

**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 September 30, 2019

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

(State or other jurisdiction of
incorporation or organization)

45-0567010

(I.R.S. Employer
Identification No.)

**102 Woodmont Blvd., Suite 610
Nashville, Tennessee**

(Address of principal executive offices)

37205

(Zip code)

(858) 704-4040

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) 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 small reporting company, or an emerging growth company.

Large accelerated filer
Non-accelerated filer

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

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 Capital Market

As of November 12, 2019, there were 25,172,931 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)**

	September 30, 2019 <u>(unaudited)</u>	December 31, 2018 <u></u>
ASSETS		
Current assets		
Cash and cash equivalents, including restricted cash of \$200	\$ 3,631	\$ 6,838
Investment in Eton Pharmaceuticals	22,120	21,420
Accounts receivable, net	2,815	1,914
Inventories	2,443	1,834
Prepaid expenses and other current assets	1,365	837
Total current assets	<u>32,374</u>	<u>32,843</u>
Property, plant and equipment, net	5,202	6,375
Operating lease right-of-use assets	5,939	-
Intangible assets, net	2,291	3,059
Investment in Surface Pharmaceuticals	4,043	4,947
Investment in Melt Pharmaceuticals	4,517	-
Goodwill	332	2,227
TOTAL ASSETS	<u><u>\$ 54,698</u></u>	<u><u>\$ 49,451</u></u>
LIABILITIES AND EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 8,144	\$ 6,250
Accrued payroll and related liabilities	1,728	2,283
Deferred revenue and customer deposits	48	119
Current portion of note payable, net of unamortized debt discount	1,007	2,529
Current portion of operating lease obligations	496	-
Current portion of finance lease obligations, net of unamortized discount	5	720
Total current liabilities	<u>11,428</u>	<u>11,901</u>
Operating lease obligations, net of current portion	5,849	-
Finance lease obligations, net of current portion and unamortized discount	29	-
Accrued expenses, net of current portion	800	800
Note payable, net of current portion and unamortized debt discount	12,865	11,999
TOTAL LIABILITIES	<u><u>30,971</u></u>	<u><u>24,700</u></u>
Commitments and contingencies		
STOCKHOLDERS' EQUITY		
Common stock, \$0.001 par value, 50,000,000 shares authorized, 25,168,841 and 24,339,610 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	25	24
Additional paid-in capital	100,630	98,938
Accumulated deficit	(76,700)	(74,211)
TOTAL HARROW HEALTH STOCKHOLDERS' EQUITY	<u>23,955</u>	<u>24,751</u>
Noncontrolling interests	(228)	-
TOTAL EQUITY	<u><u>23,727</u></u>	<u><u>24,751</u></u>
TOTAL LIABILITIES AND EQUITY	<u><u>\$ 54,698</u></u>	<u><u>\$ 49,451</u></u>

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 September 30, 2019	For the Three Months Ended September 30, 2018	For the Nine Months Ended September 30, 2019	For the Nine Months Ended September 30, 2018
Revenues:				
Sales, net	\$ 12,748	\$ 10,729	\$ 38,540	\$ 29,958
License revenues	7	10	21	30
Total revenues	12,755	10,739	38,561	29,988
Cost of sales	(4,061)	(4,191)	(13,184)	(12,419)
Gross profit	8,694	6,548	25,377	17,569
Operating expenses:				
Selling, general and administrative	8,608	6,964	25,399	20,231
Research and development	444	233	1,659	392
Impairment and disposal of long-lived assets	4,040	-	4,040	-
Total operating expenses	13,092	7,197	31,098	20,623
Loss from operations	(4,398)	(649)	(5,721)	(3,054)
Other income (expense):				
Interest expense, net	(620)	(705)	(1,939)	(2,039)
Investment gain (loss) from Melt Pharmaceuticals, net	(682)	-	4,517	-
Investment gain (loss) from Surface Pharmaceuticals, net	(400)	(128)	(904)	5,090
Investment gain (loss) from Eton Pharmaceuticals, net	(5,530)	(1,032)	700	(3,247)
Other income (expense), net	-	-	630	(255)
Total other income (expense), net	(7,232)	(1,865)	3,004	(451)
Income tax benefit, net	-	-	-	-
Total net loss including noncontrolling interests	(11,630)	(2,514)	\$ (2,717)	\$ (3,505)
Net loss attributable to noncontrolling interests	161	-	228	-
Net loss attributable to Harrow Health, Inc.	\$ (11,469)	\$ (2,514)	\$ (2,489)	\$ (3,505)
Basic and diluted net loss per share of common stock	\$ (0.45)	\$ (0.12)	\$ (0.10)	\$ (0.16)
Weighted average number of shares of common stock outstanding, basic and diluted	25,583,998	21,709,392	25,205,215	21,283,078

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

HARROW HEALTH, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the periods ended September 30, 2019 and 2018
(In thousands, except for share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Harrow Health, Inc. Stockholders' Equity	Total Noncontrolling Interest Equity	Total Stockholders' Equity
	Shares	Par Value					
	Balance at June 30, 2018	21,049,448					
Issuance of common stock in connection with:							
Exercise of warrants	1,606,735	2	2,642	-	2,644	-	2,644
Sale of stock, net of costs (ATM)	-	-	1	-	1	-	1
Stock-based compensation expense	-	-	590	-	590	-	590
Net loss	-	-	-	(2,514)	(2,514)	-	(2,514)
Balance at September 30, 2018	<u>22,656,183</u>	<u>\$ 23</u>	<u>\$ 96,771</u>	<u>\$ (92,341)</u>	<u>\$ 4,453</u>	<u>\$ -</u>	<u>\$ 4,453</u>

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Harrow Health, Inc. Stockholders' Equity	Total Noncontrolling Interest Equity	Total Stockholders' Equity
	Shares	Par Value					
	Balance at June 30, 2019	25,138,958					
Issuance of common stock in connection with:							
Exercise of warrants	25,135	-	-	-	-	-	-
Exercise of employee stock-based options, net of tax withholding	4,748	-	(44)	-	(44)	-	(44)
Stock-based payment for services provided	-	-	75	-	75	-	75
Stock-based compensation expense	-	-	328	-	328	-	328
Net loss	-	-	-	(11,469)	(11,469)	(161)	(11,630)
Balance at September 30, 2019	<u>25,168,841</u>	<u>\$ 25</u>	<u>\$ 100,630</u>	<u>\$ (76,700)</u>	<u>\$ 23,955</u>	<u>\$ (228)</u>	<u>\$ 23,727</u>

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Harrow Health, Inc. Stockholders' Equity	Total Noncontrolling Interest Equity	Total Stockholders' Equity
	Shares	Par Value					
	Balance at December 31, 2017	20,623,129					
Issuance of common stock in connection with:							
Exercise of warrants	1,606,735	2	2,642	-	2,644	-	2,644
Vesting of RSUs, net of tax withholding	60,000	-	-	-	-	-	-
Sale of stock, net of costs (ATM)	305,619	-	641	-	641	-	641
Stock-based payment for services provided	60,700	-	108	-	108	-	108
Stock-based compensation expense	-	-	1,950	-	1,950	-	1,950
Net loss	-	-	-	(3,505)	(3,505)	-	(3,505)
Balance at September 30, 2018	<u>22,656,183</u>	<u>\$ 23</u>	<u>\$ 96,771</u>	<u>\$ (92,341)</u>	<u>\$ 4,453</u>	<u>\$ -</u>	<u>\$ 4,453</u>

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Harrow Health, Inc. Stockholders' Equity	Total Noncontrolling Interest Equity	Total Stockholders' Equity
	Shares	Par Value					
	Balance at December 31, 2018	24,339,610					
Issuance of common stock in connection with:							
Exercise of warrants	788,528	1	178	-	179	-	179
Exercise of employee stock-based options, net of tax withholding	25,703	-	(44)	-	(44)	-	(44)
Stock-based payment for services provided	15,000	-	150	-	150	-	150
Stock-based compensation expense	-	-	1,408	-	1,408	-	1,408
Net loss	-	-	-	(2,489)	(2,489)	(228)	(2,717)
Balance at September 30, 2019	<u>25,168,841</u>	<u>\$ 25</u>	<u>\$ 100,630</u>	<u>\$ (76,700)</u>	<u>\$ 23,955</u>	<u>\$ (228)</u>	<u>\$ 23,727</u>

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 Nine Months Ended September 30, 2019	For the Nine Months Ended September 30, 2018
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (2,717)	\$ (3,505)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization of property, plant and equipment	1,365	1,223
Amortization of intangible assets	175	176
Amortization of operating lease right-of-use assets	386	-
Amortization of debt issuance costs and discount	394	466
Investment (gain)/loss from Eton	(700)	3,247
Investment (gain)/loss from Melt	(4,517)	-
Investment (gain)/loss from Surface	904	(5,090)
Loss on sale, impairments and disposal of assets	4,013	393
Stock-based payment for services provided	150	-
Stock-based compensation expense	1,408	1,950
Changes in assets and liabilities, net of impairments and disposals:		
Accounts receivable	(901)	(202)
Inventories	(1,413)	(275)
Prepaid expenses and other current assets	(528)	(400)
Accounts payable, accrued expenses, and other liabilities	1,721	2,153
Accrued payroll and related liabilities	(371)	518
Deferred revenue and customer deposits	(71)	69
NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES	(702)	723
CASH FLOWS FROM INVESTING ACTIVITIES		
Repayment of note receivable	-	4
Proceeds on sale and disposal of assets	4	-
Investment in patent and trademark assets	(279)	(283)
Purchases of property, plant and equipment	(589)	(1,068)
NET CASH USED IN INVESTING ACTIVITIES	(864)	(1,347)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payments on capital lease obligations	(744)	(512)
Payments on Park deferred acquisition obligation	-	(53)
Principal payments on note payable	(750)	-
Payments of costs related to amendment of note payable	(282)	-
Net proceeds from ATM sales of common stock	-	642
Net proceeds from exercise of warrants and stock options, net of taxes remitted for RSU and options	135	2,643
NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES	(1,641)	2,720
NET CHANGE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(3,207)	2,096
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, beginning of period	6,838	4,219
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, end of period	\$ 3,631	\$ 6,315
RECONCILIATION OF CASH, CASH EQUIVALENTS AND RESTRICTED CASH		
Cash and cash equivalents	\$ 3,431	\$ 6,115
Restricted cash	200	200
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD	\$ 3,631	\$ 6,315
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for income taxes	\$ 11	\$ 4
Cash paid for interest	\$ 1,546	\$ 1,006
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Issuance of stock and stock options for consulting services included in accounts payable and accrued expenses	\$ -	\$ 108

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

HARROW HEALTH, INC.
NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
For the three and nine months ended September 30, 2019 and 2018
(Dollar amounts in thousands, except share and per share data)

NOTE 1. DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION

Company and Background

Harrow Health, Inc. (together with its consolidated subsidiaries, unless the context indicates or otherwise requires, the “Company”, “Harrow” or “We”) 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, LLC (“ImprimisRx”). In addition to wholly owning ImprimisRx, the Company also has equity positions in Eton Pharmaceuticals, Inc. (“Eton”), Surface Pharmaceuticals, Inc. (“Surface”), and Melt Pharmaceuticals, Inc. (“Melt”). More recently, the Company founded its subsidiaries Mayfield Pharmaceuticals, Inc. (“Mayfield”), Radley Pharmaceuticals, Inc. (“Radley”), and Stowe Pharmaceuticals, Inc. (“Stowe”). The Company owns royalty rights in certain 505(b)(2) drug candidates being developed by Surface, Melt, Radley and Mayfield. Harrow intends to continue to create, found, and hold equity and royalty rights in, new businesses that commercialize drug candidates that are internally developed or otherwise acquired or licensed from third parties.

As discussed in more detail in Note 2, in August 2019, the Company restructured its Park Compounding, Inc. (“Park”) business, ceased operations at its Irvine, California-based pharmacy, and facilitated the transition of certain compounded formulations and related equipment from Park to the Company’s New Jersey-based compounded pharmaceutical production facilities (the “Park Restructuring”). Going forward, all compounding business is expected to be consolidated into the Company’s ImprimisRx business.

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 with the instructions to Form 10-Q and Article 8 of Regulation S-X. 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 nine months ended September 30, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2019 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, 2018.

The consolidated financial statements include the accounts of Harrow and its wholly owned subsidiaries, as well as Mayfield and Stowe, 70% majority controlled subsidiaries of Harrow, as of September 30, 2019. The remaining 30% of Mayfield is owned by Elle Pharmaceutical, LLC (“Elle”), TGV-Health, LLC and affiliated entities (collectively “TGV”) or other consultants. Mayfield was organized to develop women’s health-focused drug candidates. The remaining 30% of Stowe is owned by TGV. Stowe was organized to develop ophthalmic drug candidates. All inter-company accounts and transactions have been eliminated in consolidation.

Harrow consolidates entities in which we have a controlling financial interest. We consolidate subsidiaries in which we hold and/or control, directly or indirectly, more than 50% of the voting rights.

The condensed consolidated balance sheets at September 30, 2019 and December 31, 2018 and the condensed consolidated statements of operations, stockholders’ equity and cash flows for the periods ended September 30, 2019 include our accounts and those of our wholly owned subsidiaries as well as Mayfield and Stowe. The condensed consolidated statements of operations, stockholders’ equity and cash flows for the periods ended September 30, 2018 include our accounts and those of our wholly owned subsidiaries.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The following represents an update for the three and nine months ended September 30, 2019 to the significant accounting policies described in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

Liquidity

The Company has incurred significant operating losses and negative cash flows from operations since its inception. The Company incurred net losses of \$2,489 and \$3,505 for the nine months ended September 30, 2019 and 2018, respectively, and had an accumulated deficit of \$76,700 and \$74,211 as of September 30, 2019 and December 31, 2018, respectively. In addition, the Company used cash in operating activities of \$702 for the nine months ended September 30, 2019, while during the nine months ended September 30, 2018, operating activities provided cash of \$723.

While there is no assurance, management of the Company believes existing cash resources and restricted cash of \$3,631 at September 30, 2019, will be sufficient to sustain the Company's planned level of operations for at least the next twelve months. However, estimates of operating expenses and working capital requirements could be incorrect, and the Company could use its cash resources faster than anticipated. Further, some or all of the ongoing or planned activities may not be successful and could result in further losses.

The Company may seek to increase liquidity and capital resources through a variety of means which may include, but are not limited to: the sale of assets, investments and/or businesses, obtaining financing through the issuance of equity, debt, or convertible securities; and working to increase revenue growth through sales. There is no guarantee that the Company will be able to obtain capital when needed on terms management deems acceptable, or at all.

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 presented on as operating segments. The Company has identified two operating segments as reportable segments. See Note 15 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 income (loss) attributable to noncontrolling interests in consolidated net income (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 loss attributable to common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted loss per share is computed by dividing the income 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 stock equivalents (using the treasury stock or “if converted” method) from deferred acquisition obligations, stock options, unvested restricted stock units (“RSUs”) and warrants were 5,263,131 and 8,387,347 at September 30, 2019 and 2018, respectively, and are excluded from the calculation of diluted net loss per share for the periods presented, 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 September 30, 2019 and 2018 was 314,588 and 202,603, respectively.

The following table shows the computation of basic net loss per share of common stock for the three and nine months ended September 30, 2019 and 2018:

	For the Three Months Ended September 30,		For the Nine months Ended September 30,	
	2019	2018	2019	2018
Numerator – net loss attributable to Harrow Health, Inc.	\$ (11,469)	\$ (2,514)	\$ (2,489)	\$ (3,505)
Denominator – weighted average number of shares outstanding, basic and diluted	25,583,998	21,709,392	25,205,215	21,283,078
Net loss per share, basic and diluted	\$ (0.45)	\$ (0.12)	\$ (0.10)	\$ (0.16)

Investment in Eton Pharmaceuticals, Inc. – Related Party

The Company owns 3,500,000 shares of Eton common stock, which represents approximately 19.7% of the equity and voting interests of Eton as of September 30, 2019. At September 30, 2019, the fair market value of Eton’s common stock was \$6.32 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*, for the three months ended September 30, 2019, the Company recorded an investment loss from its Eton common stock position of \$5,530 related to the change in fair market value of the Company’s investment in Eton during the measurement period. For the nine months ended September 30, 2019, the Company recorded an investment gain from its Eton common stock position of \$700 related to the change in fair market value of the Company’s investment in Eton during the measurement period. As of September 30, 2019, the fair market value of the Company’s investment in Eton was \$22,120.

In November 2018, the Company entered into a lock-up agreement that prohibits the sale of any of its Eton common stock until November 15, 2019 without the approval of National Securities Corporation, the underwriter of Eton’s initial public offering of its common stock.

Mark Baum, the Company’s Chief Executive Officer, is a member of the board of directors of Eton.

Investment in Melt Pharmaceuticals, Inc. – Related Party

In April 2018, the Company formed Melt as a wholly owned subsidiary. In January and March of 2019, Melt entered into definitive stock purchase agreements (collectively, the “Melt Series A Preferred Stock Agreement”) with certain investors and closed on the purchase and sale of Melt’s Series A Preferred Stock (the “Melt Series A Stock”), totaling approximately \$11,400 of proceeds (collectively the “Melt Series A Round”) at a purchase price of \$5.00 per share. As a result, the Company lost voting and ownership control of Melt and ceased consolidating Melt’s financial statements. In connection with the Melt Series A Preferred Stock Agreement, Melt also entered into a Registration Rights Agreement and agreed to use commercially reasonable efforts to file, or confidentially submit, a registration statement on Form S-1 with the United States Securities and Exchange Commission by September 30, 2020 relating to an initial public offering of its common stock.

At the time of deconsolidation, the Company recorded a gain of \$5,810 and adjusted the carrying value in Melt to reflect the increased valuation of Melt and the Company's new ownership interest in accordance with Accounting Standard Codification ("ASC") 810-10-40-4(c), *Consolidation*.

The Company owns 3,500,000 common shares (which is approximately 44% of the equity interest as of September 30, 2019) 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 of Melt in its 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 and nine months ended September 30, 2019, the Company recorded equity in net loss of Melt of \$682 and \$1,293, respectively. As of September 30, 2019, the carrying value of the Company's investment in Melt was \$4,517.

