed pursuant to this Section 8.4(a) shall be entirely borne by Sintetica. In the event that Harrow wishes to seek Patent Term Extension to a Sintetica Patent or a Joint Patent and Sintetica does not agree to do so, the provisions of Section 8.4(b) shall apply as if such Sintetica Patent or Joint Patent were a Harrow Patent.

(b) Harrow shall have the right to decide on which, if any, of the Patents within Harrow Patents in the Territory it should seek Patent Term Extensions. Subject to the foregoing, Harrow shall be responsible for applying for the Patent Term Extension. Sintetica shall cooperate fully with Harrow in making such filings or actions, for example and without limitation, making available all required regulatory data and information and executing any required authorizations to apply for such Patent Term Extension. All expenses incurred in connection with activities of each Party with respect to the Patent(s) for which Patent Term Extensions are filed pursuant to this Section 8.4 (b) shall be entirely borne by Harrow.

8.5 Patent Listing; Compendia Listing. Sintetica, at Harrow's request, shall: (i) file appropriate information with the FDA in the U.S. listing any Sintetica Patents, Harrow Patents or Joint Patents in the FDA's Orange Book; and (ii) with respect to other countries in the Territory, file appropriate information, where required by any Applicable Laws, with the applicable Regulatory Authority listing any Sintetica Patents, Harrow Patents or Joint Patents in the Patent listing source in such country in the Territory, if any. The Parties shall fully cooperate with each other to effectuate the above listing requirements. It is anticipated that one or more of the Patents in Schedule 1.97 should be listable in the FDA's Orange Book and/or the Health Canada Patent Register.

8.6 Infringement of Patents by Third Parties.

(a) **Notification**. Each Party shall promptly notify the other Party in writing of any existing, alleged or threatened infringement of Sintetica Patents or Joint Patents in the Field in the Territory of which it becomes aware, and shall provide all Information in such Party's possession or Control demonstrating such infringement.

(b) **Infringement of Sintetica Patents or Joint Patents**.

(i) Harrow shall have the first right, but not the obligation, at its own expense, to bring an appropriate suit or other action against any Third Party engaged in any existing, alleged or threatened infringement of Sintetica Patents or Joint Patents in Field in the Territory, subject to Section 8.6(b)(ii) through 8.6(b)(v), below.

(ii) Harrow shall notify Sintetica of its election to take any action in accordance with Section 8.6(b)(i) within the earlier of: (1) ninety (90) days after the first notice under 8.6(a); or (2) ten (10) days before any time limit set forth in an Applicable Law or regulation. In the event Harrow does not so elect, Harrow shall so notify Sintetica in writing, and Sintetica shall have the right to commence a suit or take action to enforce the applicable Patent against such Third Party perpetrating such infringement in the Territory at its own expense. If one Party elects to bring suit or take action against the infringement, then the other Party shall have the right, prior to commencement of the trial, suit or action, to join any such suit or action.

(iii) Each Party shall provide to the Party enforcing any such rights under this Section 8.6(b) reasonable assistance in such enforcement, at such enforcing Party's request and expense, including joining such action as a party plaintiff if required by Applicable Law to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts and shall reasonably consider the other Party's comments on any important aspects of such enforcement including determination of material litigation strategy, filing of dispositive papers to the competent court.

(iv) The enforcing Party shall have the sole right to settle any claim, suit or action that it brought under this Section 8.6(b) involving Sintetica Patents or Joint Patents without the prior written consent of the other Party unless such settlement will (a) impose any liability or obligation on such other Party, (b) include the grant of any license, covenant or other rights to any Third Party that would conflict with or reduce the scope of the subject matter included under the rights and license(s) granted to such other Party under this Agreement, or (c) otherwise materially affect the licenses or other rights granted to such other Party hereunder adversely in any respect.

(v) The Party not bringing an action with respect to infringement in the Territory under this Section 8.6(b) shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the Party bringing such action. If the non-enforcing Party requests that the Parties be jointly represented by the same outside counsel, the enforcing Party shall have the right to consent to such joint representation of the Parties, such consent not to be unreasonably withheld, delayed or conditioned. For clarity, the enforcing Party can withhold its consent to such joint representation where it has a good faith basis to believe there is a conflict between the Parties.

(c) **Infringement of Harrow Patents**. For any and all infringement of any Harrow Patent, Harrow shall have the sole and exclusive right, but not the obligation, to bring, at Harrow's expense and in its sole control, an appropriate suit or other action against any person or entity engaged in such infringement of the Harrow Patent. Sintetica shall provide Harrow reasonable assistance in such enforcement, at Harrow's reasonable request and expense, including joining such action as a party plaintiff if required by Applicable Law to pursue such action. Harrow shall retain one hundred percent (100%) of any recovery in connection with such suit or other action (after reimbursing Sintetica for any of its expenses in connection with its assistance provided in accordance with this Section 8.6(c)).

(d) **Allocation of Proceeds**. If either Party recovers monetary damages from any Third Party in a suit or action brought under Sections 8.6(b), 8.7 or 8.8 related to any alleged Product Infringement, whether such damages result from the infringement of Sintetica Patents or Joint Patents, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation, action or license, and any remaining amounts shall be retained by the Party who has managed such litigation, action or license, subject to the proviso that if Harrow is the party who managed such litigation, to the extent that any amounts recovered are for lost sales of Product, Harrow shall pay to Sintetica an amount equal to the number of units of such lost product sales, multiplied by the royalty in Section 7.4.

8.7 Infringement of Third Party Rights in the Territory.

(a) **Notice**. If any Product used or sold by Harrow or its sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a Patent granted by a jurisdiction within the Territory, the Party first having notice of the claim or assertion shall promptly notify the other Party. Unless Harrow decides to carry out its own freedom to operate (FTO) analysis, Sintetica will conduct a patent freedom to operate analysis as of the Effective Date and to the best of its knowledge there should be no freedom to operate issues concerning the Commercialization of the Product in the Field in the Territory.