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

Investment in Surface Pharmaceuticals, Inc. – Related Party

In April 2017, the Company formed Surface as a wholly owned subsidiary. In May and July 2018, Surface entered into a definitive stock purchase agreement with an institutional investor for the purchase of Surface's Series A Preferred Stock (the "Surface Series A Stock") and closed on the sale, resulting in total proceeds to Surface of approximately \$21,000. At the time of the first closing in May 2018, the Company lost voting and ownership control of Surface and it ceased consolidating Surface's financial statements. The Surface Series A Stock (i) was issued at a purchase price of \$3.30 per share; (ii) will vote together with the common stock and all other shares of stock of Surface having general voting power; (iii) will be entitled to the number of votes equal to the number of shares of preferred stock held; (iv) will hold liquidation preference over all other equity interests in Surface; and (v) will have mandatory conversion requirements into Surface common stock upon events including an underwritten initial public offering ("IPO") of Surface common stock or similar transaction.

At the time of deconsolidation, the Company recorded a gain of \$5,320 and adjusted the carrying value in Surface to reflect the increased valuation of Surface and the Company's new ownership interest in accordance with ASC 810-10-40-4(c).

The Company owns 3,500,000 common shares (which is approximately 30% of the equity interest as of September 30, 2019) 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 of Surface in its 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 net loss of Surface of \$400 and \$904 during the three and nine months ended September 30, 2019. As of September 30, 2019, the carrying value of the Company's investment in Surface was \$4,043.

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

Park Restructuring

In August 2019, Park and Noice Rx, LLC ("Noice") terminated an Asset Purchase Agreement, dated July 26, 2019 (the "Park Purchase Agreement"), between the parties. Under the terms of the Park Purchase Agreement, Park had agreed to sell substantially all its assets associated with its non-ophthalmology pharmaceutical compounding business to Noice, including its pharmacy facility and equipment located in Irvine, California. The closing of the sale transaction was dependent on the California State Board of Pharmacy approving of the sale and issuing a temporary pharmacy and sterile license permit to Noice, which did not occur and led to Park ceasing operations at the close of business on August 27, 2019. The Company elected to restructure the Park business and facilitate the transition of certain compounded formulations and related equipment from Park to the Company's New Jersey-based compounded pharmaceutical production facilities. As a result of the Park Restructuring, the Company incurred non-cash impairment costs of approximately \$3,781 related to assets held at Park, primarily associated with property, plant, equipment, inventory, goodwill and other intangible assets, and \$405 in one-time costs related to severance packages and other costs associated with the Park Restructuring during the three and nine months ended September 30, 2019.

The Company has reduced the Park compounded product formulary to seven base formulations, based on factors including unit order volumes, revenues and gross margin percentages, and expect ImprimisRx to retain and re-acquire approximately half of Park's revenue after a transitional period within about six to twelve months.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued new lease accounting guidance in ASU No. 2016-02, *Leases* (Topic 842). This new guidance was initiated as a joint project with the International Accounting Standards Board to simplify lease accounting and improve the quality of and comparability of financial information for users. This new guidance would eliminate the concept of off-balance sheet treatment for "operating leases" for lessees for the vast majority of lease contracts. Under ASU No. 2016-02, at inception, a lessee must classify all leases with a term of over one year as either finance or operating, with both classifications resulting in the recognition of a defined "right-of-use" asset and a lease liability on the balance sheet. However, recognition in the income statement will differ depending on the lease classification, with finance leases recognizing the amortization of the right-of-use asset separate from the interest on the lease liability and operating leases recognizing a single total lease expense. Lessor accounting under ASU No. 2016-02 would be substantially unchanged from the previous lease requirements under GAAP. ASU No. 2016-02 took effect for public companies in fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. On January 1, 2019, the Company adopted Topic 842 using the modified retrospective transition method with no impact to stockholders' equity. As of September 30, 2019, the Company held on its condensed consolidated balance sheet \$5,939 for the right-of-use asset and \$6,345 for the related lease liability related to operating leases. The difference between the right of use asset and related lease liability is predominantly deferred rent and other related lease expenses under the new lease accounting standard. For additional information regarding how the Company is accounting for leases under Topic 842, refer to Note 12.

Recently Issued Accounting Pronouncements

In January 2017, the FASB issued ASU 2017-04, *Intangibles-Goodwill and Other*. This guidance simplifies the accounting for goodwill impairment for all entities by requiring impairment charges to be based on the first step in the current two-step impairment test under ASC 350. The updated standard eliminates the requirement to calculate a goodwill impairment charge using Step 2. If a reporting unit's carrying amount exceeds its fair value, an entity will record an impairment charge based on that difference. The impairment charge will be limited to the amount of goodwill allocated to that reporting unit. ASU 2017-04 is effective for reporting periods beginning after December 31, 2019 on a prospective basis, and early adoption is permitted. The Company does not expect ASU 2017-04 to have a material effect on the Company's financial position, results of operations and cash flows.

NOTE 3. REVENUES

The Company accounts for contracts with customers in accordance with ASC 606, *Revenues from Contracts with Customers*. The Company has two primary streams of revenues: (1) revenues recognized from our sale of products within our pharmacy services and (2) revenues 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. Revenues from our pharmacy services divisions 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 principle 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 be 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.

Intellectual Property License Revenues

The Company currently holds four intellectual property license and related agreements in which the Company has promised to grant a license or sale which provides 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 of time 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 nine months ended September 30, 2019 and 2018, consists of the following:

	For the Three Months Ended September 30,		For the Nine months Ended September 30,	
	2019	2018	2019	2018
Product sales, net	\$ 12,748	\$ 10,729	\$ 38,540	\$ 29,958
License revenues	7	10	21	30
Total revenues	<u>\$ 12,755</u>	<u>\$ 10,739</u>	<u>\$ 38,561</u>	<u>\$ 29,988</u>

Deferred revenue and customer deposits at September 30, 2019 and December 31, 2018, was \$48 and \$119, retrospectively. All deferred revenue and customer deposit amounts at December 31, 2018 were recognized as revenue during the nine months ended September 30, 2019.

NOTE 4. INVESTMENT IN MELT PHARMACEUTICALS, INC. AND AGREEMENTS - 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 royalty payments to the Company up to eight percent (8%) of 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.

In February 2019, the Company and Melt entered into a Management Services Agreement (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 pays the Company a monthly amount of \$10.

As of September 30, 2019, the Company was due \$701 from Melt for reimbursable expenses and amounts due under the Melt MSA and included in prepaid expenses and other current assets on the accompanying condensed consolidated balance sheets. During the nine months ended September 30, 2019, Melt paid the Company \$50.

The Company's Chief Executive Officer, Mark L. Baum, and Chief Medical Officer, Larry Dillaha, are members of the Melt board of directors, and several employees of the Company (including Mr. Baum, Mr. Dillaha and the Company's Chief Financial Officer, Andrew 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 Nine Months Ended September 30, 2019
Revenues, net	\$ -
Loss from operations	2,925
Net loss	<u>\$ (2,925)</u>

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

	September 30, 2019
Current assets	\$ 8,944
Non current assets	13
Total assets	<u>\$ 8,957</u>
Total liabilities	\$ 1,916
Total preferred stock and stockholders' equity	7,041
Total liabilities and stockholders' equity	<u>\$ 8,957</u>

NOTE 5. INVESTMENT IN SURFACE PHARMACEUTICALS, INC. AND AGREEMENTS - RELATED PARTY TRANSACTIONS

The Company entered into an asset purchase and license agreement in 2017, and amended it in April 2018 (the “Surface License Agreements”) with Surface. Pursuant to the terms of the Surface License Agreements, the Company assigned and licensed to Surface certain intellectual property and related rights to develop, formulate, make, sell, and sub-license formulations of certain topical eye drop formulations that utilize a proprietary delivery vehicle and a proprietary doxycycline capsule (collectively, the “Surface Products”). Surface is required to make royalty payments to the Company of four to six percent (4%-6%) of net sales of the Surface Products while any patent rights remain outstanding.

In January 2018, the Company and Surface entered into an amended Management Services Agreement (the “Surface MSA”), whereby the Company provided to Surface certain administrative services and support, including bookkeeping, web services and human resources related activities, and Surface paid the Company a monthly amount of \$10. The Surface MSA was terminated effective July 31, 2018.

During the three and nine months ended September 30, 2019, the Company was paid \$50 from Surface for amounts due under the Surface MSA. There are no amounts due from Surface to the Company as of September 30, 2019.

As of September 30, 2019, the Company owned 3,500,000 shares of Surface common stock (approximately 30% of the issued and outstanding equity interests). A Company director, Richard L. Lindstrom, and the Company’s Chief Executive Officer, Mark L. Baum, are directors of Surface. In addition, the Company’s Chief Financial Officer, Andrew R. Boll, was a director of Surface and resigned as a director of Surface concurrent with the sale of the Surface Series A Stock. Several employees and a director of the Company (including Mr. Baum, Dr. Lindstrom and Mr. Boll) entered into consulting agreements and provided consulting services to Surface. Surface is required to make royalty payments to Dr. Lindstrom of three percent (3%) of net sales of certain Surface products while certain patent rights remain outstanding. Dr. Lindstrom is also a principal of Flying L Partners, an affiliate of the funding investor who purchased the Surface Series A Stock.

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

	For the Nine Months Ended September 30, 2019
Revenues, net	\$ -
Loss from operations	3,012
Net loss	\$ (3,012)

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

	September 30, 2019
Current assets	\$ 17,024
Non current assets	48
Total assets	\$ 17,072
Total liabilities	\$ 761
Total stockholders’ equity	16,311
Total liabilities and stockholders’ equity	\$ 17,072

NOTE 6. 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 September 30, 2019 and December 31, 2018 was as follows:

	September 30, 2019	December 31, 2018
Raw materials	\$ 1,623	\$ 1,119
Work in progress	334	6
Finished goods	486	709
Total inventories	<u>\$ 2,443</u>	<u>\$ 1,834</u>

During the three and nine months ended September 30, 2019 the Company impaired \$805 of raw materials and finished goods related to the Park Restructuring.

NOTE 7. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	September 30, 2019	December 31, 2018
Prepaid insurance	\$ 58	\$ 328
Other prepaid expenses	468	334
Receivable due from Surface	-	50
Receivable due from Melt	701	-
Deposits and other current assets	138	125
Total prepaid expenses and other current assets	<u>\$ 1,365</u>	<u>\$ 837</u>

NOTE 8. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following:

	September 30, 2019	December 31, 2018
Property, plant and equipment, net:		
Computer software and hardware	\$ 1,697	\$ 1,662
Furniture and equipment	382	397
Lab and pharmacy equipment	2,631	3,184
Leasehold improvements	5,448	5,496
	<u>10,158</u>	<u>10,739</u>
Accumulated depreciation and amortization	<u>(4,956)</u>	<u>(4,364)</u>
	<u>\$ 5,202</u>	<u>\$ 6,375</u>

For the three and nine months ended September 30, 2019, depreciation related to the property, plant and equipment was \$397 and \$1,365, respectively. During the three and nine months ended September 30, 2019 the Company impaired \$445 worth of property, plant and equipment related to the Park Restructuring.

NOTE 9. INTANGIBLE ASSETS AND GOODWILL

The Company's intangible assets at September 30, 2019 consisted of the following:

	Amortization periods (in years)	Cost	Accumulated Amortization	Impairment	Net Carrying value
Patents	17-19 years	\$ 1,019	\$ (86)	\$ (259)	\$ 674
Licenses	20 years	50	(5)	-	45
Trademarks	Indefinite	334	-	-	334
Customer relationships	3-15 years	2,998	(1,142)	(619)	1,237
Trade name	5 years	16	(14)	(2)	-
Non-competition clause	3-4 years	294	(274)	(20)	-
State pharmacy licenses	25 years	45	(9)	(35)	1
		<u>\$ 4,756</u>	<u>\$ (1,530)</u>	<u>\$ (935)</u>	<u>\$ 2,291</u>

During the three and nine months ended September 30, 2019 the Company incurred impairment charges of \$612 related to intangible assets, including customer relationships, trade name, and state pharmacy licenses as a part of the Park Restructuring and \$259 of impairment charges related to patents associated with the termination of an asset agreement.

Amortization expense for intangible assets for the three and nine months ended September 30, 2019 was as follows:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Patents	\$ 22	6	\$ 37	\$ 19
Licenses	-	-	5	-
Customer relationships	26	\$ 50	128	150
Trade name	1	-	1	3
Non-competition clause	-	-	-	1
State pharmacy licenses	3	-	4	-
	<u>\$ 52</u>	<u>\$ 56</u>	<u>\$ 175</u>	<u>\$ 173</u>

Estimated future amortization expense for the Company's intangible assets at September 30, 2019 is as follows:

Remainder of 2019	\$ 55
2020	182
2021	182
2022	182
2023	182
Thereafter	1,508
	<u>\$ 2,291</u>

Changes in the carrying value of the Company's goodwill during the nine months ended September 30, 2019 were:

Balance at December 31, 2018	\$ 2,227
Impairment of Park goodwill (see Note 2)	(1,895)
Balance at September 30, 2019	<u>\$ 332</u>

NOTE 10. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	September 30, 2019	December 31, 2018
Accounts payable	\$ 6,832	\$ 4,966
Accrued litigation settlements	1,020	640
Deferred rent	-	388
Accrued interest	292	256
Accrued exit fee for note payable	800	800
Total accounts payable and accrued expenses	<u>8,944</u>	<u>7,050</u>
Less: Current portion	<u>(8,144)</u>	<u>(6,250)</u>
Non-current total accrued expenses	<u>\$ 800</u>	<u>\$ 800</u>

NOTE 11. DEBT**SWK Refinance – May 2019**

In May 2019, the Company entered into a joinder and amendment (the “Amendment”) to its term loan and security agreement dated as of July 19, 2017 (the “SWK Loan”), with SWK Funding LLC and its partners (the “Lender”), as lender and collateral agent. A summary of the material changes contained in the Amendment are as follows:

- The interest rate calculation that the loan bears is now 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 provides the Lender 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 has achieved a leverage ratio as of such date of less than 3.00:1:00, the Margin Rate shall equal 7.00%;
- Leverage ratio in the Amendment 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 twelve (12) month period, adding-back (i) actual litigation expenses for the immediately preceding twelve (12) month period, minus (ii) actual litigation expenses for the immediately preceding three (3) month period multiplied by four (4);
- The definition of the first amortization date was changed to May 14, 2020, permitting the Company to pay interest only on the principal amount loaned for the next four payments (payments are due on a quarterly basis) following the Amendment; and
- Subject to the satisfaction of certain revenue and market capitalization requirements and conditions, the Lender agreed to make available to the Company an additional principal amount of up to \$5,000.

In addition to the terms described above, the Amendment joined the Company’s recently created subsidiaries to the SWK Loan and added definitions related to excluded subsidiaries that are not considered co-borrowers and are subsidiaries of the Company which the Company believes it will eventually deconsolidate from its financials and lose 50% or more of the equity interests of the subsidiary.

Related to the Amendment, the Company incurred expenses related to legal and lender costs of \$282 that are included in debt discount and will be amortized over the term of the SWK Loan.

At September 30, 2019, future minimum payments under the Company's note payable were as follows:

	Amount
Remainder of 2019	\$ 472
2020	3,696
2021	4,121
2022	3,828
2023	7,621
Total minimum payments	19,738
Less: amount representing interest	(4,488)
Notes payable, gross	15,250
Less: unamortized discount	(1,378)
	13,872
Less: current portion, net of unamortized discount	(1,007)
Note payable, net of current portion and unamortized debt discount	\$ 12,865

For the three and nine months ended September 30, 2019, debt discount amortization related to note payable was \$127 and \$377, respectively.

NOTE 12. LEASES

The Company adopted Topic 842 on January 1, 2019. Topic 842 allows the Company to elect a package of practical expedients, which include: (i) an entity need not reassess whether any expired or existing contracts are or contain leases; (ii) an entity need not reassess the lease classification for any expired or existing leases; and (iii) an entity need not reassess any initial direct costs for any existing leases. Another practical expedient allows the Company to use hindsight in determining the lease term when considering lessee options to extend or terminate the lease and to purchase the underlying asset. The Company has elected to utilize the package of practical expedients and has not elected the hindsight methodology in its implementation of Topic 842.

The Company elected to adopt this standard using the optional modified retrospective transition method and recognized a cumulative-effect adjustment to the condensed consolidated balance sheet on the date of adoption. Comparative periods have not been restated. With the adoption of Topic 842, the Company's condensed consolidated balance sheet now contains the following line items: Right-of-use assets, Operating lease liabilities—short-term and Operating lease liabilities—long-term.

The Company determined that it held the following significant operating leases of office and laboratory space as of January 1, 2019:

- An operating lease for 10,200 square feet of office space in San Diego, California that expires in December 2021, with an option to extend the term for a five-year period;
- An operating lease for 4,500 square feet of office and lab space in Irvine, California that expires in December 2020, with an option to extend the term for up to two five-year periods. As part of the Park Restructuring, the Company assessed its obligations under this lease. As of the date of this Quarterly Report, the Company expects to sublease this space and has determined that there is a practical ability to do so, and as a result did not recognize any impairment costs related to this lease and the Company's right to use asset; and
- An operating lease for 25,000 square feet of lab, warehouse and office space in Ledgewood, New Jersey that expires in July 2024, with an option to extend the term for two additional five-year periods.

The extensions within the San Diego, California and Ledgewood, New Jersey operating lease agreements were included within the Company's calculation of the new lease standard as the Company is reasonably certain it will exercise its option to extend these leases. The Company has elected to not recognize right-of-use assets and lease liabilities arising from short-term leases, which are leases that, at the commencement date, have a lease term of 12 months or less and do not include an option to purchase the underlying asset that the lessee is reasonably certain to exercise.

The previously classified capital leases are now classified as finance leases under the new standard. The Company has determined that the identified finance leases did not contain non-lease components and require no further allocation of the total lease cost. The Company has determined that the identified operating leases did contain non-lease components and elected an accounting policy to combine non-lease and lease components to determine the total lease cost. Additionally, the operating agreements in place did not contain information to determine the rate implicit in the leases. As such, the Company calculated the incremental borrowing rate based on the assumed remaining lease term for each lease in order to calculate the present value of the remaining lease payments. At September 30, 2019, the weighted average incremental borrowing rate and the weighted average remaining lease term for the operating leases held by the Company were 6.36% and 11.43 years, respectively.

Upon adoption of Topic 842, the Company recorded a \$6,325 increase in operating lease right-of-use assets, a \$388 decrease in accounts payable and accrued expenses and a \$6,712 increase in operating lease liability. The Company did not record any cumulative effect adjustments to opening stockholders' equity. As of September 30, 2019, right-of-use assets and liabilities arising from operating leases were \$5,939 and \$6,345, respectively. During the three and nine months ended September 30, 2019, cash paid for amounts included for the operating lease liabilities was \$228 and \$676 and the Company recorded operating lease expense of \$232 and \$695 included in selling, general and administrative expenses, respectively.

Future lease payments under operating leases as of September 30, 2019 were as follows:

	Operating Leases
Remainder of 2019	\$ 229
2020	930
2021	809
2022	824
2023	843
Thereafter	5,304
Total minimum lease payments	<u>8,939</u>
Less: amount representing interest payments	<u>(2,594)</u>
Total operating lease liabilities	6,345
Less: current portion, operating lease liabilities	<u>(496)</u>
Operating lease liabilities, net of current portion	<u>\$ 5,849</u>

The Company also has two additional finance leases that are included in its lease accounting but are not considered significant.

Future lease payments under non-cancelable finance leases as of September 30, 2019 were as follows:

	Finance Leases
Remainder of 2019	\$ 2
2020	9
2021	9
2022	9
2023	10
Total minimum lease payments	<u>39</u>
Less: amount representing interest payments	<u>(5)</u>
Present value of future minimum lease payments	34
Less: unamortized discount	<u>-</u>
	34
Less: current portion, finance lease obligation	<u>(5)</u>
Finance lease obligation, net of current portion	<u>\$ 29</u>

At September 30, 2019, the weighted average incremental borrowing rate and the weighted average remaining lease term for the finance leases held by the Company were 6.36% and 4.33 years, respectively.

For the three and nine months ended September 30, 2019, debt discount amortization related to a finance lease obligation was \$1 and \$17, respectively, and included in interest expense, net.

For the three and nine months ended September 30, 2019, depreciation expense related to the equipment held under the finance lease obligations was \$2 and \$148, respectively.

For the three and nine months ended September 30, 2019, cash paid and expense recognized for interest expense related to the finance lease obligation was \$2 and \$17, respectively.

Future minimum lease payments under operating leases and future minimum finance lease payments as of December 31, 2018 were as follows (in thousands):

	Finance Leases	Operating Leases
2019	\$ 751	\$ 797
2020	-	857
2021	-	742
2022	-	320
2023	-	330
Thereafter	-	196
	<u>\$ 751</u>	<u>\$ 3,242</u>
Less: Amounts representing interest	(15)	
Less: Amounts representing unamortized discount	(16)	
Total obligation under capital leases	720	
Less: Current portion of capital leases	(720)	
Long term capital lease obligation	<u>\$ -</u>	

NOTE 13. STOCKHOLDERS' EQUITY AND STOCK-BASED COMPENSATION

Common Stock

In March 2019, the Company issued 15,000 shares of its restricted common stock, with a fair value of \$75, as consideration for commission expenses incurred during the nine months ended September 30, 2019.

During the nine months ended September 30, 2019, the Company issued 23,831 shares of its common stock upon the cashless exercise of 73,555 options to purchase common stock, with exercise prices ranging from \$1.70 to \$4.17 per share, net of 6,584 shares of common stock withheld for payroll tax withholdings totaling \$48.

During the nine months ended September 30, 2019, the Company issued 1,872 shares of its common stock upon the exercise of 1,872 options to purchase common stock, with exercise prices ranging from \$1.70 to \$3.20 per share, and received net proceeds of \$5.

During the nine months ended September 30, 2019, the Company issued 688,473 shares of its common stock upon the cashless exercise of 964,532 warrants to purchase common stock with an exercise price of \$1.79 per share.

During the nine months ended September 30, 2019, the Company issued 100,055 shares of its common stock upon the exercise of 100,055 warrants to purchase common stock with an exercise price of \$1.79 per share, and received net proceeds of \$179.

During the nine months ended September 30, 2019, 77,895 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 (the "2017 Plan" together with the 2007 Plan, the "Plans"). As of September 30, 2019, the 2017 Plan provides for the issuance of a maximum of 2,000,000 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 1,002,906 shares available for future issuances under the 2017 Plan at September 30, 2019.

Stock Options

A summary of stock option activity under the Plans for the nine months ended September 30, 2019 is as follows:

	<u>Number of shares</u>	<u>Weighted Avg. Exercise Price</u>	<u>Weighted Avg. Remaining Contractual Life</u>	<u>Aggregate Intrinsic Value</u>
Options outstanding - January 1, 2019	2,482,009	\$ 5.10		
Options granted	362,000	\$ 6.19		
Options exercised	(75,427)	\$ 3.78		
Options cancelled/forfeited	(86,976)	\$ 4.61		
Options outstanding - September 30, 2019	<u>2,681,606</u>	\$ 5.30	5.32	\$ 3,613
Options exercisable	<u>1,538,341</u>	\$ 4.62	5.86	\$ 2,753
Options vested and expected to vest	<u>2,575,030</u>	\$ 5.25	5.36	\$ 3,557

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 September 30, 2019, based on the closing price of the Company's common stock of \$5.62 on that date.

During the nine months ended September 30, 2019, 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 nine months ended September 30, 2019 typically included one of 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; 100% of the shares subject to the option vest on a quarterly basis in equal installments over three years; and 90% of the shares subject to the option vest and become exercisable on the second month after the grant date and the remaining 10% of the shares subject to the option vest and become exercisable quarterly in equal installments thereafter over the next 11 months. Certain option awards provide for accelerated vesting if there is a change in control (as defined in the Plan) 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. Beginning on April 1, 2018, the Company began calculating expected volatility based solely on the historical volatilities of the common stock of the Company. In the past, the expected volatility was based on the historical volatilities of the common stock of the Company and comparable publicly traded companies, the Company previously utilized this methodology based on its estimate that it had limited relevant historical data regarding the volatility of its stock price on which to base a meaningful estimate of expected volatility. 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 by the Black-Scholes-Merton option pricing model with the following assumptions used for valuing options granted to employees:

	2019	
Weighted-average fair value of options granted	\$	3.64
Expected terms (in years)		5.8 - 6.1
Expected volatility		64% - 67%
Risk-free interest rate		2.19% - 2.68%
Dividend yield		-

The following table summarizes information about stock options outstanding and exercisable at September 30, 2019:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$ 1.47 - \$2.60	797,312	6.93	\$ 2.05	580,002	\$ 2.11
\$ 2.76 - \$4.66	461,121	6.35	\$ 3.96	435,445	\$ 3.98
\$ 5.49 - \$6.36	440,350	8.16	\$ 6.15	150,389	\$ 6.06
\$ 6.64 - \$8.99	977,793	2.27	\$ 8.01	367,475	\$ 8.24
\$ 42.80	5,030	0.87	\$ 42.80	5,030	\$ 42.80
\$ 1.47 - \$42.80	<u>2,681,606</u>	5.32	\$ 5.30	<u>1,538,341</u>	\$ 4.62

As of September 30, 2019, there was approximately \$4,033 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 4.62 years. The stock-based compensation expense for all stock options was \$159 and \$699 during the three and nine months ended September 30, 2019, 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. Unvested portions of RSUs issued to consultants are remeasured on an interim basis until vesting criteria is met.

During the nine months ended September 30, 2019, 185,000 RSUs with a fair market value of \$1,139 were issued to certain employees; the RSUs vest in full on the third anniversary of the grant date.

During the nine months ended September 30, 2019, the Company's board of directors were granted 38,860 RSUs with a fair market value \$300 which vests on a quarterly basis, over one year in equal installments.

A summary of the Company's RSU activity and related information for the nine months ended September 30, 2019 is as follows:

	<u>Number of RSUs</u>	<u>Weighted Average Grant Date Fair Value</u>
RSUs unvested - January 1, 2019	1,275,680	\$ 2.16
RSUs granted	223,860	\$ 6.39
RSUs vested	(77,895)	\$ 2.20
RSUs cancelled/forfeited	-	
RSUs unvested at September 30, 2019	<u>1,421,645</u>	<u>\$ 2.79</u>

As of September 30, 2019, the total unrecognized compensation expense related to unvested RSUs was approximately \$1,200, which is expected to be recognized over a weighted-average period of 0.33 years, based on estimated and actual vesting schedules of the applicable RSUs. The stock-based compensation for RSUs during the three and nine months ended September 30, 2019 was \$169 and \$709, 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 nine months ended September 30, 2019 is as follows:

	<u>Number of Shares Subject to Warrants Outstanding</u>	<u>Weighted Avg. Exercise Price</u>
Warrants outstanding - January 1, 2019	2,206,973	\$ 1.91
Granted	-	
Exercised	(1,064,587)	1.79
Expired	-	
Warrants outstanding and exercisable - September 30, 2019	<u>1,142,386</u>	<u>\$ 2.01</u>
Weighted average remaining contractual life of the outstanding warrants in years - September 30, 2019	<u>3.35</u>	

A list of the warrants outstanding as of September 30, 2019 is included in the following table:

Warrant Series	Issue Date	Warrants Outstanding	Exercise Price	Expiration Date
Lender warrants	5/11/2015	125,000	\$ 1.79	5/11/2025
Settlement warrants	8/16/2016	40,000	\$ 3.75	8/16/2021
PIPE investors and placement agent warrants	12/27/2016	362,000	\$ 1.79	12/27/2019
Lender warrants	7/19/2017	615,386	\$ 2.08	7/19/2024
		<u>1,142,386</u>	\$ 2.01	

Subsidiary Stock-Based Transactions

Mayfield Pharmaceuticals, Inc.

Mayfield issued 1,000,000 shares of its common stock to Elle in connection with acquisition of certain drug candidate intellectual property and rights in February 2019.

Mayfield issued 300,000 shares of its common stock to TGV in connection with acquisition of certain drug candidate intellectual property and rights in July 2019.

During the nine months ended September 30, 2019, Mayfield issued 2,450,000 shares of its restricted common stock that vest upon various performance based milestones and service periods to consultants of Mayfield, including Mayfield's CEO candidate and to Harrow employees, including 725,000 shares to Mark Baum, CEO of the Company, and 362,500 shares to Andrew Boll, CFO of the Company.

Stowe Pharmaceuticals, Inc.

In July 2019, Stowe agreed to issue 1,750,000 shares of its common stock to TGV in connection with acquisition of certain drug candidate intellectual property and rights.

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 September 30		For the Nine Months Ended September 30	
	2019	2018	2019	2018
Employees - selling, general and administrative	\$ 252	\$ 527	\$ 1,158	\$ 1,790
Directors - selling, general and administrative	75	75	225	160
Consultants - selling, general and administrative	76	-	175	108
Total	<u>\$ 403</u>	<u>\$ 602</u>	<u>\$ 1,558</u>	<u>\$ 2,058</u>

NOTE 14. COMMITMENTS AND CONTINGENCIES

Dr. Sobol

In December 2016, Louis L. Sobol, M.D. (“Sobol”) filed a lawsuit in the U.S. District Court for the Eastern District of Michigan, Southern Division against the Company, asserting claims on behalf of himself and an as-yet-uncertified class of consumers. The claims allege violations under the Telephone Consumer Protection Act, 47 U.S.C. § 227 via the Company’s alleged transmittal of advertisements to its clients via facsimile. The Court approved the parties’ proposed settlement agreement in the spring of 2019. During the year ended December 31, 2018, the Company accrued \$640 for expected damages related to this matter and the proposed settlement amount. As a result of the low claim rate of approximately 1.4%, the Company’s total damages were \$571, which was paid in October 2019.

Allergan USA

In September 2017, Allergan USA, Inc. (“Allergan”) filed a lawsuit in the U.S. District Court for the Central District of California against the Company, primarily claiming violations under the federal Lanham Act and California’s Sherman Act. The Court granted in part and denied in part each parties’ motions for summary judgement, resolving all issues except for whether Allergan was entitled to damages related to the Company’s purported Lanham Act violations. The parties went to trial in May 2019 to litigate damages related to the Lanham Act, and a jury found the Company liable for only \$48 in lost profit damages, which was accrued as an expense during the period ended September 30, 2019 (see Note 10). In July 2019, the Court entered a permanent injunction, the scope of which is limited to compounded drugs prepared in, dispensed from within, or shipped to the state of California. The injunction requires the Company to: (1) only dispense drugs from a 503(a) facility with a “Valid Prescription Order”; (2) abide by the FDA’s anticipatory compounding guidelines; and (3) only use bulk drug substances identified on a list established by the Secretary of Health and Human Services or FDA’s interim “Category 1” list. The Company believes it was already in compliance with the order, prior to the injunction being ordered. On October 2, 2019, Allergan and the Company filed a joint stipulation to voluntarily dismiss each parties’ respective pending appeals arising out of the lawsuit. No economic consideration was exchanged between the parties related to the filing of the joint stipulation. This formally resolved all pending disputes between the parties.

California Board of Pharmacy

In March 2018, the California Board of Pharmacy filed an accusation against Park related to a compounded formulation the Company believes was legally dispensed and was, without its knowledge, inappropriately administered to a patient unknown to Park, by the prescribing healthcare professional. Park filed a response to the accusation and requested a formal hearing. In April 2019, Park agreed to, and the California State Board of Pharmacy approved terms of a settlement agreement (the “Settlement Agreement”) that became effective on May 29, 2019. Pursuant to the terms of the Settlement Agreement, Park was required to, and did, surrender its California pharmacy license by August 27, 2019.

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 claims for 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 a claim related to its purported termination of the APA. In October 2019, NDS voluntarily dismissed all claims related to breach of contract, leaving only claims related to the scope of the post-termination obligations to be litigated. 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 death of Jade Erick. In April 2018, Erick filed an amendment to the lawsuit, naming us as a co-defendant. In September 2018, co-defendant Dr. Kelly filed a cross-complaint against the Company and various Spectrum entities. 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. 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, 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.

Anna Sue Gaukel et al.

In June 2019, Anna Sue Gaukel and Lawrence Gaukel served the Company with a lawsuit filed in state court in Idaho against Imprimis Pharmaceuticals, Inc. asserting class action allegations and product liability claims related to Mrs. Gaukel’s doctor’s use of a compounded drug injection in each of her eyes. In June 2019, the Company removed the case to Federal Court and subsequently answered the complaint. The case continues to be in its early phase. 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, 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 used 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 \$26 and \$63 were made during the three and nine months ended September 30, 2019, respectively. \$27 and \$75 was incurred as royalty expense during the three and nine months ended September 30, 2019 and included in accounts payable to Dr. Lindstrom at September 30, 2019.

Sales and Marketing Agreements

During 2017, the Company entered various sales and marketing agreements with certain organizations, to provide exclusive sales and marketing representation services to Harrow in select geographies in the U.S., in connection with our ophthalmic compounded formulations.

Under the terms of the sales and marketing agreements, the Company is 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, as applicable. \$0 and \$75 of stock-based payments were made and \$732 and \$1,914 were incurred under these agreements for commission expenses during the three and nine months ended September 30, 2019, 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 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. \$207 and \$672 and \$118 and \$315 were incurred under these agreements as royalty expenses for the three and nine months ended September 30, 2019 and 2018, respectively, and \$207 and \$118 were included in accounts payable at September 30, 2019 and 2018, respectively.

Mayfield License

In July 2019, Mayfield entered into a License Agreement (the "TGV License") with TGV to acquire intellectual property rights for use in the women's health field, related to Mayfield's proprietary drug candidate MAY-66. The TGV License provides that TGV will cooperate with Mayfield in transferring all embodiments of the intellectual property (including know-how) related to the TGV License, assist in obtaining and protecting its patent rights for the acquired intellectual property and that Mayfield will use commercially reasonable efforts to research, develop and commercialize products based on the acquired intellectual property. In connection with the TGV License, Mayfield is obligated to make royalty payments to TGV equal to a low single digit percentage of net sales received by Mayfield in connection with the sale or licensing of any product based on the licensed intellectual property. In addition, Mayfield issued 300,000 shares of its common stock to TGV and is required to make certain milestone payments to TGV over the development of MAY-66 and any related products based on the licensed intellectual property.

Stowe License

In July 2019, Stowe entered into a License Agreement (the “Stowe License”) with TGV, to acquire intellectual property rights for use in the ophthalmology and otic health field, related to Stowe’s proprietary drug candidate STE-006. The Stowe License provides that TGV will cooperate with Stowe in transferring all embodiments of the intellectual property (including know-how) related to the Stowe License, assist in obtaining and protecting its patent rights for the acquired intellectual property and that Stowe will use commercially reasonable efforts to research, develop and commercialize products based on the acquired intellectual property. In connection with the Stowe License, Stowe is obligated to make royalty payments to TGV equal to a low single digit percentage of net sales received by Stowe in connection with the sale or licensing of any product based on the licensed intellectual property. In addition, Stowe issued 1,750,000 shares of its common stock to TGV and is required to make certain milestone payments to TGV over the development of STE-006 and any related products based on the licensed intellectual property.

NOTE 15. SEGMENT INFORMATION AND CONCENTRATIONS

Beginning on January 1, 2019, the Company began evaluating performance of the Company based on operating segments. Segment performance for its two operating segments are based on segment contribution. The Company’s reportable segments consist of (i) its commercial stage pharmaceutical compounding business (Pharmaceutical Compounding), generally including the operations of ImprimisRx and Park businesses; 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 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 nine months ended September 30, 2019:

	For the Three Months Ended September 30, 2019		
	Pharmaceutical Compounding	Pharmaceutical Drug Development	Total
Net revenues	\$ 12,755	\$ -	\$ 12,755
Cost of sales	(4,061)	-	(4,061)
Gross profit	8,694	-	8,694
Operating expenses:			
Selling, general and administrative	6,244	44	6,288
Research and development	193	96	289
Segment contribution	\$ 2,257	\$ (140)	\$ 2,117
Corporate			2,280
Research and development			155
Amortization			40
Asset sales and impairments, net			4,040
Operating loss			\$ (4,398)

	For the Nine Months Ended September 30, 2019		
	Pharmaceutical Compounding	Pharmaceutical Drug Development	Total
Net revenues	\$ 38,561	\$ -	\$ 38,561
Cost of sales	(13,184)	-	(13,184)
Gross profit	25,377	-	25,377
Operating expenses:			
Selling, general and administrative	17,763	130	17,893
Research and development	851	359	1,210
Segment contribution	\$ 6,763	\$ (489)	\$ 6,274
Corporate			7,341
Research and development			449
Amortization			165
Asset sales and impairments, net			4,040
Operating loss			\$ (5,721)

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 September 30, 2019 and December 31, 2018 are located in the U.S.