(b) **Defense**. Harrow shall have the first right, but not the obligation, at its own expense, to defend any such Third Party claim or assertion of infringement of a Patent as described in Section 8.7(a) above. If Harrow does not commence actions to defend such claim within sixty (60) days after it receives notice thereof or if Harrow discontinues the defense of any such action after filing, then to the extent allowed by Applicable Law, Sintetica shall have the right, but not the obligation, to control the defense of such claim by counsel of its choice, at Sintetica's expense. The non-defending Party shall reasonably cooperate with the Party conducting the defense of the claim or assertion, including if required to conduct such defense, furnishing a power of attorney. Any awards or amounts received in bringing any such action shall be first allocated to reimburse the each Party's expenses in such action, and any remaining amounts shall be retained by the defending Party. Notwithstanding the above, at all times during the Term if, as part of obtaining Regulatory Approval for the Product in the United States, there is so called Hatch Waxman litigation where Harrow will be the defendant in such litigation, then Harrow shall be solely responsible for managing the litigation, including selection of counsel, and shall be responsible for all associated costs, including external legal fees.

(c) **Settlement; Licenses**. The defending Party shall have the sole right to settle any claim, suit or action that it brought under this Section 8.7 unless such settlement will (a) impose any liability or obligation on such other Party, (b) include the grant of any license, covenant or other rights to any Third Party that would conflict with or reduce the scope of the subject matter included under the rights and licenses granted to such other Party under this Agreement, or (c) otherwise materially affect the licenses or other rights granted to such other Party hereunder adversely in any respect. In the event that it is determined by any court of competent jurisdiction or Harrow reasonably determines (based on the opinion of independent patent counsel) that the Exploitation of Product, conducted in accordance with the terms and conditions of this Agreement, infringes any patent, copyright, trademark, data exclusivity right or trade secret right arising under Applicable Law of any Third Party, the Parties shall use Commercially Reasonable Efforts to (i) modify such activities so as to render it non-infringing or, if the Parties determine that such modification is not possible, to (ii) procure a license from such Third Party authorizing Harrow to continue to conduct such activities, including the right for Harrow to sublicense such rights to Sintetica in accordance with Section 2.3. In the latter case, in the event that Harrow, after using Commercially Reasonable Efforts, determines that such alternatives is not available or commercially feasible, Harrow may, at its discretion, terminate this Agreement in accordance with Section 11.5.

(d) **Payment of Amounts.** In the event that Harrow is required to license Third Party intellectual property rights in order to Commercialize the Product in the Territory, Harrow shall be entitled to take as a credit against the royalty due to Sintetica in Section 7.4 in an amount equal to fifty percent (50%) of the amount actually paid to the Third Party, with the proviso that under no circumstances shall the royalty due to Sintetica ever be reduced to less than $2.00 per unit of Product. For clarification, Harrow's being "required to license Third Party intellectual property rights in order to Commercialize the Product in the Territory" means that the events and conditions – including opinion of independent patent counsel where applicable – set forth in the second sentence of Section 8.7(c) have given rise to case (ii) of such Section.

8.8 Patent Oppositions and Other Proceedings.

(a) **Third-Party Patent Rights**. If either Party desires to bring an opposition, action for declaratory judgment, nullity action, interference, declaration for non-infringement, reexamination or other attack upon the validity, title or enforceability of a Patent Controlled by a Third Party and having one or more claims that covers a Product, or the use, sale, offer for sale or importation of a Product in the Field in the Territory (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, a Third Party's claim or assertion of infringement under Section 8.7, in which case the provisions of Section 8.7 shall govern), such Party shall so notify the other Party and the Parties shall promptly confer to determine whether to bring such action or the manner in which to settle such action. Harrow shall have the first right, but not the obligation, to bring at its own expense and in its sole control such action in the Territory. If Harrow does not bring such an action in the Territory, within ninety (90) days of notification thereof pursuant to this Section 8.8(a) (or earlier, if required by the nature of the proceeding), then Sintetica shall have the right, but not the obligation, to bring, at Sintetica's sole expense, such action. The Party not bringing an action under this Section 8.8(a) shall be entitled to separate representation in such proceeding by counsel of its own choice and at its own expense, and shall cooperate fully with the Party bringing such action. Any awards or amounts received in bringing any such action shall be first allocated to reimburse each Party's expenses in such action, and any remaining amounts shall be retained by the Party who brings such action.

(b) **Parties' Patent Rights**. If any Sintetica Patent or Joint Patent becomes the subject of any proceeding commenced by a Third Party within the Territory in connection with an opposition, reexamination request, action for declaratory judgment, nullity action, interference or other attack upon the validity, title or enforceability thereof (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, an action for infringement against a Third Party under Section 8.6, in which case the provisions of Section 8.6 shall govern), then the Party responsible for filing, preparing, prosecuting and maintaining such Patent as set forth in Section 8.3 hereof, shall control such defense at its own expense. The controlling Party shall permit the non-controlling Party to participate in the proceeding to the extent permissible under Applicable Law, and to be represented by its own counsel in such proceeding, at the non-controlling Party's expense. If either Party decides that it does not wish to defend against such action, then the other Party shall have a backup right to assume defense of such Third-Party action at its own expense. Any awards or amounts received in bringing any such action shall be first allocated to reimburse each Party's expenses in such action, and any remaining amounts shall be retained by the controlling Party.

ARTICLE 9.
REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Mutual Representations and Warranties. Each of the Parties hereby represents and warrants to the other Party as of the Effective Date that:

(a) **Organization.** It is a corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.

(b) **Binding Agreement.** This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).

(c) **Authorization.** The execution, delivery, and performance of this Agreement by such Party have been duly authorized by all necessary corporate action and do not conflict with any agreement, instrument, or understanding, oral or written, to which it is a party or by which it is bound, nor violate any Applicable Law or any order, writ, judgment, injunction, decree, determination, or award of any court or governmental body, or administrative or other agency presently in effect applicable to such Party.