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 nine months ended September 30, 2019 and 2018.

The Company receives its active pharmaceutical ingredients from three main suppliers. These suppliers collectively accounted for 69% and 66% of active pharmaceutical ingredient purchases during the three and nine months ended September 30, 2019, respectively, and 58% and 51% during the three and nine months ended September 30, 2018, respectively.

NOTE 16. SUBSEQUENT EVENTS

The Company has performed an evaluation of events occurring subsequent to September 30, 2019 through the filing date of this Quarterly Report. Based on its evaluation, no events other than those described below need to be disclosed.

From October 1, 2019 through the date of the filing of this Quarterly Report, the Company issued 250 shares of its common stock upon the exercise of 250 options to purchase common stock, with exercise price of \$2.76 per share, and received net proceeds of \$1.

From October 1, 2019 through the date of the filing of this Quarterly Report, the Company issued 3,840 shares of its common stock related to the cashless exercise of 9,374 options to purchase common stock with an exercise price of \$1.83.

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, 2018 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: 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; successful completion and close of the sale of Park Compounding, Inc.; the successful transfer of assets and/or revenues among our 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. 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 one of the nation’s leading ophthalmology pharmaceutical businesses, ImprimisRx. In addition to wholly owning ImprimisRx, we also have equity positions in Eton Pharmaceuticals, Inc. (“Eton”), Surface Pharmaceuticals, Inc. (“Surface”), and Melt Pharmaceuticals, Inc. (“Melt”). More recently, we founded our drug development subsidiaries Mayfield Pharmaceuticals, Inc. (“Mayfield”), Radley Pharmaceuticals, Inc. (“Radley”), and Stowe Pharmaceuticals, Inc. (“Stowe”). We also own royalty rights in certain 505(b)(2) drug candidates being developed by Surface, Melt, Radley and Mayfield. We intend to continue to create, and hold equity and royalty rights, in, new businesses that commercialize drug candidates that are internally developed or otherwise acquired or licensed from third parties.

Pharmaceutical Compounding Businesses

Pharmaceutical Compounding

Pharmaceutical compounding is the science of combining different active pharmaceutical ingredients (APIs), all of which are approved by the U.S. Food and Drug Administration (“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 and 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.

ImprimisRx

ImprimisRx is our ophthalmology focused pharmaceutical compounding business. We offer thousands of physician customers and their patients critical medicines to meet 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 pharmacies, or for in-office use, made according to current good manufacturing practices (or “cGMPs”) or other FDA guidance documents, in our FDA-registered outsourcing facility (“NJOF”).

Pharmaceutical Development Businesses

We have ownership interests in Eton, Surface, Melt, Mayfield and Radley and hold royalty interests in certain of their drug candidates. These companies are pursuing market approval for their drug candidates under the United States Federal Food, Drug, and Cosmetic Act (“FDCA”), including 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, Mayfield, and Stowe, which we intend to operate similar to Eton, Surface and Melt. In addition, we intend to create additional subsidiaries that will be focused on the development and FDA approval of certain proprietary drug formulations that we currently own, will in-license/acquire and/or otherwise develop.

De-Consolidated Businesses

Eton Pharmaceuticals, Inc.

Eton is a pharmaceutical company focused on developing and commercializing innovative products utilizing the FDA’s 505(b)(2) regulatory pathway. Its pipeline includes several products and drug candidates in various stages of development across a variety of dosage forms. Eton’s pipeline is focused on innovative 505(b)(2) products and obtaining FDA marketing approval for currently marketed but unapproved drugs.

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. We own 3,500,000 shares of Eton common stock, which we estimate is approximately 19.7% of the equity and voting interests issued and outstanding of Eton as of September 30, 2019.

Surface Pharmaceuticals, Inc.

Surface is a development-stage pharmaceutical company focused on development and commercialization of innovative therapeutics for ocular surface diseases and is seeking FDA approval for the commercialization of its drug candidates through the Section 505(b)(2) regulatory pathway under the FDCA. In 2017 and amended in April 2018, Harrow entered into asset purchase and license agreements (the “Surface License Agreements”) and transferred to Surface its current drug pipeline, which consists of three proprietary drug candidates. Surface’s patent-pending topical eye drop drug candidates, SURF-100 and SURF-200, utilize a patented delivery vehicle known as Klarity Drops (“Klarity”), that was invented by Harrow board member and Surface’s chairman of the board and renowned ophthalmologist Dr. Richard Lindstrom. Klarity is designed to protect and rehabilitate the ocular surface pathology for patients with dry eye disease, or DED. Surface’s drug candidate SURF-300 is a patent-pending oral capsule that will target patients also suffering from DED signs and symptoms.

In May and July 2018, Surface closed on an offering of its Series A Preferred Stock. At that time, we lost our controlling interest and deconsolidated Surface from our consolidated financial statements. We own 3,500,000 shares of Surface which we estimate is approximately 30% of the equity and voting interests as of September 30, 2019.

Melt Pharmaceuticals, Inc.

Melt is a development-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 through the FDA’s 505(b)(2) regulatory pathway 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. Pursuant to the terms of the Melt Asset Purchase Agreement, Melt is required to make royalty payments to the Company equal to five percent (5%) of net sales of MELT-100, while any patent rights remain outstanding, subject to other conditions.

During January and March 2019, Melt closed on the sale of its Series A Preferred Stock. At the time of the closing of the Melt Series A Round, we lost our controlling interest, and deconsolidated Melt from our consolidated financial statements. We own 3,500,000 shares of Melt common stock, which we estimate is approximately 44% of the equity and voting interests.

Consolidated Businesses

Mayfield Pharmaceuticals, Inc.

Mayfield, a consolidated subsidiary of Harrow, is a development-stage women’s health-focused pharmaceutical company. Mayfield is focused on enhancing women’s lives by developing products that address significant and conspicuous unmet needs. Its development programs focus on using known molecules in dosage forms for new indications, and by developing new chemical entities with known mechanisms of action. Mayfield recently licensed worldwide rights to a first in class drug candidate with antibacterial, antiviral and antifungal activity for the women’s health field. MAY-66 a patented new chemical entity drug candidate, is being studied to treat recurrent bacterial vaginosis. In February 2019, Mayfield acquired drug formulation assets and intellectual property, including three recently issued patents, for MAY-44, a drug candidate for the treatment of dyspareunia, or pain experienced by women during sexual intercourse. In addition to MAY-44, Mayfield is also developing MAY-88 for patients suffering from interstitial cystitis, which it will acquire from Harrow.

Mayfield and Harrow acquired the intellectual property associated with MAY-44 in January 2019 from Elle Pharmaceutical LLC (the “Mayfield Asset Purchase Agreement”) in exchange for \$25,000, with an additional \$175,000 due upon third party financing of Mayfield, 1,000,000 shares of Mayfield common stock and a 7.5% royalty rate on sales of the product.

In July 2019, Mayfield entered into a License Agreement (the “TGV License”) with TGV-Health, LLC and affiliated entities (collectively, “TGV”), to acquire intellectual property rights for use in the women’s health field, related to Mayfield’s proprietary drug candidate MAY-66. The TGV License provides that TGV will cooperate with Mayfield in transferring all embodiments of the intellectual property (including know-how) related to the TGV License, assist in obtaining and protecting its patent rights for the acquired intellectual property and that Mayfield will use commercially reasonable efforts to research, develop and commercialize products based on the acquired intellectual property. In connection with the TGV License, Mayfield is obligated to make royalty payments to TGV equal to a low single digit percentage of net sales received by Mayfield in connection with the sale or licensing of any product based on the licensed intellectual property. In addition, Mayfield issued 300,000 shares of its common stock to TGV and is required to make certain milestone payments to TGV over the development of MAY-66 and any related products based on the licensed intellectual property.

We own 2,500,000 shares of Mayfield common stock, and control 70% of the equity and voting interests issued and outstanding of Mayfield at September 30, 2019. We intend to pursue a deconsolidating transaction for Mayfield during 2019. Once deconsolidated, we expect Mayfield to be run by experienced life science executive, Melissa Bradford-Klug.

Radley Pharmaceuticals, Inc.

Radley, a consolidated subsidiary of Harrow, is a development-stage pharmaceutical company focused on the development of proprietary 505(b)(2) drug candidates focused on rare diseases. Radley currently has three proprietary drug candidates in its pipeline. During 2019, and prior to initiating significant development activities and costs related to these drug candidates, we intend to meet with the FDA to establish and understand the expected clinical and regulatory path to approval for these drug candidates. We are also pursuing investigator-initiated studies for some of Radley’s drug candidates with two well-known healthcare institutions based in the New York and Boston areas. We believe this approach will allow us to better understand and weigh the economic costs, clinical feasibility and potential benefits associated with pursuing development activities associated with these drug candidates. Radley is also pursuing additional asset acquisition and licensing opportunities with a focus in oncology-related therapies.

Stowe Pharmaceuticals, Inc.

Stowe is a consolidated subsidiary of Harrow that was formed in 2019, focused on the development of its proprietary ophthalmic drug candidate STE-006. STE-006 is a patented, new chemical entity, small molecule topical drug candidate intended to treat various bacterial, fungal, and viral infections in the eye. In initial preclinical models, STE-006 was shown to be significantly more effective compared to current conventional therapies against numerous bacterial and viral pathogens, including strains of methicillin-resistant staphylococcus aureus, or MRSA, and herpes simplex virus. STE-006 has several patents covering matter of composition, methods of production, methods of use and molecule, which are valid until 2038.

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, 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 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 conceivably 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.

On August 30, 2019, the Centers for Medicare & Medicaid Services (“CMS”) issued an update to the Hospital Outpatient Prospective Payment System, with an effective date of October 1, 2019 (the “MLN Update”). The MLN Update included clarification on guidance for intraocular or periocular injections of combinations of anti-inflammatory drugs and antibiotics, including the family of Dropless® formulations made and sold by ImprimisRx. Specifically, the MLN Update stated that nothing in the current CMS policy is intended to preclude physicians or other professionals from discussing the potential benefits and drawbacks of Dropless Therapy® formulations with their patients, and to prescribe them if the patient so elects. Last year, ImprimisRx sold over 200,000 units of its Dropless formulations and believes this MLN Update may positively impact revenues from these formulations.

Recent Developments

The following describes certain developments in 2019 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.

Melt Pharmaceuticals Asset Purchase Agreement and Series A Round

As described more fully above under the sub-heading “Melt Pharmaceuticals, Inc.”, we entered into the Melt Asset Purchase Agreement with our previously wholly owned subsidiary, Melt. Following closing of the Melt Series A Round, in January 2019, we lost controlling interest in Melt. Pursuant to the terms of the Melt Asset Purchase Agreement, we assigned and licensed to Melt certain intellectual property and related rights to develop, formulate, make, sell, and sub-license its current drug candidate pipeline.

Mayfield Pharmaceuticals MAY-44 Asset Purchase Agreement

As described more fully above under the sub-heading “Mayfield Pharmaceuticals, Inc.”, in February 2019, we along with our subsidiary, Mayfield, entered the Mayfield Asset Purchase Agreement with Elle to acquire intellectual property associated with its drug candidate, MAY-44.

SWK Refinance – May 2019

In May 2019, we entered into a joinder and amendment (the “Amendment”) to our term loan and security agreement dated as of July 19, 2017 (the “SWK Loan”), with SWK Funding LLC and its partners (the “Lender”), as lender and collateral agent. A summary of the material changes contained in the Amendment are as follows:

- The interest rate calculation that the loan bears is now 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, we provide the Lender evidence that we have achieved a leverage ratio as of such date of less than 4.00:1:00, the Margin Rate shall equal 9.00%; and if we have achieved a leverage ratio as of such date of less than 3.00:1:00, the Margin Rate shall equal 7.00%;
- Leverage ratio in the Amendment 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 us for the immediately preceding twelve (12) month period, adding-back (i) actual litigation expenses for the immediately preceding twelve (12) month period, minus (ii) actual litigation expenses for the immediately preceding three (3) month period multiplied by four (4);
- The definition of the first amortization date was changed to May 14, 2020, permitting us to pay interest only on the principal amount loaned for the next four payments (payments are due on a quarterly basis) following the Amendment; and
- Subject to the satisfaction of certain revenue and market capitalization requirements and conditions, the Lender agreed to make available to us an additional principal amount of up to \$5,000,000.

In addition to the terms described above, the Amendment joined our recently created subsidiaries to the SWK Loan and added definitions related to excluded subsidiaries that are not considered co-borrowers and are subsidiaries ours which we believe will eventually be deconsolidated from our financials and we will lose 50% or more of the equity interests of the subsidiary.

Mayfield Pharmaceuticals MAY-66 License

As described more fully above under the sub-heading “Mayfield Pharmaceuticals, Inc.”, in July 2019, our subsidiary Mayfield, entered the TGV License Agreement to acquire intellectual property associated with its drug candidate, MAY-66.

Stowe License

In July 2019, Stowe entered into a License Agreement (the “Stowe License”) with TGV (collectively, “TGV”), to acquire intellectual property rights for use in the ophthalmology and otic health fields, related to Stowe’s proprietary drug candidate STE-006. The Stowe License provides that TGV will cooperate with Stowe in transferring all embodiments of the intellectual property (including know-how) related to the Stowe License, assist in obtaining and protecting its patent rights for the acquired intellectual property and that Stowe will use commercially reasonable efforts to research, develop and commercialize products based on the acquired intellectual property. In connection with the Stowe License, Stowe is obligated to make royalty payments to TGV equal to a low single digit percentage of net sales received by Stowe in connection with the sale or licensing of any product based on the licensed intellectual property. In addition, Stowe issued 1,750,000 shares of its common stock to TGV and is required to make certain milestone payments to TGV over the development of STE-006 and any related products based on the licensed intellectual property.

Park Restructuring

On August 30, 2019, Park Compounding, Inc. (“Park”) a wholly owned subsidiary of Harrow Health, Inc., and Noice Rx, LLC (“Noice”) terminated the Asset Purchase Agreement, dated July 26, 2019 (the “Purchase Agreement”), between the parties. Under the terms of the Purchase Agreement, Park had agreed to sell substantially all its assets associated with its non-ophthalmology pharmaceutical compounding business to Noice, including its pharmacy facility and equipment located in Irvine, California. The closing of the sale transaction was dependent on the California State Board of Pharmacy approving of the sale and issuing a temporary pharmacy and sterile license permit to Noice, which did not occur and led to Park ceasing operations at the close of business on August 27, 2019.

Following closure of the Park pharmacy, the Company elected to restructure the Park business and facilitate the transition of certain compounded formulations and related equipment from Park to the Company’s New Jersey-based compounded pharmaceutical production facilities (the “Park Restructuring”). As a result of the Park Restructuring, the Company incurred non-cash impairment costs of approximately \$3,781 related to assets held at Park, primarily associated with property, plant, equipment, goodwill and other intangible assets and, in addition, to incur approximately \$405,000 in one-time costs related to severance packages and other costs associated with the Park Restructuring, during the three and nine months ended September 30, 2019. Going forward, all compounding business is expected to be consolidated into the Company’s ImprimisRx business.

We have reduced the Park compounded product formulary to seven base formulations, based on factors including unit order volumes, revenues and gross margin percentages, and expect ImprimisRx to retain and re-acquire approximately half of Park’s revenue after a transitional period within about six to twelve months.

Results of Operations

The following period-to-period comparisons of our financial results for the three and nine months ended September 30, 2019 and 2018, 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 and revenues received from royalty payments owed to us pursuant to out-license arrangements.

The following presents our revenues for the three and nine months ended September 30, 2019 and 2018:

	For the Three Months Ended			For the Nine Months Ended		
	September 30,		\$	September 30,		\$
	2019	2018	Variance	2019	2018	Variance
Product sales, net	\$ 12,748,000	\$ 10,729,000	\$ 2,019,000	\$ 38,540,000	\$ 29,958,000	\$ 8,582,000
License revenues	7,000	10,000	(3,000)	21,000	30,000	(9,000)
Total revenues	<u>\$ 12,755,000</u>	<u>\$ 10,739,000</u>	<u>\$ 2,016,000</u>	<u>\$ 38,561,000</u>	<u>\$ 29,988,000</u>	<u>\$ 8,573,000</u>

The increase in revenues between periods was largely attributable to increased sales of our proprietary formulations and furtherance of our ophthalmology-related pharmaceutical compounded formulations. Our gross ophthalmology-related sales were approximately \$12,263,000 and \$35,337,000 for the three and nine months ended September 30, 2019, compared to \$8,860,000 and \$24,102,000 during the same periods last year, respectively. Net revenues generated from NJOF totaled \$8,860,000 and \$24,102,000 during the three and nine months ended September 30, 2019, respectively, and \$6,378,000 and \$16,876,000 during the three and nine months ended September 30, 2018, respectively.

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 nine months ended September 30, 2019 and 2018:

	For the Three Months Ended			For the Nine Months Ended		
	September 30,			September 30,		
	2019	2018	\$ Variance	2019	2018	\$ Variance
Cost of sales	\$ 4,061,000	\$ 4,191,000	\$ (130,000)	\$ 13,184,000	\$ 12,419,000	\$ 765,000

The decrease in our cost of sales during the three months ended September 30, 2019 compared to the three months ended September 30, 2018 was largely attributable to improved utilization of capacity at our compounding facilities. The increase in our cost of sales during the nine months ended September 30, 2019 compared to the nine months ended September 30, 2018 was largely attributable to an increase in unit volumes sold.

Gross Profit and Margin

	For the Three Months Ended			For the Nine Months Ended		
	September 30,			September 30,		
	2019	2018	\$ Variance	2019	2018	\$ Variance
Gross Profit	\$ 8,694,000	\$ 6,548,000	\$ 2,146,000	\$ 25,377,000	\$ 17,569,000	\$ 7,808,000
Gross Margin	68%	61%	7%	66%	59%	7%

The increase in gross profit and gross margin between periods is largely attributable to increased efficiencies in our production process, extension of beyond using dating, or BUD, of some of our products, utilization of capacities as a result of increased output and unit volumes and an increase in sales prices.

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 nine months ended September 30, 2019 and 2018:

	For the Three Months Ended			For the Nine Months Ended		
	September 30,			September 30,		
	2019	2018	Variance	2019	2018	Variance
Selling, general and administrative	<u>\$ 8,608,000</u>	<u>\$ 6,964,000</u>	<u>\$ 1,644,000</u>	<u>\$ 25,399,000</u>	<u>\$ 20,231,000</u>	<u>\$ 5,168,000</u>

The increase in selling, general and administrative expenses between periods was largely attributable to increased sales commission amounts, severance costs associated with the Park Restructuring and legal expenses incurred associated with ongoing litigation.

Research and Development Expenses

Our research and development expenses primarily include expenses related to the development of acquired intellectual property, investigator-initiated research and evaluations and other costs related to the clinical development of our assets.

The following presents our research and development expenses for the three and nine months ended September 30, 2019 and 2018:

	For the Three Months Ended			For the Nine Months Ended		
	September 30,			September 30,		
	2019	2018	Variance	2019	2018	Variance
Research and development	<u>\$ 444,000</u>	<u>\$ 233,000</u>	<u>\$ 211,000</u>	<u>\$ 1,659,000</u>	<u>\$ 392,000</u>	<u>\$ 1,267,000</u>

The increase in research and development expenses between periods was primarily attributable to the increase in formulation development studies for new ophthalmic formulations and clinical programs related to our drug development segment during the three and nine months ended September 30, 2019.

Impairment and Disposal of Long-Lived Assets

During the three and nine months ended September 30, 2019, we recorded a loss of \$4,040,000 related to the impairment and disposal of long-lived assets. \$3,781,000 of these costs were related to the Park Restructuring and \$259,000 of these expenses were related to the impairment of patents and patent applications related to a terminated asset purchase agreement.

Interest Expense, net

Interest expense, net was \$620,000 and \$1,939,000 for the three and nine months ended September 30, 2019 compared to \$705,000 and \$2,039,000 during the same period last year. The decrease during the periods ending September 30, 2019 as compared to the same periods in 2018 was primarily due to interest expense recognition related to a decrease in the amortization of our capital lease obligations.

Investment Gain (Loss) from Melt, net

During the nine months ended September 30, 2019, we recorded a net gain of \$4,517,000 related to our investment in Melt. We recorded a gain of \$5,810,000 for the deconsolidation of Melt, and a loss of \$1,293,000 for our share of losses based on our ownership of Melt after its deconsolidation. We began using equity method accounting for our investment in Melt beginning on January 30, 2019, the date we no longer had a controlling interest. Prior to that date, Melt's losses were consolidated within our statements of operations.

Investment loss from Surface

During the three and nine months ended September 30, 2019, we recorded a loss of \$400,000 and \$904,000, respectively, for our share of losses based on our ownership of Surface. During the three and nine months ended September 30, 2018, we recorded a loss of \$128,000 and \$230,000, respectively, for our share of losses based on our ownership of Surface prior to its deconsolidation. During the nine months ended September 30, 2018, we recorded a gain of \$5,320,000 in the deconsolidation of Surface. We began using equity method accounting for our investment in Surface beginning on June 11, 2018, the date we no longer had a controlling interest. Prior to that date, Surface's losses were consolidated within our statements of operations.

Investment Gain (Loss) from Eton, net

We recorded a loss of \$(5,530,000) and gain of \$700,000 related to the change in fair market value of Eton's common stock for the three and nine months ended September 30, 2019, respectively. During the three and nine months ended September 30, 2018, we recorded a loss of \$(1,032,000) and \$(3,247,000), respectively, for our share of losses based on our ownership of Eton. We began recording our investment in Eton at fair market value, and ceased equity method accounting for our investment in Eton, in November 2018 following Eton's IPO and our ownership percent falling below 20%.

Other Income (Expense), net

During the nine months ended September 30, 2019, we recorded other income, net of \$630,000. This was the result of income of \$630,000 related to expenses that were paid by us and will be reimbursed by Melt following its deconsolidation. During the three and nine months ended September 30, 2018, we recorded other expense, net of \$255,000. This was due to a loss of \$393,000 related to the impairment and write-off of a note receivable, and income of \$138,000 related to expenses that were paid by us and reimbursed by Surface following its deconsolidation.

Net Loss

The following table presents our net loss for the three and nine months ended September 30, 2019 and 2018:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Net loss attributable to Harrow Health, Inc.	\$ (11,469,000)	\$ (2,514,000)	\$ (2,489,000)	\$ (3,505,000)
Net loss per share, basic and diluted	\$ (0.45)	\$ (0.12)	\$ (0.10)	\$ (0.16)

Financial Information About Segments and Geographic Areas

Beginning on January 1, 2019, we began evaluating 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 compounding business (Pharmaceutical Compounding), generally including the operations of our ImprimisRx and Park businesses; 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 15 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 September 30, 2019 was \$3,631,000, compared to \$6,838,000 at December 31, 2018. Since inception through December 31, 2018, we have incurred aggregate losses of \$74,211,000. These losses are primarily due to selling, general and administrative and research and development expenses incurred in connection with developing and seeking regulatory approval for a former drug candidate, which activities we have now discontinued, the development and commercialization of novel compounded formulations and the development of our pharmacy operations.

As of the date of this Quarterly Report, we believe that cash and cash equivalents of \$3,431,000 and restricted investments of \$200,000 totaling approximately \$3,631,000 at September 30, 2019, will be sufficient to sustain our planned level of operations and capital expenditures for at least the next 12 months. We also 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, our plans for this period may change, our estimates of our operating expenses, capital expenditures 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 could 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 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 compounded formulations and technologies, integrating and developing our compounding operations, pursuing potential future strategic transactions as opportunities arise, including potential acquisitions of additional pharmacy, outsourcing facilities, drug company and manufacturers, 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 Nine Months Ended September 30,	
	2019	2018
Net cash provided by (used in) operating activities	\$ (702,000)	\$ 723,000
Net cash used in investing activities	(864,000)	(1,347,000)
Net cash provided by (used in) financing activities	(1,641,000)	2,720,000
Net change in cash and cash equivalents	(3,207,000)	2,096,000
Cash and cash equivalents at beginning of the period	6,838,000	4,219,000
Cash and cash equivalents at end of the year	<u>\$ 3,631,000</u>	<u>\$ 6,315,000</u>

Operating Activities

Net cash provided by (used in) operating activities was \$(702,000), compared to \$723,000 in operating activities during the same period in the prior year. The increase in net cash used in operating activities during the periods was mainly attributed to increased unit volumes and sales, and the addition of new formulations which temporarily reduced operating efficiencies.

Investing Activities

Net cash used in investing activities during the nine months ended September 30, 2019 and 2018 was \$(864,000) and \$(1,347,000), respectively. Cash used in investing activities in 2019 and 2018, was primarily associated with equipment purchases and upgrades and investments in our intellectual property portfolio.

Financing Activities

Net cash provided by (used in) financing activities during the nine months ended September 30, 2019 and 2018 was \$(1,641,000) and \$2,720,000, respectively. Cash used in financing activities during the nine months ended September 30, 2019 was mostly related to principal payments on our note payable and finance leases.

Sources of Capital

Our principal source of cash consists of cash provided by operating activities from our pharmaceutical compounding business. We may also sell some or all of our ownership interests in Eton, Surface, Melt and/or our other subsidiaries. We just recently began producing cash from our operations during 2018, however historically and during the three and nine months ended September 30, 2019, we have not generated sufficient revenues to support our operations and may not be able to continue to do so.

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 and options 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 included in the agreements governing the loan from SWK Funding, LLC and its partners. 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 September 30, 2019. 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 September 30, 2019, 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 September 30, 2019, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II
OTHER INFORMATION

Item 1. Legal Proceedings

Dr. Sobol

In December 2016, Louis L. Sobol, M.D. (“Sobol”) filed a lawsuit in the U.S. District Court for the Eastern District of Michigan, Southern Division against us, asserting claims on behalf of himself and an as-yet-uncertified class of consumers. The claims allege violations under the Telephone Consumer Protection Act, 47 U.S.C. § 227 via our alleged transmittal of advertisements to our clients via facsimile. The Court approved the parties’ proposed settlement agreement in the spring of 2019 and total damages related to this case of \$570,751 were paid in October 2019.

Allergan USA

In September 2017, Allergan USA, Inc. (“Allergan”) filed a lawsuit in the U.S. District Court for the Central District of California against Imprimis Pharmaceuticals, Inc., primarily claiming violations under the federal Lanham Act and California’s Sherman Act. The Court granted in part and denied in part each parties’ motions for summary judgement, resolving all issues except for whether Allergan was entitled to damages related to Imprimis’ purported Lanham Act violations. The parties went to trial in May 2019 to litigate damages related to the Lanham Act, and a jury found Imprimis liable for only \$48,500 in lost profit damages. In July 2019, the Court entered a permanent injunction, the scope of which is limited to compounded drugs prepared in, dispensed from within, or shipped to the State of California. The injunction requires Imprimis to: (1) only dispense drugs from a 503(a) facility with a “Valid Prescription Order”; (2) abide by the FDA’s anticipatory compounding guidelines; and (3) only use bulk drug substances identified on a list established by the Secretary of Health and Human Services or FDA’s interim “Category 1” list. We believe we were already in compliance with its order prior to the injunction being ordered. On October 2, 2019, we and Allergan filed a joint stipulation to voluntarily dismiss each parties’ respective pending appeals arising out of the lawsuit. No economic consideration was exchanged between the parties related to the filing of the joint stipulation. The stipulation formally resolved all pending disputes between the parties.

Novel Drug Solutions et al.

In April 2018, Novel Drug Solutions, LLC and Eyecare Northwest, PA, (collectively “NDS”) filed a lawsuit against us in the U.S. District Court of Delaware asserting claims for breach of contract. The claims stem from an asset purchase agreement between us and NDS entered into in 2013. In July 2019, NDS filed a second amended complaint which added a claim related to its purported termination of the APA. In October 2019, NDS voluntarily dismissed all claims related to breach of contract, leaving only claims related to the scope of the post termination obligations to be litigated. We believe the claims are meritless and have previously and will continue to dispute all claims asserted against us and intend to vigorously defend against these allegations. Nonetheless, we 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.

California Board of Pharmacy

In March 2018, the California Board of Pharmacy filed an accusation against Park related to a compounded formulation the Company believes was legally dispensed and was, without its knowledge, inappropriately administered to a patient unknown to Park, by the prescribing healthcare professional. Park filed a response to the accusation and requested a formal hearing. In April 2019, Park agreed to and the California State Board of Pharmacy approved terms of a settlement agreement (the “Settlement Agreement”) that became effective on May 29, 2019. Pursuant to the terms of the Settlement Agreement, Park was required to, and did, surrender its California pharmacy license by August 27, 2019.

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 death of Jade Erick. In April 2018, Erick filed an amendment to the lawsuit, naming us as a co-defendant. In September 2018, co-defendant Dr. Kelly filed a cross-complaint against us and various Spectrum entities. The cross-complaint seeks indemnity and contribution from us and Spectrum. We answered the claims filed by Dr. Kelly in October 2018. The case is currently in the discovery phase. We believe the claims are meritless and have previously and will continue to dispute all claims asserted against us and intend to vigorously defend against these allegations. Nonetheless, we 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.

Anna Sue Gaukel et al.

In June 2019, Anna Sue Gaukel and Lawrence Gaukel served Imprimis with a lawsuit filed in state court in Idaho against Imprimis Pharmaceuticals, Inc. asserting class action allegations and product liability claims related to Mrs. Gaukel’s doctor’s use of a compounded drug injection in each of her eyes. In June 2019, Imprimis removed the case to Federal Court and subsequently answered the complaint. The case continues to be in its early phase. We believe the claims are meritless and have previously and will continue to dispute all claims asserted against us and intend to vigorously defend against these allegations. Nonetheless, we 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.

General and Other

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

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.

Risks Related to Our Business

Until last year, we incurred losses in every year of our operations, and we may not be profitable in the future.

Until 2018, we incurred losses in every year of our operations. As of September 30, 2019, our accumulated deficit was \$(76,700,000). We could incur increasing operating losses in the foreseeable future for our commercialization activities, research and development and our pharmaceutical compounding business which would impact net income. Recent changes to the accounting for equity investments require those investments to be measured at fair market value, which may cause our earnings (losses) to become volatile as the stock prices of those equity investments fluctuate. Although we have been generating revenue from our pharmaceutical compounding operations, our ability to generate the revenues necessary to achieve profitability will depend on many factors, including those discussed in this “Risk Factors” section. Our business plan and strategies involve costly activities that are susceptible to failure, and, therefore, we may not be able to generate sufficient revenue to support and sustain our business or reach the level of sales and revenues necessary to achieve and sustain profitability.

We may not receive sufficient revenue to fund our operations and recover our development costs.

Our business plan involves the preparation and sale of our proprietary formulations through our compounding pharmacies and outsourcing facilities. We have limited experience operating pharmacies and commercializing compounded formulations, and we may be unable to successfully manage this business or generate sufficient revenue to recover our development costs and operational expenses. We may have only limited success in marketing and selling our proprietary formulations. Although we have established and plan to grow our internal sales teams to market and sell our proprietary formulations and other non-proprietary products, we have limited experience with such activities and may not be able to generate sufficient physician and patient interest in our formulations to generate significant revenue from sales of these products. In addition, we are substantially dependent on our ImprimisRx compounding pharmacies and outsourcing facilities, along with any pharmacy partners with which we may contract to compound and sell our formulations using our quality standards and specifications, in a timely manner and sufficient volumes to accommodate the number of prescriptions they receive. Our pharmacies may be unable to compound our formulations successfully and we may be unable to acquire, build or enter into arrangements with pharmacies or outsourcing facilities of sufficient size, reputation and quality to implement our business plan, which would cause our business to suffer.

We sell certain of our proprietary formulations primarily through pharmaceutical compounding facilities we own, but we may not be successful in our efforts to integrate these businesses into our operations.

Our business strategy includes establishing a small compounding pharmacy group, whether through acquisitions, establishing new pharmacies or entering into licensing arrangements with third-party pharmacies and outsourcing facilities, to market and sell our proprietary formulations and other non-proprietary products in all 50 states and in certain geographies outside of the U.S.

We currently have compounding facilities in New Jersey. We may plan to expand our pharmacy operations and personnel and developing our facilities into a unified group compounding pharmacy facilities. We have been developing “ImprimisRx” as a uniform brand for certain compounding facilities and ophthalmology focused pharmaceutical compounding business. We have limited experience acquiring, building or operating compounding pharmacies or other prescription dispensing facilities or commercializing our formulations through ownership of or licensing arrangements with pharmacies. In addition, as we have in the past, we have purchased and operated certain pharmaceutical compounding businesses and pharmacies, and subsequently divested or sold those associated assets, we may pursue similar strategies in the future. Those things considered, we may experience difficulties implementing and/or executing on our compounding pharmacy strategy, including difficulties that arise as a result of our lack of experience, and we may be unsuccessful and our plans may change materially. For instance:

- we have experienced delays and increased costs in our outsourcing facility construction efforts;
- we may not be successful in completing future construction plans on a timely basis or within budget;
- we may not be successful in our efforts to integrate, manage or otherwise realize the benefits we expect from acquisitions of our ImprimisRx compounding pharmacies or any additional pharmacy businesses or outsourcing facilities we to acquire, sell or build in the future;
- we may not be able to satisfy applicable federal and state licensing and other requirements for any of our pharmacy businesses in a timely manner or at all;
- changes to federal and state pharmacy regulations may restrict compounding operations or make them more costly;
- we may be unable to achieve a sufficient physician and patient customer base to sustain our pharmacy operations;
- market acceptance of compounding pharmacies generally may be curtailed or delayed; and
- we may not be able to enter into licensing or other arrangements with third-party pharmacies or outsourcing facilities when desired, on acceptable terms or at all.

Moreover, all our efforts to expand pharmacy operations will involve significant costs and other resources, which we may not be able to afford and may disrupt our other operations and distract management and employees from the other aspects of our business. As a result, our business could materially suffer if we are unable to further develop a group of unified compounding facilities and, even if we are successful, we may be unable to generate sufficient revenue to recover our costs.

We are dependent on market acceptance of compounding pharmacies and compounded formulations, and physicians may be unwilling to prescribe, and patients may be unwilling to use, our proprietary customizable compounded formulations.

We currently distribute our proprietary formulations through compounding pharmacies and an outsourcing facility. Formulations prepared and dispensed by compounding pharmacies contain FDA-approved ingredients, but are not themselves approved by the FDA. Thus, our compounded formulations have not undergone the FDA approval process and only limited data, if any, may be available about the safety and efficacy of our formulations for any particular indication. Certain compounding pharmacies have been subject to widespread negative media coverage in recent years, and the actions of these pharmacies have resulted in increased scrutiny of compounding pharmacy activities from the FDA and state governmental agencies. For example, the FDA has issued formal requests to compounding pharmacies and outsourcing facilities to conduct a recall of all non-expired, purportedly sterile drug products and to cease sterile compounding operations due to lack of sterility assurance. As a result, some health care providers may be reluctant to purchase and use compounded drugs. Our growth and future sales depend not only on our ability to demonstrate in the face of increased scrutiny the quality and safety of our pharmacies and outsourcing facilities and our compliance with more stringent regulatory standards at the federal and state levels, but also on the continued acceptance of compounded drugs and formulations, particularly outsourced compounded drugs and formulations, in the marketplace.

An incident similar to the fungal meningitis outbreak in 2012, which was caused by a compounding pharmacy employing a non-sterile-to-sterile business model, could cause our customers to reduce their use of compounded formulations significantly or even stop using compounded drugs altogether. States have in the past, and could in the future, enact regulation prohibiting or restricting the use of compounding pharmacies and outsourcing facilities in response to such incidents. Such prohibitions or restrictions by states or reduced customer demand as a result of an incident with compounded drugs and formulations could have a material adverse effect on our business, results of operations and financial condition.