(d) **No Further Approval.** It is not aware of any government authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any Applicable Law, currently in effect, necessary for, or in connection with, the transactions contemplated by this Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its obligations under this Agreement.

(e) **No Inconsistent Obligations.** Neither Party is under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement, or that would impede the diligent and complete fulfillment of its obligations hereunder.

(f) **No Debarment.** Neither Party nor any of its respective Affiliates has been debarred by the FDA, is not subject to any similar sanction of other Governmental Authorities in the Territory, and, to its Knowledge, neither Party nor any of its respective Affiliates has used, or will engage, in any capacity, in connection with this Agreement or any ancillary agreements (if any), any Person who either has been debarred by any Regulatory Authority, or is the subject of a conviction described in Section 306 of the FFDCA.

9.2 Additional Representations and Warranties of Sintetica. Sintetica represents and warrants as of the Effective Date to Harrow that:

(a) Sintetica has all rights necessary to grant the licenses under Article 2 of this Agreement.

(b) Sintetica owns all of the Sintetica Technology and the Product free of any encumbrance, lien, or claim of ownership by any Third Party.

(c) To Sintetica's knowledge, the Exploitation of the Product as it exists as of the Effective Date in the Field in the Territory will not infringe or misappropriate the Patents or other intellectual property or proprietary rights of any Third Party in the Territory.

(d) To the extent permissible under Applicable Law, all current and former officers, employees and independent contractors of Sintetica who are inventors of or have otherwise contributed in a material manner to the creation or development of any Sintetica Technology or the Product have received all consideration for their contributions to such Sintetica Technology and have executed and delivered to Sintetica or any such Affiliate an assignment or other agreement regarding the protection of proprietary information and the assignment to Sintetica of all of their rights, title and interest in any and all Sintetica Technology and the Product.

(e) Sintetica has not previously entered into any agreement, whether written or oral, with respect to, or otherwise assigned, transferred, licensed, conveyed, or otherwise encumbered its right, title, or interest in or to Sintetica Technology or Product for the Field in the Territory.

(f) With respect to the development of the Product as of the Effective Date, the Product shall have been developed in conformance with GMP and all Applicable Laws.

(g) Other than the Product, Sintetica is not currently developing specifically for the Territory any other product that will be used as a topical ophthalmic anesthetic.

9.3 Covenants of Sintetica.

(a) During the Term, Sintetica shall not, and shall cause its Affiliates not to, grant to any Third Party rights that conflict with the rights granted to Harrow, or otherwise assign, transfer, license, convey, or otherwise encumber its right, title, or interest in or to the Sintetica Technology, the Joint Technology or the Product, *provided that*, such covenant shall not regard or extend to the any product outside of the Field or the Territory.

(b) To the extent permissible under Applicable Law all employees, agents, advisors, consultants or contractors of Sintetica shall be under an obligation to assign all of their right, title and interest in and to any Sintetica Inventions and any Joint Inventions, whether or not patentable, and intellectual property rights therein, to Sintetica as the owner thereof. Harrow shall have no obligation to contribute to any remuneration of any inventor employed or previously employed by Sintetica in respect of any Inventions, Information and other discoveries made in furtherance of this Agreement, including any intellectual property rights therein, which are assigned to Sintetica. Sintetica shall pay all such remuneration due to such inventors with respect to such Inventions.

(c) During the Term, Sintetica will not offer to any Third Party product developed by Sintetica that will be used in the Territory as a topical ophthalmic anesthetic without first offering Harrow the opportunity to Exploit such product in the Territory. The Parties agree that such first offer rights of Harrow shall be subject to usual terms and conditions for exercise of such rights, and to negotiate in good faith, and in a reasonable time after the Effective Date, such terms and conditions.

9.4 Additional Representation and Warranties of Harrow. Harrow represents and warrants to Sintetica that:

(a) Harrow has and/or will (continue to) have all rights necessary to grant Sintetica the licenses which granting is contemplated under this Agreement.

(b) As of the Effective Date Harrow owns all of the Harrow Technology free of any encumbrance, lien, or claim of ownership by any Third Party.

(c) Any development activities carried out by or for Harrow under Section 3.2 shall be designed so as to not knowingly cause a refusal of any Regulatory Approvals nor any unnecessary delays in obtaining such Regulatory Approvals.

9.5 Covenants of Harrow.

(a) To the extent permissible under Applicable Law, all employees, agents, advisors, consultants or contractors of Harrow shall be under an obligation to assign all of their right, title and interest in and to any Joint Inventions, whether or not patentable, and intellectual property rights therein, to Harrow as the owner thereof. Sintetica shall have no obligation to contribute to any remuneration of any inventor employed or previously employed by Harrow in respect of any Inventions, Information and other discoveries made in furtherance of this Agreement, including any intellectual property rights therein, which are assigned to Harrow. Harrow shall pay all such remuneration due to such inventors with respect to such Inventions.

9.6 No Other Representations or Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS ARTICLE 9, THE PARTIES MAKE NO REPRESENTATIONS OR WARRANTIES OF ANY KIND WHATSOEVER, EITHER EXPRESS OR IMPLIED, WRITTEN OR ORAL, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, INCLUDING ANY EXPRESS OR IMPLIED WARRANTY OF QUALITY, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR WARRANTY OF NON-INFRINGEMENT OR AS TO THE VALIDITY OF ANY PATENTS.

ARTICLE 10.
CONFIDENTIALITY

10.1 Nondisclosure. Each Party agrees that, during the Term and for a period of ten (10) years thereafter, a Party (the "Receiving Party") receiving Confidential Information of the other Party (the "Disclosing Party") shall (a) maintain in confidence such Confidential Information using not less than the efforts such Receiving Party uses to maintain in confidence its own confidential or proprietary Information of similar kind and value, (b) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted below, and (c) not use such Confidential Information for any purpose except those purposes permitted by this Agreement (it being understood that this Section 10.1 shall not create or imply any rights or licenses not expressly granted under this Agreement). Notwithstanding anything to the contrary in the foregoing, the obligations of confidentiality and non-use with respect to any trade secret within such Confidential Information shall survive such ten (10) year period for so long as such Confidential Information remains protected as a trade secret under Applicable Law.

10.2 Exceptions**.** The obligations in Section 10.1 shall not apply with respect to any portion of the Confidential Information that the Receiving Party can show by competent evidence:

(a) is publicly disclosed by the Disclosing Party, either before or after it is disclosed to the Receiving Party hereunder;

(b) is known to the Receiving Party or any of its Affiliates, without any obligation to keep it confidential or any restriction on its use, prior to disclosure by the Disclosing Party;

(c) is subsequently disclosed to the Receiving Party or any of its Affiliates on a non-confidential basis by a Third Party that, to the Receiving Party's Knowledge, is not bound by a similar duty of confidentiality or restriction on its use;

(d) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party or any of its Affiliates, generally known or available, either before or after it is disclosed to the Receiving Party;

(e) is independently discovered or developed by or on behalf of the Receiving Party or any of its Affiliates without the use of Confidential Information belonging to the Disclosing Party; or

(f) is the subject of written permission to disclose provided by the Disclosing Party.

10.3 Authorized Disclosure. The Receiving Party may disclose Confidential Information belonging to the Disclosing Party only to the extent such disclosure is reasonably necessary in the following instances:

(a) filing or prosecuting Patents as permitted by this Agreement;

(b) preparing and submitting Regulatory Materials and obtaining and maintaining Regulatory Approvals as permitted by this Agreement;

(c) prosecuting or defending litigation, including responding to a subpoena in a Third Party litigation;

(d) complying with Applicable Law or court or administrative orders;

(e) to Harrow's sublicensees or prospective sublicensees, subcontractors or prospective subcontractors, consultants, agents and advisors on a "need-to-know" basis in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement, each of whom prior to disclosure must be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are substantially similar to those set forth in this Article 10; provided, however, that, in each of the above situations, the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information pursuant to this Section 10.3(e) to treat such Confidential Information as required under this Article 10. Notwithstanding the foregoing, the Parties recognize and agree that any Confidential Information which divulgation may prejudice Patent filings or prosecutions shall only be disclosed in accordance with this paragraph (e) to those consultants, agents and advisors who have a need to on a "need-to-know" basis for carrying out such filings or prosecutions on behalf of a Party.

If and whenever any Confidential Information is disclosed in accordance with this Section 10.3, such disclosure shall not cause any such information to cease to be Confidential Information except to the extent that such disclosure results in a public disclosure of such information (other than by breach of this Agreement). Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to clauses (a) through (e) of this Section 10.3, it will, except where impracticable, give reasonable advance notice to the other Party of such disclosure and use not less than the same efforts to secure confidential treatment of such information as it would to protect its own confidential information from disclosure.

10.4 Terms of this Agreement. The Parties acknowledge that this Agreement and all of the respective terms of this Agreement shall be treated as Confidential Information of both Parties.

10.5 Securities Filings. Notwithstanding anything to the contrary in this Article 10, in the event either Party proposes to file with the Securities and Exchange Commission or the securities regulators of any state or other jurisdiction a registration statement or any other disclosure document that describes or refers to the terms and conditions of this Agreement or any related agreements between the Parties, such Party shall notify the other Party of such intention and shall provide the other Party with a copy of relevant portions of the proposed filing at least five (5) Business Days prior to such filing (and any revisions to such portions of the proposed filing a reasonable time prior to the filing thereof), including any exhibits thereto that refer to the other Party or the terms and conditions of this Agreement or any related Agreements between the Parties. The Party making such filing shall cooperate in good faith with the other Party to obtain confidential treatment of the terms and conditions of this Agreement or any related Agreements between the Parties that the other Party requests be kept confidential or otherwise afforded confidential treatment, and shall only disclose Confidential Information that it is reasonably advised by outside counsel is legally required to be disclosed. No such notice shall be required if the description of or reference to this Agreement or a related agreement between the Parties contained in the proposed filing has been included in any previous filing made by the either Party in accordance with this Section 10.6 or otherwise approved by the other Party.

10.6 Relationship to Confidentiality Agreement. This Agreement supersedes the Prior Confidentiality Agreement; provided however, that all "Confidential Information" disclosed or received by the Parties and their Affiliates thereunder shall be deemed Confidential Information hereunder and shall be subject to the terms and conditions of this Agreement.

10.7 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that could result to a Party upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 10. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 10.

ARTICLE 11.
TERM AND TERMINATION

11.1 Term. This Agreement shall become effective as of the Effective Date and shall continue, unless earlier terminated pursuant to this Article 11, in full force and effect until the tenth year from the date of the first Regulatory Approval of an NDA for the Product in a country in the Territory for the Licensed Indication (the "Initial Term"). Without prejudice to Sintetica's rights under section 11.6 (d), this Agreement may be extended at Harrow's request for an additional ten year period (the "Renewal Term(s)") provided that in any year of the Initial Term at least 100,000 units of Product are sold annually within the Territory by Harrow. The Initial Term and the Renewal Term(s) shall constitute the term of this Agreement (the "Term").