In August 2017, FDA issued a MedWatch notification regarding our curcumin emulsion and two adverse events that had been associated with the use of these emulsions by prescribing physicians. We issued a press release on August 7, 2017, clarifying certain facts regarding the notice which outlined our belief that the adverse events associated with the two patients occurred due to an allergic reaction caused by the products being inappropriately administered and obtained by the prescribing physician, and our use of curcumin and excipients in our curcumin emulsion formulation met regulatory standards required for dispensing of the curcumin emulsion. In September 2017, the FDA released a letter confirming that the alleged misuse of certain ingredients in our curcumin emulsions were due to mislabeling by the underlying supplier, and not of our own misdoing. Separately, in December 2017, we were issued a warning letter from the FDA alleging that, in their interpretation of our public communications, we had made false or misleading claims and omitted risk and side effect information regarding certain of our ophthalmology focused compounded medications. We immediately performed a full review of our public communications referenced in the warning letter and responded to the FDA in January 2018. Notwithstanding our continued belief that our public communications were not in fact false and misleading, we have been in communication with the FDA and are taking steps to address the items outlined in the FDA letter. In June 2019, our outsourcing facility was issued a warning letter related to an April 2017 inspection and our use of certain active pharmaceutical ingredients in our compounded medications. We responded to the warning letter in July 2019. We will continue to work with the FDA to assure that all allegations in the warning letters have been addressed. We believe, to date, we have addressed all of the material items of concern in the FDA's warning letters and those related to the MedWatch notification (and any other requirements observed by FDA and noted to us), and we do not believe there will be any further action taken by FDA in these matters. Nonetheless, these items increased further scrutiny and negative publicity on us as a company. At times, we have become aware of negative views of regulators related to certain formulations, and as a result discontinued compounding certain drug formulations in an attempt help mitigate potential regulatory risk. As a result of the MedWatch notice, warning letters and other regulatory notifications, some physicians may be hesitant to prescribe and some patients may be hesitant to purchase and use non-FDA approved compounded formulations, particularly when an FDA-approved potential alternative is available. For other reasons physicians may be unwilling to prescribe or patients may be unwilling to use our proprietary compounded formulations, including the following: legal proscriptions on our ability to discuss the efficacy or safety of our formulations with potential users to the extent applicable data is available; our pharmacy operations are primarily operating on a cash-pay basis and reimbursement may or may not be available from third-party payors, including the government Medicare and Medicaid programs; and certain formulations are not required to be prepared and are not presently being prepared in a manufacturing facility governed by cGMP requirements. Any failure by physicians, patients and/or third-party payors to accept and embrace compounded formulations could substantially limit our market and cause our operations to suffer.

Our business is significantly impacted by state and federal statutes and regulations.

Our proprietary formulations are comprised of active pharmaceutical ingredients that are components of drugs that have received marketing approval from the FDA, although our proprietary compounded formulations have not themselves received FDA approval. FDA approval is not required in order to market and sell our compounded formulations. In the future we may choose to pursue FDA approval to market and sell certain potential drug candidates. The marketing and sale of compounded formulations is subject to and must comply with extensive state and federal statutes and regulations governing compounding pharmacies. These statutes and regulations include, among other things, restrictions on compounding for office use or in advance of receiving a patient-specific prescription or, for outsourcing facilities, requirements regarding preparation, such as regular FDA inspections and cGMP requirements, prohibitions on compounding drugs that are essentially copies of FDA-approved drugs, limitations on the volume of compounded formulations that may be sold across state lines, and prohibitions on wholesaling or reselling. These and other restrictions on the activities of compounding pharmacies and outsourcing facilities may significantly limit the market available for compounded formulations, compared to the market available for FDA-approved drugs.

Our pharmacy business is impacted by federal and state laws and regulations governing the following: the purchase, distribution, management, compounding, dispensing, reimbursement, marketing and labeling of prescription drugs and related services; FDA and/or state regulation affecting the pharmacy and pharmaceutical industries, including state pharmacy licensure and registration or permit standards; rules and regulations issued pursuant to HIPAA and other state and federal laws related to the use, disclosure and transmission of health information; and state and federal controlled substance laws. Our failure to comply with any of these laws and regulations could severely limit or curtail our pharmacy operations, which would materially harm our business and prospects. Further, our business could be adversely affected by changes in these or any newly enacted laws and regulations, and federal and state agency interpretations of the statutes and regulations. Statutory or regulatory changes could require us to make changes to our business model and operations and/or could require us to incur significantly increased costs to comply with such regulations.

If one of our pharmacies fails to comply with state statutes and regulations, the pharmacy could be required to cease operations or become subject to restrictions that could adversely affect our business.

State pharmacy laws require pharmacy locations in those states be licensed as an in-state pharmacy to dispense pharmaceuticals. In addition, state controlled substance laws require registration and compliance with state pharmacy licensure, registration or permit standards promulgated by the state's pharmacy licensing authority. Pharmacy and controlled substance laws often address the qualification of an applicant's personnel, the adequacy of its prescription fulfillment and inventory control practices and the adequacy of its facilities. If one of our pharmacies, or with which we may partner is found not to comply with state pharmacy and controlled substance laws and regulations, the pharmacy could be required to cease operations or become subject to burdensome restrictions and limitations on its business. For example, in March 2018, the California Board of Pharmacy filed an accusation against our subsidiary, Park related to a compounded formulation we believe was legally dispensed and was, without our knowledge, inappropriately administered to a patient unknown to us, by the prescribing healthcare professionals. While we dispute all claims against Park, we did enter into a settlement agreement with the California Board of Pharmacy and surrendered Park's pharmacy license and ceased its sterile compounding operations. We intend to transfer approximately half of Park's business to our New Jersey based pharmacy. Although we distribute our proprietary formulations through other compounding pharmacies, and not solely through Park, the loss of Park's ability to compound sterile formulations could have an adverse impact on our ability to implement our business plan in a timely manner.

If we or our partner facilities fail to comply with the Controlled Substances Act, FDCA, or similar state statutes and regulations, the pharmacy facilities could be required to cease operations or become subject to restrictions that could adversely affect our business.

State pharmacy laws require pharmacy locations in those states to be licensed as an in-state pharmacy to dispense pharmaceuticals. In addition, state controlled substance laws require registration and compliance with state pharmacy licensure, registration or permit standards promulgated by the state's pharmacy licensing authority. Pharmacy and controlled substance laws often address the qualification of an applicant's personnel, the adequacy of its prescription fulfillment and inventory control practices and the adequacy of its facilities. These laws also subject pharmacies to oversight by state boards of pharmacy and other regulators that could impose burdensome requirements or restrictions on operations if a pharmacy is found not in compliance with these laws. We believe that our compounding pharmacies are in material compliance with applicable regulatory requirements. Further, if any of our compounding pharmacies (including Park) fail to comply with regulatory requirements, they could be forced to permanently or temporarily cease or limit their compounding operations, which would severely limit our ability to market and sell our proprietary formulations and would materially harm our operations and prospects. Any noncompliance could also result in complaints or adverse actions by other state boards of pharmacy. FDA inspection of a facility to determine compliance with the FDCA, if not successful, may result in the loss of FDCA exemptions provided under Sections 503A and 503B, warning letters, injunctions, prosecution, fines and loss of required government licenses, certifications and approvals, any of which could involve significant costs and could cause us to be unable to realize the expected benefits of these pharmacies' operations.

Further, under federal law, Section 503A of the FDCA seeks to limit the amount of compounded products that a pharmacy can dispense interstate. The interpretation and enforcement of this provision is dependent on the FDA entering into a standard Memorandum of Understanding ("MOU") with each state setting forth limits on shipments of interstate compounding. Previously, the draft MOU presented by the FDA in February 2015 intended to limit interstate shipments of compounded drug units to 30% of all compounded and non-compounded units dispensed or distributed by the pharmacy per month, the excess of which the FDA considered an "inordinate amount." The FDA stated in the guidance issued in February 2015 that it would not enforce interstate restrictions until after it published a final MOU and made it available to states for signature for some designated period of time. If the final MOU was drafted and released by the FDA and was not signed by a particular state, then interstate shipments of compounded preparations from a pharmacy located in that state would be limited to quantities not greater than 5% of total prescription orders dispensed or distributed by the pharmacy; however, we are not aware that the FDA currently enforces or has in the past enforced the 5% rule and, under current draft guidance, the FDA had historically stated that it would not enforce the 5% rule until a final MOU was made available to states for signature. The FDA originally proposed a 180-day period for states to agree to the final MOU after the final version was presented, which to date has not occurred, before it would begin to enforce the 5% rule. In January of 2018, the FDA released a "2018 Compounding Policy Priorities Plan" (the "2018 Compounding Plan") which provided an overview of the key priorities the FDA plans to focus on in 2018 in connection with compounding regulations. One of the priorities outlined in the 2018 Compounding Plan addressed the current status of the MOU and the FDA's plan to release a revised MOU (the "Revised MOU"). Pursuant to the statements in the Compounding Plan, the Revised MOU would consider amounts shipped interstate by a compounder to be inordinate amounts if the "number of prescriptions of compounded drugs distributed interstate during any calendar month is greater than 50 percent." Importantly, instead of that number serving as a "hard limit, for state action," the 50% target would trigger certain additional reporting requirements. The Revised MOU will also provide states more time to report to the FDA, and flexibility on identifying when amounts are inordinate, considering the size and scope of compounding operations. Until the Revised MOU is issued and presented to states to consider, the extent of interstate dispensing restrictions imposed by Section 503A is unknown. However, if the final Revised MOU contains a 50% limit on interstate distribution, dependent on the additional reporting requirements to be outlined in the Revised MOU, our pharmacy operations could be materially limited. Additionally, the permanent injunction entered on July 22, 2019, by the United States District Court of the Central District of California in the Allergan litigation (also referenced in Item. 1 Legal Proceedings), enjoins the Company from engaging in activities that are inconsistent with current FDA guidelines for 503A and 503B operations. While the Company believes its operations fully comply with the injunction, if the Court were to find the Company to be in violation of the injunction, further sanctions including fines and limitations on the pharmacies' operations could occur.

There are many competitive risks related to marketing and selling our proprietary formulations and operating our compounding pharmacy business.

The pharmaceutical and pharmacy industries are highly competitive. We compete against branded drug companies, generic drug companies, outsourcing facilities and other compounding pharmacies. We are significantly smaller than some of our competitors. Currently we lack some of the financial and other resources needed to develop, produce, distribute and market our proprietary formulations at a level to capture a significant market share in these sectors. The drug products available through branded and generic drug companies with which our formulations compete have been approved for marketing and sale by the FDA and are required to be manufactured in facilities compliant with cGMP standards. Although we prepare our compounded formulations in accordance with the standards provided by the United States Pharmacopeia (“USP”) <795> and USP <797> and applicable state and federal law, our proprietary compounded formulations are not required to be, and have not been, approved for marketing and sale by the FDA. As a result, some physicians may be unwilling to prescribe, and some patients may be unwilling to use, our formulations. Additionally, under federal and state laws applicable to our current compounding pharmacy operations, we are not permitted to prepare significant amounts of a specific formulation in advance of a prescription, compound quantities for office use or utilize a wholesaler for distribution of our formulations; instead, our compounded formulations must be prepared and dispensed in connection with a physician prescription for an individually identified patient. Pharmaceutical companies, on the other hand, are able to sell their FDA-approved products to large pharmaceutical wholesalers, which can in turn sell to and supply hospitals and retail pharmacies. Even if we are successful in registering certain of our facilities as outsourcing facilities, our business may not be scalable on the scope available to our competitors that produce FDA-approved drugs, which may limit our potential for profitable operations. These facets of our operations may subject our business to limitations our competitors with FDA-approved drugs may not face.

Our future success depends in large part on our ability to maintain a competitive position with respect to biotechnology and related pharmaceutical technologies.

Biotechnology and related pharmaceutical technologies have undergone and continue to be subject to rapid and significant change. Our future success will depend in large part on our ability to maintain a competitive position with respect to these technologies. Products developed by our competitors, including FDA-approved drugs and compounded formulations created by other pharmacies, could render our products and technologies obsolete or unable to compete. Any products that we develop may become obsolete before we recover expenses incurred in their development, which may require us to raise additional funds that may or may not be available. The competitive environment requires an ongoing, extensive search for medical and technological innovations and the ability to develop and market these innovations effectively, and we may not be competitive with respect to these factors. Other competitive factors include the safety and efficacy of a product, the size of the market for a product, the timing of market entry relative to competitive products, the availability of alternative compounded formulations or approved drugs, the price of a product relative to alternative products, the availability of third-party reimbursement, the success of sales and marketing efforts, brand recognition and the availability of scientific and technical information about a product. Although we believe we are positioned to compete favorably with respect to many of these factors, if our proprietary formulations are unable to compete with the products of our competitors, we may never gain market share or achieve sustained profitability.

If a compounded drug formulation provided through our compounding services leads to patient injury or death or results in a product recall, we may be exposed to significant liabilities and reputational harm.

The success of our business, including our proprietary formulations and pharmacy operations, is highly dependent upon medical and patient perceptions of us and the actual safety and quality of our products. We could be adversely affected if we, any other compounding pharmacies or our formulations and technologies are subject to negative publicity. We could also be adversely affected if any of our formulations or other products we sell, any similar products sold by other companies, or any products sold by other compounding pharmacies prove to be, or are asserted to be, harmful to patients. For instance, if any of the components of approved drugs or other ingredients used to produce our compounded formulations have quality or other problems that adversely affect the finished compounded preparations, our sales could be adversely affected. Because of our dependence upon medical and patient perceptions, adverse publicity associated with illness or other adverse effects resulting from the use or misuse of our products, any similar products sold by other companies, or any other compounded formulations could have a material adverse impact on our business.

To assure compliance with USP guidelines, we have a policy whereby 100% of all sterile compound batches produced by our ImprimisRx compounding pharmacies are tested prior to their delivery to patients and physicians both in-house and externally by an independent, FDA-registered laboratory that has represented to us that it operates in compliance with current good laboratory practices. However, we could still become subject to product recalls and termination or suspension of our state pharmacy licenses if we fail to fully implement this policy, if the laboratory testing does not identify all contaminated products, or if our products otherwise cause or appear to have caused injury or harm to patients. In addition, laboratory testing may produce false positives, which could harm our business and impact our pharmacy operations and licensure even if the impacted formulations are ultimately found to be sterile and no patients are harmed by them. If adverse events or deaths or a product recall, either voluntarily or as required by the FDA or a state board of pharmacy, were associated with one of our proprietary formulations or any compounds prepared by our ImprimisRx compounding pharmacies or any pharmacy partner, our reputation could suffer, physicians may be unwilling to prescribe our proprietary formulations or order any prescriptions from such pharmacies, we could become subject to product and professional liability lawsuits, and our state pharmacy licenses could be terminated or restricted. If any of these events were to occur, we may be subject to significant litigation or other costs and loss of revenue, and we may be unable to continue our pharmacy operations and further develop and commercialize our proprietary formulations.

We carry product and professional liability insurance which may be inadequate.

Although we have secured product and professional liability insurance for our pharmacy operations and the marketing and sale of our formulations, our current or future insurance coverage may prove insufficient to cover any liability claims brought against us. Because of the increasing costs of insurance coverage, we may not be able to maintain insurance coverage at a reasonable cost or at a level adequate to satisfy liabilities that may arise.

Our ability to generate revenues will be diminished if we fail to obtain acceptable prices or an adequate level of reimbursement from third-party payors.

Currently, our ImprimisRx compounding pharmacies operate on mostly a cash-pay basis and do not submit large amounts of claims for reimbursement through Medicare, Medicaid or other third-party payors. As part of our Imprimis Cares initiative, we work with third-party insurers, pharmacy benefit managers and buying groups to offer patient-specific customizable compounded formulations at accessible prices. We plan to continue to devote time and other resources to seek reimbursement and patient pay opportunities for these and other compounded formulations. 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 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 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 conceivably 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. If government and other third-party payors do not provide adequate coverage and reimbursement levels for our formulations, the market acceptance for our formulations may be limited.

Additionally, we are making efforts to normalize the pricing for our currently available proprietary compounded formulations. Any efforts to attain optimized pricing for our Dropless Therapy or any of our other proprietary formulations could fail, which could make our products less attractive or unavailable to some patients or could reduce our margins.

We may not be able to correctly estimate our future operating expenses, which could lead to cash shortfalls.

The estimates of our future operating and capital expenditures are based upon our current business plan, our current operations and our current expectations regarding the commercialization of our proprietary formulations. Our projections have varied significantly in the past as a result of changes to our business model and strategy, our termination of efforts to pursue FDA approval of a drug candidate in November 2013, our acquisitions of compounding facilities and various product and corporate development opportunities since 2014, and the expenses in developing our pharmacy facilities into outsourcing facilities and registering them as such with the FDA. We may not accurately estimate the potential revenues and expenses of our operations. If we are unable to correctly estimate the amount of cash necessary to fund our business, we could spend our available financial resources much faster than we expect. If we do not have sufficient funds to continue to operate and develop our business, we could be required to seek additional financing earlier than we expect, which may not be available when needed or at all, or be forced to delay, scale back or eliminate some or all of our proposed operations.

If we do not successfully identify and acquire rights to potential formulations and successfully integrate them into our operations, our growth opportunities may be limited.

We plan to pursue the development of new proprietary compounded formulations in the ophthalmology and/or other therapeutic areas, which may include continued activities to develop and commercialize current assets or, if and as opportunities arise, potential acquisitions of new intellectual property rights and assets. We also intend to seek opportunities to introduce new lower-cost compounded formulation alternatives to higher-priced FDA-approved drugs. However, we expect acquisitions of compounding pharmacies to provide us with only limited research and development support and access to additional novel compounded formulations. We have historically relied, and we expect to continue to rely, primarily upon third parties to provide us with additional development opportunities. We may seek to enter into acquisition agreements or licensing arrangements to obtain rights to develop new formulations in the future, but only if we are able to identify attractive formulations and negotiate acquisition or license agreements on terms acceptable to us, which we may not be able to do. Moreover, we have limited resources to acquire additional potential product development assets and integrate them into our business. Acquisition opportunities may involve competition among several potential purchasers, which could include large multi-national pharmaceutical companies and other competitors that have access to greater financial resources than we do. If we are unable to obtain rights to development opportunities from third parties and we are unable to rely upon our compounding pharmacies and current and future relationships with pharmacists, physicians and other inventors to provide us with additional development opportunities, our growth and prospects could be limited.

Our product development strategy is to focus on a select few therapeutic areas in which we believe there is broad market potential, large unmet needs and/or unique value to physicians and patients and to develop and offer formulations within these therapeutic areas that could afford us with gross margins. However, our expectations and assumptions about market potential and patient needs may prove to be wrong and we may invest capital and other resources on formulations that do not generate sufficient revenues for us to recoup our investment.