11.2 Termination for Material Breach. Either Party (the "Non-Breaching Party") may terminate this Agreement in the event the other Party (the "Breaching Party") has materially breached this Agreement and such material breach has not been cured within ninety (90) days after receipt of written notice of such breach by the Breaching Party from the Non-Breaching Party (the "Cure Period"). The written notice describing the alleged material breach shall provide sufficient detail to put the Breaching Party on notice of such material breach. Any termination of this Agreement pursuant to this Section 11.2 shall become effective at the end of the Cure Period, unless the Breaching Party has cured any such material breach prior to the expiration of such Cure Period, or, if such material breach is not susceptible to cure within the Cure Period, then, such Cure Period shall be extended for an additional ninety (90) days so long as the Breaching Party continues to use Commercially Reasonable Efforts to cure such material breach during such extension period and only if and for so long as the Breaching Party has provided to the Non-Breaching Party a written plan that is reasonably calculated to effect a cure of such material breach, such plan is accepted by the Non-Breaching Party (such acceptance not to be unreasonably withheld, conditioned, or delayed), and the Breaching Party commits to and carries out such plan as provided to the Non-Breaching Party. The right of either Party to terminate this Agreement as provided in this Section 11.3 shall not be affected in any way by such Party's waiver of or failure to take action with respect to any previous breach under this Agreement.

11.3 Termination for Bankruptcy.

(a) Either Party may terminate this Agreement in its entirety upon providing written notice to the other Party on or after the time that such other Party makes a general assignment for the benefit of creditors, files an insolvency petition in bankruptcy, petitions for or acquiesces in the appointment of any receiver, trustee or similar officer to liquidate or conserve its business or any substantial part of its assets, commences under the laws of any jurisdiction any proceeding involving its insolvency, bankruptcy, reorganization, adjustment of debt, dissolution, liquidation or any other similar proceeding for the release of financially distressed debtors, or becomes a party to any proceeding or action of the type described above, and such proceeding or action remains un-dismissed or un-stayed for a period of more than sixty (60) days.

(b) All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code and other similar laws in any jurisdiction outside the U.S. (collectively, the "Bankruptcy Laws"), licenses of rights to "intellectual property" as defined under the Bankruptcy Laws. If a case is commenced during the Term by or against a Party under Bankruptcy Laws then, unless and until this Agreement is rejected as provided pursuant to such Bankruptcy Laws, such Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 trustee) shall perform all of the obligations in this Agreement intended to be performed by such Party. If a case is commenced during the Term by or against a Party under the Bankruptcy Laws, this Agreement is rejected as provided for under the Bankruptcy Laws, and the non-bankrupt Party elects to retain its rights hereunder as provided for under the Bankruptcy Laws, then the Party subject to such case under the Bankruptcy Laws (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 trustee), shall provide to the non-bankrupt Party copies of all Patents and Information necessary for the non-bankrupt Party to prosecute, maintain and enjoy its rights under the terms of this Agreement. All rights, powers and remedies of the non-bankrupt Party as provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Laws) in the event of the commencement of a case by or against a Party under the Bankruptcy Laws. In particular, it is the intention and understanding of the Parties to this Agreement that the rights granted to the Parties under this Section 11.3 are essential to the Parties' respective businesses and the Parties acknowledge that damages are not an adequate remedy. The Parties acknowledge and agree that the milestone payments made under Article 8 shall not (i) constitute royalties within the meaning of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, or (ii) relate to licenses of intellectual property hereunder.

11.4 Termination by Harrow for Safety Reasons. Harrow shall have the right to terminate this Agreement at any time upon providing thirty (30) days prior written notice to Sintetica: (a) if senior executives responsible for Harrow's pharmacovigilance and clinical science functions determine in good faith after consultation with, and receipt of a written communication from: (a) a Regulatory Authority; or (b) an independent medical advisor that the risk/benefit profile of the Product is such that the Product cannot continue to be Developed or Commercialized or administered to patients safely; or (b) upon the occurrence of serious adverse events related to the use of the Product that after consultation with, and receipt of a written communication from: (a) a Regulatory Authority; or (b) an independent medical advisor cause Harrow to conclude that the continued use of the Product by patients will result in patients being exposed to a product in which the risks outweigh the benefits. During the thirty (30) day notice period, the Parties shall begin to wind-down their respective activities under the Agreement to the extent related to the Product.

11.5 Termination by Harrow for Patent Reasons. Harrow shall have the right to terminate this Agreement in accordance with the reasons as set forth in the last sentence of Section 8.7(c).

11.6 Termination by Sintetica. Sintetica shall have the right to terminate this Agreement at any time by giving prior written notice to Harrow;

(a) if Harrow Develops or Commercializes in the Territory any Competing Product in the Field, or if it purchases any Product sourced from a Third Party in breach of its obligations under this Agreement; for the avoidance of doubt Harrow's Purchases of Product from a Third Party resulting from a Material Delivery Delay shall not entitle Sintetica to terminate pursuant to this Section 11.6(a);

(b)

(i) if Harrow has not launched the Product in any country in the Territory (x) within one (1) year of the relative Regulatory Approval of the NDA unless such delay is due to the lack of Product or (y) because Harrow has received an infringement patent opinion as contemplated in Section 5.3, or

(ii) if an approved NDA is not maintained by Harrow,

provided that, in each of cases (i) and (ii), such conditions or events are not a result of, or directly caused by, a lack of support from Sintetica as set forth in Article 4 or Sintetica's Supply Failure as set forth in Article 6, or any material breach by Sintetica of any obligation under this Agreement;

(c)

(i) if the filing of an NDA is delayed more than the 30-month period set forth in Section 3.2 for Harrow additional development activities as contemplated in such Section, or

(ii) if any competent Government Authorities has refused to issue any required Regulatory Approvals for reasons relating solely to the development activities carried out by or for Harrow as contemplated in Section 3.2;

(d) if Harrow fails to purchase any MAQs as required for any calendar year of the Term; and

(e) if any action of any Government Authorities forces the general cessation of Harrow's selling and marketing activities of pharmaceutical products.

In cases (a), (b)(i)(y), (c) or (e), termination shall be effective immediately upon Harrow receipt of Sintetica termination notice. In the other cases termination shall be effective sixty (60) days after Harrow receipt of termination notice if the condition giving rise to such termination has not been fully cured by Harrow within such thirty (60) day period. For the avoidance of doubt, Harrow's failure to Commercialize the Product in Canada shall only give rise to Sintetica's ability to terminate Harrow's rights with respect to Canada only, and Harrow's rights in the USA shall continue without interruption.

11.7 Effects of Termination. All of the following effects of termination are in addition to the other rights and remedies that may be available to either of the Parties under this Agreement and shall not be construed to limit any such rights or remedies. In the event of expiration or termination of this Agreement:

(i) notwithstanding anything contained in this Agreement to the contrary, all rights and licenses granted herein to Harrow shall terminate and Harrow shall cease any and all Development, Commercialization activities and Regulatory Activities with respect to the Product in the Territory, as soon as reasonably practical in accordance with Applicable Law;

(ii) Harrow shall assign all rights in the NDAs to Sintetica unless termination is by Harrow under Section 11.2 or 11.3, for which Harrow shall retain ownership of the NDAs;

(iii) Except as set forth in 11.7(v), all payment obligations hereunder shall terminate, other than those that are accrued and unpaid as of the effective date of such termination;

(iv) All milestone payments already paid or accrued prior to termination or expiration shall remain, respectively, non-refundable or due and payable;

(v) Notwithstanding 11.7(iii), for any and all terminations by Sintetica under Section 11.2, or Section 11.3, Section 11.6(a), Section 11.6(d) or Section 11.6(e), all net sales milestones set forth in Section 7.3 shall become immediately due and payable, as shall the first regulatory milestone set forth in Section 7.2 if Sintetica has already made the PDUFA filing fee payment pursuant to Section 4.2.

(vi) Harrow shall have the right to sell or otherwise dispose of any inventory of the Product on hand at the time of such termination, subject to Harrow making any payments to Sintetica in accordance with Section 7.3 or Section 7.4;

(vii) Sintetica shall have the right to assume activities under Sections 8.6(b) and 8.8(b) with respect to Sintetica Patents; and

(viii) Each party shall be free to exploit its rights in all Joint Patents as it sees fit without any obligation or accounting to the other Party.

11.8 Survival. In the event of termination of this Agreement, in addition to the provisions of this Agreement that continue in effect in accordance with their terms, the following provisions of this Agreement shall survive: Articles 1, 7 (but only to the extent relating to milestone events occurring on or prior to the date of termination or for sales of Product pursuant to Section 11.7(vi)), 9, 10, 11, 12, 13 (solely as to activities arising during the Term), and 14 and Sections 2.2, 3.4, 4.5, 7.6, 8.1, 8.2 (with respect to any disclosure obligations that arise on or prior to termination), 8.3(a)and 3.2 (for both such Sections, solely as to the licenses granted therein which shall survive the Term), 8.3(c), 8.3(d)(ii), 8.3(d)(iii) and 8.6(d) (to the extent any suit or action under that section is still pending upon termination).

11.9 Remedies**.** Notwithstanding anything to the contrary in this Agreement, except as otherwise set forth in this Agreement, termination or expiration of this Agreement shall not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration, nor prejudice either Party's right to obtain performance of any obligation.

ARTICLE 12.
DISPUTE RESOLUTION

12.1 Exclusive Dispute Resolution Mechanism. The Parties agree that, except for Disputes regarding nonconforming or defective Product as set forth in Section 6.10, the procedures set forth in this Article 12 shall be the exclusive mechanism for resolving any Dispute (as defined below). Notwithstanding the foregoing, any for any Dispute regarding nonconforming or defective Product as set forth in Section 6.10 for which the independent laboratory is unable to make a determination resolving the Dispute using the procedure described in such Section, the other procedures set forth in this Article 12 shall then be the exclusive mechanism for resolving such Dispute.

12.2 Mediation. Any dispute, controversy or claim arising out of or relation to this contract (a ***"Dispute")***, including the validity, invalidity, breach or termination thereof, shall be submitted to mediation in accordance with the Rules of Mediation of the London Court of International Arbitration (***"LCAI"***) in force on the date when the request for mediation was submitted in accordance with these Rules. The seat of the mediation shall be in London, England. The mediation shall be conducted in English.

12.3 Arbitration. Any Dispute which has not been fully resolved by mediation within sixty (60) days from the date when the mediator(s) has (have) been confirmed or appointed by LCAI, shall be finally settled by arbitration conducted in accordance with the London Court of International Arbitration Rules in force at the time the request for arbitration is filed. The arbitral tribunal shall be composed of one arbitrator. The arbitration shall be in English language and shall be held in London, England. The expenses of the arbitration shall be borne by the losing party as determined by arbitration, except in the case of a settlement, in which case the parties shall share between themselves such expenses as agreed to in the settlement agreement.

12.4 Preliminary Injunctions. Notwithstanding anything in this Agreement to the contrary, a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis.

12.5 Patent and Trademark Disputes. Notwithstanding anything in this Agreement to the contrary, any and all issues regarding the scope, construction, validity, and enforceability of any Patent or trademark relating to Product that is the subject of this Agreement shall be determined in a court or other tribunal, as the case may be, of competent jurisdiction under the applicable patent or trademark laws of the country in which such Patent or trademark rights were granted or arose.

12.6 Confidentiality. Any and all activities conducted under this Article 12, including any and all proceedings and decisions under Sections 12.3 or 12.5, shall be deemed Confidential Information of each of the Parties, and shall be subject to Article 10.

ARTICLE 13.
INDEMNIFICATION

13.1 Indemnification by Harrow. Harrow hereby agrees to defend, indemnify and hold harmless Sintetica and its Affiliates, and each of their respective directors, officers, employees, agents and representatives (each, an "Sintetica Indemnitee") from and against any and all claims, suits, actions, demands, liabilities, expenses and/or losses, including reasonable legal expenses and attorneys' fees (collectively, the "Losses"), to which any Sintetica Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party (each, a "Claim") to the extent such Losses arise directly or indirectly out of: (a) the practice by Harrow or sublicensee of any license granted to it under Article 2; (b) the use, handling, storage, sale marketing, export, import or other disposition of Product by Harrow or sublicensees or subcontractors, including any Product Liabilities; (c) the material breach by Harrow of any warranty, representation, covenant or agreement made by Harrow in this Agreement; and (d) the gross negligence, or willful misconduct (including to the extent such gross negligence or willful misconduct gives rise to any Product Liabilities under any legal theory) of Harrow or sublicensee, or any officer, director, employee, agent or representative thereof; except, with respect to each of subsections (a) through (d) above, to the extent such Losses arise directly or indirectly from the gross negligence or willful misconduct of any Sintetica Indemnitee or the breach by Sintetica of any warranty, representation, covenant or agreement made by Sintetica in this Agreement.