We may be unable to successfully develop and commercialize our proprietary formulations or any other assets we may acquire.

We have acquired assets related to compoundable formulations and we have entered into one license agreement for rights to commercialize a compounding formulation. We are currently pursuing development and commercialization opportunities with respect to certain of these formulations, and we are in the process of assessing certain of our other assets in order to determine whether to pursue their development or commercialization. In addition, we expect to consider the acquisition of additional intellectual property rights or other assets in the future. Once we determine to pursue a potential drug candidate, we develop a commercialization strategy for it, which may include marketing and selling the formulation in compounded form through compounding pharmacies or outsourcing facilities, or pursuing FDA approval of the drug candidate. We may incorrectly assess the risks and benefits of the commercialization options or we may not pursue a commercialization strategy that proves to be successful. If we are unable to successfully commercialize one or more of our proprietary formulations, our operating results would be adversely affected. Even if we are able to successfully sell one or more proprietary formulations, we may never recoup our investment in acquiring or developing the formulations. Our failure to identify and expend our resources on formulations and technologies with commercial potential and execute an effective commercialization strategy for each of our formulations would negatively impact the long-term profitability of our business.

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

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 SWK debt instrument contain various restrictive covenants, including, among others, our obligation to deliver to SWK certain financial and other information, our obligation to comply with certain notice and insurance requirements, and our inability, without SWK's 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, SWK 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 \$59,000,000 in funds through equity and debt financings since January 2015. 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 convertible 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, such as the financial and operating covenants included in our loan agreement with SWK. 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.

We have in the past and may in the future participate in strategic transactions that could impact our liquidity, increase our expenses and distract our management.

From time to time we consider engaging in strategic transactions, such as out-licensing or in-licensing of compounds or technologies, acquisitions of companies, and asset purchases. We may also consider a variety of different business arrangements in the future, including strategic partnerships, joint ventures, spin-offs, restructurings, divestitures, business combinations and investments. In addition, another entity may pursue us or certain of our assets or aspects of our operations as an acquisition target. Any such transactions may require us to incur expenses specific to the transaction and not incident to our operations, may increase our near- and long-term expenditures, may pose significant integration challenges, may require us to hire or otherwise engage personnel with additional expertise, or may result in our selling or licensing of our assets or technologies under terms that may not prove profitable, any of which could harm our operations and financial results. Such transactions may also entail numerous other operational and financial risks, including, among others, exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to develop acquired products, drug candidates, technologies or businesses.

As part of our efforts to complete any significant transaction, we would need to expend significant resources to conduct business, legal and financial due diligence, with the goal of identifying and evaluating material risks involved in the transaction. We may be unsuccessful in ascertaining or evaluating all the risks and, as a result, we may not realize the expected benefits of the transaction, whether due to unidentified risks, integration difficulties, regulatory setbacks or other events. We may incur material liabilities for the past activities of any businesses we partner with or acquire. If any of these events occur, we could be subject to significant costs and damage to our reputation, business, results of operations and financial condition.

If we are unable to establish, train and maintain an effective sales and marketing infrastructure, we will not be able to commercialize our drug candidates successfully.

We have started to build an internal sales and marketing infrastructure to implement our business plan by developing internal sales teams and education campaigns to market our proprietary formulations. We will need to expend significant resources to further establish and grow this internal infrastructure and properly train sales personnel with respect to regulatory compliance matters. We may also choose to engage or enter into other arrangements with third parties to provide sales and marketing services for us in place of or to supplement our internal commercialization infrastructure. We may not be able to secure sales personnel or relationships with third-party sales organizations that are adequate in number or expertise to successfully market and sell our proprietary formulations and pharmacy services. Further, any third-party organizations we may seek to partner with or engage may not be able to provide sales and marketing services in accordance with our expectations and standards, may be more expensive than we can afford or may not be available on otherwise acceptable terms or at all. If we are unable to establish and maintain compliant and adequate sales and marketing capabilities, through our own internal infrastructure or third-party services or other arrangements, we may be unable to sell our formulations or services or generate meaningful revenue.

Our business and operations would suffer in the event of cybersecurity or other system failures.

Despite the implementation of security measures, our internal computer systems and those of any third parties with which we partner are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any cybersecurity or system failure, accident or breach to date, if an event were to occur, it could result in a material disruption of our operations, substantial costs to rectify or correct the failure, if possible, and potentially violation of HIPAA and other privacy laws applicable to our operations. If any disruption or security breach resulted in a loss of or damage to our data or applications or inappropriate disclosure of confidential or protected information, we could incur liability, further development of our proprietary formulations could be delayed, and our pharmacy operations could be disrupted, subject to restriction or forced to terminate their operations, any of which could severely harm our business and prospects.

We depend upon consultants, outside contractors and other third-party service providers for key aspects of our business.

We are substantially dependent on consultants and other outside contractors and service providers for key aspects of our business. For instance, we rely upon pharmacist, physician and research consultants and advisors to provide us with significant assistance in the evaluation of product development opportunities, and we have engaged or supported, and expect to continue to engage or support, consultants, advisors, clinical research organizations (“CROs”) and others to design, conduct, analyze and interpret the results of any clinical or non-clinical trials or other studies in connection with the research and development of our products. If any of our consultants or other service providers terminates its engagement with us, or if we are unable to engage highly qualified replacements as needed on commercially reasonable terms, we may be unable to successfully execute our business plan. We must effectively manage these third-party service providers to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, these third parties often engage in other business activities and may not devote sufficient time and attention to our activities and we may have only limited contractual rights in connection with the conduct of the activities we have engaged the service providers to perform. If we are unable to effectively manage our outsourced activities or if the quality, timeliness or accuracy of the services provided by third-party service providers is compromised for any reason, our development activities may be extended, delayed or terminated, and we may not be able to commercialize our formulations or advance our business.

Risks Related to Product Development, Regulatory Approval, Manufacturing and Commercialization

If we seek FDA approval to market and sell any of our proprietary formulations, such as with drug candidates being developed by Stowe, Radley, Mayfield, Melt, and Surface, we may be unable to demonstrate the necessary safety and efficacy to obtain such FDA approval.

Historically, our business strategy was focused on developing and commercializing product opportunities as compounded formulations. In 2017 and in the future we, alone or with project partners, may seek FDA regulatory approval to market and sell one or more of our assets as a FDA-approved drug. Obtaining FDA approval to market and sell pharmaceutical products is costly, time consuming, uncertain and subject to unanticipated delays. The FDA or other regulatory agencies may not approve a drug candidate on a timely basis or at all. Before we obtain FDA approval for the sale of any potential drug candidates, we will be required to demonstrate through preclinical studies and clinical trials that it is safe and effective for each intended use, which we may not be able to do. A failure to demonstrate safety and efficacy of a drug candidate to the FDA’s satisfaction would result in our failure to obtain FDA approval. Moreover, even if the FDA were to grant regulatory approval of a drug candidate, the approval may be limited to specific therapeutic areas or limited as to its distribution, which could reduce revenue potential, and we will be subject to extensive and costly post-approval requirements and oversight with respect to commercialization of the drug candidate.

Delays in the completion of, or the termination of, any clinical or non-clinical trials for any drug candidates for which we may seek FDA approval could adversely affect our business.

Clinical trials are very expensive, time consuming, unpredictable and difficult to design and implement. The results of clinical trials may be unfavorable, they may continue for several years, and they may take significantly longer to complete and involve significantly more costs than expected. Delays in the commencement or completion of clinical testing could significantly affect product development costs and plans with respect to any drug candidate for which we seek FDA approval. The commencement and completion of clinical trials can be delayed and experience difficulties for a number of reasons, including delays and difficulties caused by circumstances over which we may have no control. For instance, approvals of the scope, design or trial site may not be obtained from the FDA and other required bodies in a timely manner or at all, agreements with acceptable terms may not be reached in a timely manner or at all with CROs to conduct the trials, a sufficient number of subjects may not be recruited and enrolled in the trials, and third-party manufacturers of the materials for use in the trials may encounter delays and problems in the manufacturing process, including failure to produce materials in sufficient quantities or of an acceptable quality to complete the trials. If we were to experience delays in the commencement or completion of, or if we were to terminate, any clinical or non-clinical trials we pursue in the future, the commercial prospects for the applicable drug candidates may be limited or eliminated, which may prevent us from recouping our investment in research and development efforts for the drug candidate and would have a material adverse effect on our business, results of operations, financial condition and prospects.

We depend on the success of our drug candidates, and those we have royalty rights to, which have not yet demonstrated efficacy for their target or any other indications. If we are unable to generate revenues from our drug candidates, our ability to create stockholder value will be limited.

Our drug candidates are in the early stages of clinical development. We do not generate revenues from any FDA approved drug products. We expect to submit an Investigational New Drug Application (“IND”) or foreign equivalent to the FDA or international regulatory authorities seeking approval to initiate our clinical trials in humans in the United States or other countries yet to be determined. We plan on submitting our clinical trial protocols and receive approvals from the FDA and international regulatory authorities before we can commence any clinical trials. We may not be successful in obtaining acceptance from the FDA or comparable foreign regulatory authorities to start our clinical trials. If we do not obtain such acceptance, the time in which we expect to commence clinical programs for any drug candidate will be extended and such extension will increase our expenses and increase our need for additional capital. Moreover, there is no guarantee that our clinical trials will be successful or that we will continue clinical development in support of an approval from the FDA or comparable foreign regulatory authorities for any indication. We note that most drug candidates never reach the clinical development stage and even those that do commence clinical development have only a small chance of successfully completing clinical development and gaining regulatory approval. Therefore, our business currently depends entirely on the successful development, regulatory approval and commercialization of our drug candidates, which may never occur.

If we are not able to obtain any required regulatory approvals for our drug candidates, we will not be able to commercialize our drug candidate and our ability to generate revenue will be limited.

We must successfully complete clinical trials for our drug candidates before we can apply for marketing approval. Even if we complete our clinical trials, it does not assure marketing approval. Our clinical trials may be unsuccessful, which would materially harm our business. Even if our initial clinical trials are successful, we are required to conduct additional clinical trials to establish our drug candidates’ safety and efficacy, before an NDA or Biologics License Application (“BLA”), or their foreign equivalents can be filed with the FDA or comparable foreign regulatory authorities for marketing approval of our drug candidates.

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in early phases of pre-clinical and clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates. The research, testing, manufacturing, labeling, packaging, storage, approval, sale, marketing, advertising and promotion, pricing, export, import and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. We are not permitted to market our drug candidates as prescription pharmaceutical products in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. In the United States, the FDA generally requires the completion of clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before an NDA is approved. Regulatory authorities in other jurisdictions impose similar requirements. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are eventually approved for commercialization. We have not submitted an NDA to the FDA or comparable applications to other regulatory authorities. If our development efforts for our drug candidates, including regulatory approval, are not successful for their planned indications, or if adequate demand for our drug candidates is not generated, our business will be materially adversely affected.

Our success depends on the receipt of regulatory approval and the issuance of such regulatory approvals is uncertain and subject to a number of risks, including the following:

- the results of toxicology studies may not support the filing of an IND for our drug candidates;
- the FDA or comparable foreign regulatory authorities or Institutional Review Boards, or “IRB”, may disagree with the design or implementation of our clinical trials;
- we may not be able to provide acceptable evidence of our drug candidates’ safety and efficacy;
- the results of our clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA, European Medicines Agency (the “EMA”), or other regulatory agencies for marketing approval;

- the dosing of our drug candidates in a particular clinical trial may not be at an optimal level;
- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to our drug candidates;
- the data collected from clinical trials may not be sufficient to support the submission of an NDA, BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Failure to obtain regulatory approval for our drug candidates for the foregoing, or any other reasons, will prevent us from commercializing our drug candidates, and our ability to generate revenue will be materially impaired. We cannot guarantee that regulators will agree with our assessment of the results of the clinical trials we intend to conduct in the future or that such trials will be successful. The FDA, EMA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional clinical trials, or pre-clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of our drug candidates.

Excluding any activities through our ownership interest in Eton, we have not submitted an NDA or received regulatory approval to market our drug candidates in any jurisdiction. We have only limited experience in filing the applications necessary to gain regulatory approvals and expect to rely on consultants and third party contract research organizations, or “CROs”, with expertise in this area to assist us in this process. Securing regulatory approvals to market a product requires the submission of pre-clinical, clinical, and/or pharmacokinetic data, information about product manufacturing processes and inspection of facilities and supporting information to the appropriate regulatory authorities for each therapeutic indication to establish a drug candidate’s safety and efficacy for each indication. Our drug candidates may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining regulatory approval or prevent or limit commercial use with respect to one or all intended indications.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the drug candidates involved, the jurisdiction in which regulatory approval is sought and the substantial discretion of the regulatory authorities. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application may cause delays in the approval or rejection of an application. Regulatory approval obtained in one jurisdiction does not necessarily mean that a drug candidate will receive regulatory approval in all jurisdictions in which we may seek approval, but the failure to obtain approval in one jurisdiction may negatively impact our ability to seek approval in a different jurisdiction. Failure to obtain regulatory marketing approval for our drug candidates in any indication will prevent us from commercializing the drug candidate, and our ability to generate revenue will be materially impaired.

If we fail to successfully commercialize any of our drug candidates, we may need to acquire additional drug candidates and our business will be adversely affected.

We have never commercialized any drug candidates and do not have any other compounds in pre-clinical testing, lead optimization or lead identification stages beyond our drug candidates. We cannot be certain that any of our drug candidates will prove to be sufficiently effective and safe to meet applicable regulatory standards for any indication. If we fail to successfully commercialize any of our drug candidates for their targeted indications, whether as stand-alone therapies or in combination with other therapeutic agents, our business would be adversely affected.

Even if we receive regulatory approval for any of our drug candidates, we may not be able to successfully commercialize the product and the revenue that we generate from its sales, if any, may be limited.

If approved for marketing, the commercial success of our drug candidates will depend upon each product's acceptance by the medical community, including physicians, patients and health care payors. The degree of market acceptance for any of our drug candidates will depend on a number of factors, including:

- demonstration of clinical safety and efficacy;
- relative convenience, dosing burden and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe our drug candidates, and the target patient population to try new therapies;
- efficacy of our drug candidates compared to competing products;
- the introduction of any new products that may in the future become available targeting indications for which our drug candidates may be approved;
- new procedures or therapies that may reduce the incidences of any of the indications in which our drug candidates may show utility;
- pricing and cost-effectiveness;
- the inclusion or omission of our drug candidates in applicable therapeutic and vaccine guidelines;
- the effectiveness of our own or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in approved labeling from regulatory authorities;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors or to receive the necessary pricing approvals from government bodies regulating the pricing and usage of therapeutics; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement or government pricing approvals.

If any of our drug candidates are approved, but do not achieve an adequate level of acceptance by physicians, health care payors, and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of our drug candidates may require significant resources and may never be successful.

In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our drug candidates successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render our drug candidates not commercially viable. For example, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for any of our drug candidates, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve any of our drug candidates with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that indication. Further, the FDA or comparable foreign regulatory authorities may place conditions on approvals or require risk management plans or a Risk Evaluation and Mitigation Strategy, "REMS", to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA may also require a REMS for an approved product when new safety information emerges. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of our drug candidates. Moreover, product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of our drug candidates.

Even if we obtain marketing approval for any of our drug candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our drug candidates could be subject to labeling and other restrictions and withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our drug candidates.

Even if we obtain regulatory approval for any of our drug candidates for an indication, the FDA or foreign equivalent may still impose significant restrictions on their indicated uses or marketing or the conditions of approval, or impose ongoing requirements for potentially costly and time-consuming post-approval studies, including Phase 4 clinical trials, and post-market surveillance to monitor safety and efficacy. Our drug candidates will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post-market information. These requirements include registration with the FDA, as well as continued compliance with current Good Clinical Practices regulations, or “cGCPs”, for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current cGMP, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents.

The FDA has the authority to require a REMS as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria or requiring patient testing, monitoring and/or enrollment in a registry.

With respect to sales and marketing activities by us or any future partner, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state and local laws in the United States and similar legal requirements in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific/educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

In addition, if any of our drug candidates are approved for a particular indication, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product’s approved labeling. If we receive marketing approval for our drug candidates, physicians may nevertheless legally prescribe our products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed.

If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, problems with the facility where the product is manufactured, or we or our manufacturers fail to comply with applicable regulatory requirements, we may be subject to the following administrative or judicial sanctions:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- issuance of warning letters or untitled letters;
- clinical holds;
- injunctions or the imposition of civil or criminal penalties or monetary fines;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- suspension or imposition of restrictions on operations, including costly new manufacturing requirements; or
- product seizure or detention or refusal to permit the import or export of product.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our drug candidates and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase our product liability exposure.

Obtaining and maintaining regulatory approval of our drug candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our drug candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our drug candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a drug candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the drug candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials, as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a drug candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/ or to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our drug candidates will be harmed.

Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our drug candidates. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In the United States, the Medicare Modernization Act, or "MMA", changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for our drug candidates and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

The Health Care Reform Law is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The Health Care Reform Law revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the law imposed a significant annual fee on companies that manufacture or import branded prescription drug products.

The Health Care Reform Law remains subject to legislative efforts to repeal, modify or delay the implementation of the law. Efforts to date have generally been unsuccessful. If the Health Care Reform Law is repealed or modified, or if implementation of certain aspects of the Health Care Reform Law are delayed, such repeal, modification or delay may materially adversely impact our business, strategies, prospects, operating results or financial condition. We are unable to predict the full impact of any repeal or modification in the implementation of the Health Care Reform Law on us at this time.

In addition, other legislative changes have been proposed and adopted in the United States since the Health Care Reform Law was enacted. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce or eliminate our profitability.

Our drug candidates may face competition sooner than expected.

Our success will depend in part on our ability to obtain and maintain patent protection for our certain of our drug candidates and technologies and to prevent third parties from infringing upon our proprietary rights. We must also operate without infringing upon patents and proprietary rights of others, including by obtaining appropriate licenses to patents or other proprietary rights held by third parties, if necessary. However, the applications we have filed or may file in the future may never yield patents that protect our inventions and intellectual property assets. Failure to obtain patents that sufficiently cover our formulations and technologies would limit our protection against compounding pharmacies, outsourcing facilities, generic drug manufacturers, pharmaceutical companies and other parties who may seek to copy our products, produce products substantially similar to ours or use technologies substantially similar to those we own.