13.2 Indemnification by Sintetica. Sintetica hereby agrees to defend, indemnify and hold harmless Harrow and its Affiliates and each of their respective directors, officers, employees, agents and representatives (each, a "Harrow Indemnitee") from and against any and all Losses to which any Harrow Indemnitee may become subject as a result of any Claim to the extent such Losses arise directly or indirectly out of: (a) the material breach by Sintetica of any warranty, representation, covenant or agreement made by Sintetica in this Agreement; and (b) the gross negligence or willful misconduct (including to the extent such gross negligence, or willful misconduct gives rise to any Product Liability under any legal theory) of Sintetica, or any officer, director, employee, agent or representative thereof; except, with respect to each of subsections (a) through (b) above, to the extent such Losses arise directly or indirectly from the gross negligence or willful misconduct of any Harrow Indemnitee or the breach by Harrow of any warranty, representation, covenant or agreement made by Harrow in this Agreement.

13.3 Indemnification Procedures.

(a) **Notice.** Promptly after a Sintetica Indemnitee or a Harrow Indemnitee (each, an "Indemnitee") receives notice of a pending or threatened Claim, such Indemnitee shall give written notice of the Claim to the Party from whom the Indemnitee is entitled to receive indemnification pursuant to Sections 13.1 or 13.2, as applicable (the "Indemnifying Party"). However, an Indemnitee's delay in providing or failure to provide such notice will not relieve the Indemnifying Party of its indemnification obligations, except to the extent it can demonstrate prejudice due to the delay or lack of notice.

(b) **Defense.** Upon receipt of notice under Section 13.3 from the Indemnitee, the Indemnifying Party shall have the duty to either compromise or defend, at its own expense and by counsel (reasonably satisfactory to Indemnitee), such Claim. The Indemnifying Party shall promptly (and in any event not more than twenty (20) days after receipt of the Indemnitee's original notice) notify the Indemnitee in writing that it acknowledges its obligation to indemnify (which notice shall not be deemed or construed to be an admission of liability, either under this Article 13 or otherwise) the Indemnitee with respect to the Claim pursuant to this Section 13.3 and of its intention either to compromise or defend such Claim. Once the Indemnifying Party gives such notice to the Indemnitee, the Indemnifying Party is not liable to the Indemnitee for the fees of other counsel or any other expenses subsequently incurred by the Indemnitee in connection with such defense, other than the Indemnitee's reasonable expenses of investigation and cooperation. However, the Indemnitee shall have the right to employ separate counsel and to control the defense of a Claim at its own expense.

(c) **Cooperation.** The Indemnitee shall cooperate fully with the Indemnifying Party and its legal representatives in the investigation and defense of any Claim. The Indemnifying Party shall keep the Indemnitee informed on a reasonable and timely basis as to the status of such Claim (to the extent the Indemnitee is not participating in the defense of such Claim) and conduct the defense of such Claim in a prudent manner.

(d) **Settlement.** If an Indemnifying Party assumes the defense of a Claim, no compromise or settlement of such Claim may be effected by the Indemnifying Party without the Indemnitee's written consent (such consent not to be unreasonably withheld, delayed or conditioned). Notwithstanding the foregoing, the Indemnitee's consent shall not be required of a settlement where: (i) there is no finding or admission of any violation of law or any violation of the rights of any person and no effect on any other claims that may be made against the Indemnitee; (ii) the sole relief provided is monetary damages that are paid in full by the Indemnifying Party; and (iii) the Indemnitee's rights under this Agreement are not adversely affected. If the Indemnifying Party fails to assume defense of a Claim within a reasonable time, the Indemnitee may settle such Claim on such terms as it deems appropriate with the consent of the Indemnifying Party (such consent not to be unreasonably withheld, delayed or conditioned), and the Indemnifying Party shall be obligated to indemnify the Indemnitee for such settlement as provided in this Article 13.

13.4 Insurance. Each Party shall, at its own expense, procure and maintain during the Term and for a period of five (5) years thereafter, insurance policy/policies, including product liability insurance, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated; provided, that each Party shall procure and maintain a minimum $5,000,000 Commercial and General Liability and $5,000,000 Product Liability. Such insurance shall not be construed to create a limit of a Party's liability with respect to its indemnification obligations under this Article 13. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with prompt written notice of cancellation, non-renewal or material change in such insurance that could materially adversely affect the rights of such other Party hereunder, and shall provide such notice within thirty (30) days after any such cancellation, non-renewal or material change.

13.5 Limitation of Liability. EXCEPT FOR A PARTY'S INDEMNIFICATION OBLIGATIONS SET FORTH IN THIS ARTICLE 13, AND ANY BREACH OF ARTICLE 10 (CONFIDENTIALITY)**,** IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY (OR THE OTHER PARTY'S AFFILIATES OR SUBLICENSEES) IN CONNECTION WITH THIS AGREEMENT FOR LOST REVENUE, LOST PROFITS, LOST SAVINGS, LOSS OF USE, DAMAGE TO GOODWILL, OR ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR INDIRECT DAMAGES UNDER ANY THEORY, INCLUDING CONTRACT, NEGLIGENCE, OR STRICT LIABILITY, EVEN IF THAT PARTY HAS BEEN PLACED ON NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

ARTICLE 14.
MISCELLANEOUS

14.1 Designation of Affiliates. Each Party may discharge any obligations and exercise any rights hereunder through delegation of its obligations or rights to any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

14.2 Notices. All notices and other communications given or made pursuant hereto shall be in writing and shall be deemed to have been duly given on the date delivered, if delivered personally, or on the second Business Day after being sent by reputable overnight courier (with delivery tracking provided, signature required and delivery prepaid), in each case, to the parties at the following addresses, or on the date sent and confirmed by electronic transmission to the telecopier number specified below or confirmatory return email to the email address specified below (or at such other address, telecopier number or email address for a party as shall be specified by notice given in accordance with this Section 14.2).

If to Harrow:

Harrow Health, Inc.
102 Woodmont Blvd., Suite 610
Nashville, TN 37205 USA
Attention: CFO

with copies to:

Polsinelli PC
100 N. 4th Street
Suite 1000
St. Louis, MO 63102

Attn: Andrew M. Solomon
Email: asolomon@polsinelli.com

If to Sintetica:

Sintetica S.A.
Via Penate 5
6850 Mendrisio, Switzerland
Attn: CEO

with copies to:

Sintetica S.A.
Via Penate 5
6850 Mendrisio, Switzerland
Attn: Legal Affairs

14.3 Force Majeure. A Party shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by Force Majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting Force Majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a Force Majeure affecting such Party. If a Force Majeure persists for more than ninety (90) days, then the Parties shall discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such Force Majeure, without prejudice to the rights set forth in Section 11.3. The Parties agree the effects of the COVID-19 pandemic that is ongoing as of the Effective Date (including related government orders) may be invoked as a Force Majeure for the purposes of this Agreement even though the pandemic is ongoing and those effects may be reasonably foreseeable (but are not known for certain) as of the Effective Date. In addition, a Force Majeure may include reasonable measures affirmatively taken by a Party to respond to any epidemic, pandemic, or spread of infectious disease (including the COVID-19 pandemic), such as requiring employees to stay home, closures of facilities, delays of Clinical Trials, or cessation of activities in response to an epidemic or other Force Majeure event.

14.4 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment without the other Party's consent to Affiliates or to a successor to substantially all of the business of such Party to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other transaction. Any successor or assignee of rights and/or obligations permitted hereunder shall, in writing to the other Party, expressly assume performance of such rights and/or obligations. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section shall be null, void and of no legal effect.

14.5 Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

14.6 English Language. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement, shall be in the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

14.7 Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

14.8 Further Assurance. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof.

14.9 Relationship of the Parties. It is expressly agreed that Sintetica, on the one hand, and Harrow, on the other hand, shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency, including for tax purposes. Neither Sintetica nor Harrow shall have the authority to make any statements, representations or commitments of any kind, or to take any action which shall be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of that Party and not of the other Party and all expenses and obligations incurred by reason of such employment shall be for the account and expense of such Party.

14.10 Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural shall include the singular, and the use of any gender shall be applicable to all genders. Whenever this Agreement refers to a number of days without using a term otherwise defined herein, such number refers to calendar days. The captions of this Agreement are for the convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The terms “including,” “include,” “includes” or “for example” shall not limit the generality of any description preceding such term and as used herein shall have the same meaning as “including, but not limited to” or “including, without limitation.” The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

14.11 Governing Laws. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof shall be governed by and construed under the laws of the State of Delaware, USA without giving effect to any choice of law principles that would require the application of the laws of a different state.

14.12 Entire Agreement. This Agreement, including all Exhibits to this Agreement, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof; provided, that the Prior Confidentiality Agreement shall continue in full force and effect in accordance with its terms. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party. In the event of any inconsistency between the body of this Agreement and either any Exhibits to this Agreement or any subsequent agreements ancillary to this Agreement, unless otherwise expressly stated to the contrary in such Exhibit or ancillary agreement, the terms contained in this Agreement shall control.

14.13 Headings. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

14.14 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile, .pdf or other electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were the original signatures.

SIGNATURE PAGE FOLLOWS

IN WITNESS WHEREOF, the Parties have caused this Agreement to be signed by their duly authorized representatives as of the date indicated below.

HARROW HEALTH, INC.

By: */s/ Mark Baum*
Name: Mark Baum
Title: Chief Executive Offiver
Date: 7/24/2021

SINTETICA S.A.

By: */s/ Miro Venturi*
Name: Miro Venturi
Title: Corporate CEO
Date: 7/25/2021

SINTETICA S.A.

By: */s/ Rocco Arcidiacono*
Name: Rocco Arcidiacono
Title: Member of the Board
Date: 7/25/2021

EXHIBIT 31.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER UNDER
SECTION 302 OF THE SARBANES-OXLEY ACT

I, Mark L. Baum, certify that:

(1) I have reviewed this quarterly report on Form 10-Q of Harrow Health, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: August 10, 2021

/s/ Mark L. Baum

Mark L. Baum
Chief Executive Officer
Principal Executive Officer

EXHIBIT 31.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER UNDER
SECTION 302 OF THE SARBANES-OXLEY ACT

I, Andrew R. Boll, certify that:

(1) I have reviewed this quarterly report on Form 10-Q of Harrow Health, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: August 10, 2021

/s/ Andrew R. Boll

Andrew R. Boll
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION REQUIRED BY
SECTION 1350 OF TITLE 18 OF THE UNITED STATES CODE

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned hereby certifies in his capacity as the specified officer of Harrow Health, Inc. (the "Company"), that, to the best of his knowledge, the Quarterly Report of the Company on Form 10-Q for the fiscal quarter ended June 30, 2021 fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods presented in the financial statements included in such report.

Date: August 10, 2021

/s/ Mark L. Baum
Mark L. Baum *Chief Executive Officer*
(Principal Executive Officer)

Date: August 10, 2021

/s/ Andrew R. Boll
Andrew R. Boll *Chief Financial Officer*
(Principal Financial and Accounting Officer)

This certification accompanies this Report on Form 10-Q pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.