We also intend to seek data exclusivity or market exclusivity for our drug candidates provided under the FDCA, and similar laws in other countries. The FDCA provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Even if our drug candidates are considered to be reference products eligible for three years of exclusivity under the FDCA, another company could market competing products if the FDA approves a full NDA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the products. Moreover, an amendment or repeal of the FDCA could result in a shorter exclusivity period for our drug candidates, which would have a material adverse effect on our business.

If we market any of our drug candidates in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

The FDA enforces laws and regulations which require that the promotion of pharmaceutical products be consistent with the approved prescribing information. While physicians may prescribe an approved product for a so-called "off label" use, it is unlawful for a pharmaceutical company to promote its products in a manner that is inconsistent with its approved label and any company which engages in such conduct can subject that company to significant liability. Similarly, industry codes in the EU and other foreign jurisdictions prohibit companies from engaging in off-label promotion and regulatory agencies in various countries enforce violations of the code with civil penalties. While we intend to ensure that our promotional materials are consistent with our label, regulatory agencies may disagree with our assessment and may issue untitled letters, warning letters or may institute other civil or criminal enforcement proceedings. In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include the U.S. Anti-Kickback Statute, U.S. False Claims Act and similar state laws. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

The U.S. Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not, in all cases, meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, recent health care reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amends the intent requirement of the U.S. Anti-Kickback Statute and criminal health care fraud statutes; a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the U.S. Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the U.S. False Claims Act. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid.

Over the past few years, several pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicare or Medicaid for non-covered, off-label uses; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Most states also have statutes or regulations similar to the U.S. Anti-Kickback Statute and the U.S. False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include substantial civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, substantial criminal fines and imprisonment.

We will be completely dependent on third parties to manufacture our drug candidates, and our commercialization of our drug candidates could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of our drug candidates or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture the active pharmaceutical ingredient, ("API"), in our drug candidates for use in our clinical trials or for commercial product, if any. In addition, we do not have the capability to encapsulate any of our drug candidates as a finished drug product for commercial distribution. As a result, we will be obligated to rely on contract manufacturers, if and when any of our drug candidates are approved for commercialization. We have not entered into an agreement with any contract manufacturers for commercial supply and may not be able to engage a contract manufacturer for commercial supply of any of our drug candidates on favorable terms to us, or at all.

The facilities used by our contract manufacturers to manufacture our drug candidates must be approved by the FDA or comparable foreign regulatory authorities pursuant to inspections that will be conducted after we submit an NDA or BLA to the FDA or their equivalents to other relevant regulatory authorities. We will not control the manufacturing process of, and will be completely dependent on, our contract manufacturing partners for compliance with cGMPs for manufacture of both active drug substances and finished drug products. These cGMP regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to our drug candidates. If our contract manufacturers do not successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our drug candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our drug candidates, if approved.

Our contract manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. We will not have control over our contract manufacturers' compliance with these regulations and standards. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market any of our drug candidates, delays, suspensions or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we will not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect our ability to develop, obtain regulatory approval for or market any of our drug candidates.

If, for any reason, these third parties are unable or unwilling to perform, we may not be able to terminate our agreements with them, and we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our API or finished products or should cease doing business with us, we could experience significant interruptions in the supply of any of our drug candidates or may not be able to create a supply of our drug candidates at all. Were we to encounter manufacturing issues, our ability to produce a sufficient supply of any of our drug candidates might be negatively affected. Our inability to coordinate the efforts of our third party manufacturing partners, or the lack of capacity available at our third party manufacturing partners, could impair our ability to supply any of our drug candidates at required levels. Because of the significant regulatory requirements that we would need to satisfy in order to qualify a new bulk or finished product manufacturer, if we face these or other difficulties with our current manufacturing partners, we could experience significant interruptions in the supply of any of our drug candidates if we decided to transfer the manufacture of any of our drug candidates to one or more alternative manufacturers in an effort to deal with the difficulties.

Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our potential products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to a future contract manufacturer caused by problems at suppliers could delay shipment of any of our drug candidates, increase our cost of goods sold and result in lost sales.

We cannot guarantee that our future manufacturing and supply partners will be able to reduce the costs of commercial scale manufacturing of any of our drug candidates over time. If the commercial-scale manufacturing costs of any of our drug candidates are higher than expected, these costs may significantly impact our operating results. In order to reduce costs, we may need to develop and implement process improvements. However, in order to do so, we will need, from time to time, to notify or make submissions with regulatory authorities, and the improvements may be subject to approval by such regulatory authorities. We cannot be sure that we will receive these necessary approvals or that these approvals will be granted in a timely fashion. We also cannot guarantee that we will be able to enhance and optimize output in our commercial manufacturing process. If we cannot enhance and optimize output, we may not be able to reduce our costs over time.

We expect to rely on third parties to conduct clinical trials for our drug candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize any of our drug candidates and our business would be substantially harmed.

We expect to enter into agreements with third-party CROs to conduct and manage our clinical programs including contracting with clinical sites to perform our clinical studies. We plan to rely heavily on these parties for execution of clinical studies for our drug candidates and will control only certain aspects of their activities. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs and clinical sites will not relieve us of our regulatory responsibilities. We and our CROs will be required to comply with cGCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA and its foreign equivalents enforce these cGCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA or other regulatory authorities will determine that any of our clinical trials comply with cGCPs. In addition, our clinical trials must be conducted with products produced under cGMP regulations and will require a large number of test subjects. Our failure or the failure of our CROs or clinical sites to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties.

Although we intend to design the clinical trials for our drug candidates in consultation with CROs, we expect that the CROs will manage all of the clinical trials conducted at contracted clinical sites. As a result, many important aspects of our drug development programs would be outside of our direct control. In addition, the CROs and clinical sites may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements. If the CROs or clinical sites do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of any of our drug candidates for the subject indication may be delayed or our development program materially and irreversibly harmed. We cannot control the amount and timing of resources these CROs and clinical sites will devote to our program or any of our drug candidates. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of our clinical trials, which could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party CROs or clinical sites terminate, we may not be able to enter into arrangements with alternative CROs or clinical sites. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any such clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our financial results and the commercial prospects for any of our drug candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Any termination or suspension of, or delays in the commencement or completion of, any necessary studies of any of our drug candidates for any indications could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

The commencement and completion of clinical studies can be delayed for a number of reasons, including delays related to:

- the FDA or a comparable foreign regulatory authority failing to grant permission to proceed and placing the clinical study on hold;
- subjects for clinical testing failing to enroll or remain in our trials at the rate we expect;
- a facility manufacturing any of our drug candidates being ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of cGMP requirements or other applicable requirements, or cross-contaminations of drug candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- subjects choosing an alternative treatment for the indications for which we are developing our drug candidates, or participating in competing clinical studies;
- subjects experiencing severe or unexpected drug-related adverse effects;
- reports from clinical testing on similar technologies and products raising safety and/or efficacy concerns;
- third-party clinical investigators losing their license or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or employing methods consistent with the clinical trial protocol, cGMP requirements, or other third parties not performing data collection and analysis in a timely or accurate manner;
- inspections of clinical study sites by the FDA, comparable foreign regulatory authorities, or IRBs finding regulatory violations that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study, or that prohibit us from using some or all of the data in support of our marketing applications;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by such contractors in support of our marketing applications;
- one or more IRBs refusing to approve, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- deviations of the clinical sites from trial protocols or dropping out of a trial;
- adding new clinical trial sites;
- the inability of the CRO to execute any clinical trials for any reason; and
- government or regulatory delays or “clinical holds” requiring suspension or termination of a trial.

Product development costs for any of our drug candidates will increase if we have delays in testing or approval or if we need to perform more or larger clinical studies than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit our study protocols to the FDA, comparable foreign regulatory authorities, and IRBs for reexamination, which may impact the costs, timing or successful completion of that study. If we experience delays in completion of, or if we, the FDA or other regulatory authorities, the IRB, or other reviewing entities, or any of our clinical study sites suspend or terminate any of our clinical studies of any of our drug candidates, its commercial prospects may be materially harmed and our ability to generate product revenues will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical studies may also ultimately lead to the denial of regulatory approval of our drug candidates. In addition, if one or more clinical studies are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of any of our drug candidates could be significantly reduced.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing of drug candidates is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical studies and early clinical trials may not be predictive of the results of later-stage clinical trials. We cannot assure you that the FDA or comparable foreign regulatory authorities will view the results as we do or that any future trials of any of our drug candidates will achieve positive results. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Any future clinical trial results for our drug candidates may not be successful.

In addition, a number of factors could contribute to a lack of favorable safety and efficacy results for any of our drug candidates. For example, such trials could result in increased variability due to varying site characteristics, such as local standards of care, differences in evaluation period and surgical technique, and due to varying patient characteristics including demographic factors and health status.

Even though we may apply for orphan drug designation for a drug candidate, we may not be able to obtain orphan drug marketing exclusivity.

There is no guarantee that the FDA, EMA or their foreign equivalents will grant any future application for orphan drug designation for any of our drug candidates, which would make us ineligible for the additional exclusivity and other benefits of orphan drug designation.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of regulatory review and approval process. In addition to the potential period of exclusivity, orphan designation makes a company eligible for grant funding of up to \$400,000 per year for four years to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. There can be no assurance that we will receive orphan drug designation for any of our drug candidates in the indications for which we think they might qualify, if we elect to seek such applications.

Although we may pursue expedited regulatory approval pathways for a drug candidate, it may not qualify for expedited development or, if it does qualify for expedited development, it may not actually lead to a faster development or regulatory review or approval process.

Although we believe there may be an opportunity to accelerate the development of certain of our drug candidates through one or more of the FDA's expedited programs, such as fast track, breakthrough therapy, accelerated approval or priority review, we cannot be assured that any of our drug candidates will qualify for such programs.

For example, a drug may be eligible for designation as a breakthrough therapy if the drug is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Although breakthrough designation or access to any other expedited program may expedite the development or approval process, it does not change the standards for approval. If we apply for breakthrough therapy designation or any other expedited program for our drug candidates, the FDA may determine that our proposed target indication or other aspects of our clinical development plans do not qualify for such expedited program. Even if we are successful in obtaining a breakthrough therapy designation or access to any other expedited program, we may not experience faster development timelines or achieve faster review or approval compared to conventional FDA procedures. Access to an expedited program may also be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory approval for such drug candidate.

If we are unable to protect our proprietary rights, we may not be able to prevent others from using our intellectual property, which may reduce the competitiveness and value of the related assets.

Our success will depend in part on our ability to obtain and maintain patent protection for our formulations and technologies and to prevent third parties from infringing upon our proprietary rights. We must also operate without infringing upon patents and proprietary rights of others, including by obtaining appropriate licenses to patents or other proprietary rights held by third parties, if necessary. The primary means by which we will be able to protect our formulations and technologies from unauthorized use by third parties is to obtain valid and enforceable patents that cover them. As of February 28, 2019, we owned and/or licensed nine U.S. issued patents, two international issued patents, and 32 U.S. patent applications, including 29 utility (including continuation, continuation-in-part and divisional) and three provisional patent applications, and we owned seven international patent applications filed under the Patent Cooperation Treaty and 42 foreign patent applications. However, the applications we have filed or may file in the future may never yield patents that protect our inventions and intellectual property assets. Failure to obtain patents that sufficiently cover our formulations and technologies would limit our protection against other compounding pharmacies and outsourcing facilities, generic drug manufacturers, pharmaceutical companies and other parties who may seek to copy our products, produce products substantially similar to ours or use technologies substantially similar to those we own. We have made, and expect to continue to make, significant investments in certain of our proprietary formulations prior to the grant of any patents covering these formulations, and we may not receive a sufficient return on these investments if patent coverage or other appropriate intellectual property protection is not obtained and their competitiveness and value decreases.

The patent and intellectual property positions of pharmacies and pharmaceutical companies, including ours, are uncertain and involve complex legal and factual questions. There is no guarantee that we have developed or obtained or will in the future develop or obtain the rights to products or processes that are patentable, that patents will issue from any pending applications or that claims allowed will be sufficient to protect the technology we have developed or may in the future develop or to which we have acquired or may in the future acquire development rights. In addition, we cannot be certain that patents issued to us will not be challenged, invalidated, infringed or circumvented, including by our competitors, or that the rights granted thereunder will provide competitive advantages to us.

We also rely on unpatented trade secrets and know-how and continuing technological innovation in order to develop our formulations, which we seek to protect, in part, by confidentiality agreements with our employees, consultants, collaborators and others, including certain service providers. We also have invention or patent assignment agreements with our current employees and certain consultants. Nonetheless, our employees and consultants may breach these agreements, and we may not have adequate remedies for the breach. Our trade secrets may otherwise become known or be independently discovered by competitors or could be developed by a person not bound by an invention assignment agreement with us, in which case we may have no rights to use the applicable invention.

We may face additional competition outside of the U.S. as a result of a lack of patent coverage in some territories and differences in patent prosecution and enforcement laws in foreign countries.

Filing, prosecuting, defending and enforcing patents on our proprietary formulations throughout the world is extremely expensive. We do not currently have patent protection outside of the U.S. that covers any of our proprietary formulations or other assets that we are currently pursuing. Competitors may use our technologies to develop their own products in jurisdictions where we have not obtained patent protection.

Even if the international patent applications we have filed or may in the future file are issued or approved, it is likely that the scope of protection provided by such patents would be different from, and possibly less than, the scope provided by corresponding U.S. patents. As a result, patent rights we are able to obtain may not be sufficient to prevent generic competition. Further, the extent of our international market opportunity may be dependent upon the enforcement of patent rights in various other countries. A number of countries in which we could file patent applications have a history of weak enforcement and/or compulsory licensing of intellectual property rights. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patents and other intellectual property protection, particularly those relating to biotechnology and/or pharmaceuticals, which would make it difficult for us to stop a third party from infringing any of our intellectual property rights. Moreover, attempting to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business.

Our proprietary formulations and technologies could potentially conflict with the rights of others.

The preparation or sale of our proprietary formulations and use of our technologies may infringe on the patent or other intellectual property rights of others. If our products infringe or conflict with the patent or other intellectual property rights of others, third parties could bring legal actions against us claiming damages and seeking to enjoin our manufacturing and marketing of our affected products. Patent litigation is costly and time consuming and may divert management's attention and our resources. We may not have sufficient resources to bring any actions to a successful conclusion. If we are not successful in defending against these legal actions should they arise, we may be subject to monetary liability or be forced to alter our products, cease some or all of our operations relating to the affected products, or seek to obtain a license in order to continue manufacturing and marketing the affected products, which may not be available on acceptable terms or at all.

We are dependent on our Chief Executive Officer, Mark L. Baum, and other key persons for the continued growth and development of our Company.

Our Chief Executive Officer, Mark L. Baum, has played a primary role in creating and developing our current business model. Further, Mr. Baum has played a primary role in securing much of our material intellectual property rights and related assets, as well as the means to make and distribute our current products. We are highly dependent on Mr. Baum for the implementation of our business plan and the future development of our assets and our business, and the loss of Mr. Baum's services and leadership would likely materially adversely impact our Company. We presently maintain key man insurance for Mr. Baum. In addition, our loan agreement identifies other key persons including, but not limited to, our Chief Financial Officer, Andrew R. Boll and our President of ImprimisRx, John P. Saharek.

If we are unable to attract and retain key personnel and consultants, we may be unable to maintain or expand our business.

We have been focusing on building our management, pharmacy, research and development, sales and marketing and other personnel to pursue our current business model. To achieve our planned growth, we may have significant difficulty attracting and retaining necessary employees. Because of the specialized nature of our business, the ability to develop products and to compete will remain highly dependent upon our ability to attract and retain qualified pharmacy, scientific, technical and commercial employees and consultants. There is intense competition to hire qualified personnel in our industry, and we may be unable to continue to attract and retain the qualified personnel necessary for the development of our business. The loss of key employees or consultants or the failure to recruit or engage new employees and consultants could have a material adverse effect on our business.

Risks Related to Our Common Stock

If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results, which could cause our stock price to fall.

Effective internal controls are necessary for us to provide reliable financial results. If we cannot provide reliable financial results, our consolidated financial statements could be misstated, our reputation may be harmed and the trading price of our common stock could decline. As we discussed in Part I - Item 4 of this Quarterly Report, our management concluded that our internal controls over financial reporting were effective as of September 30, 2019. However, our controls over financial processes and reporting may not continue to be effective or we may identify material weaknesses or significant deficiencies in our internal controls in the future. Any failure to remediate any future material weaknesses or successfully implement required new or improved controls, could harm our operating results, cause us to fail to meet our reporting obligations or result in material misstatements in our consolidated financial statements or other public disclosures. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

A consistently active trading market for shares of our common stock may not be sustained.

Historically, trading in our common stock has been sporadic and volatile and our common stock has been "thinly-traded." There have been, and may in the future be, extended periods when trading activity in our shares is minimal, compared to a seasoned issuer with a large and steady volume of trading activity. The market for our common stock is also characterized by significant price volatility compared to seasoned issuers, and we expect that such volatility may continue. As a result, the trading of relatively small quantities of shares may disproportionately influence the market price of our common stock. A consistently active and liquid trading market in our securities may never develop or be sustained.

Our stock price may be volatile.

The market price of our common stock is likely to be highly volatile and could fluctuate widely in response to various factors, many of which are beyond our control, including the following: our ability to execute our business plan; operating results that fall below expectations; industry or regulatory developments; investor perception of our industry or our prospects; economic and other external factors; and the other risk factors discussed in this "Risk Factors" section.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock.

We have the right to issue shares of preferred stock without obtaining stockholder approval. If we were to issue preferred stock, it may have rights, preferences and privileges superior to those of our common stock.

We are authorized to issue 5,000,000 shares of “blank check” preferred stock, with such rights, preferences and privileges as may be determined from time to time by our board of directors. Our board of directors is empowered, without stockholder approval, to issue preferred stock at any time in one or more series and to fix the dividend rights, dissolution or liquidation preferences, redemption prices, conversion rights, voting rights and other rights, preferences and privileges for any series of our preferred stock that may be issued. The issuance of shares of preferred stock, depending on the rights, preferences and privileges attributable to the preferred stock, could reduce the voting rights and powers of our common stockholders and the portion of our assets allocated for distribution to our common stockholders in a liquidation event, and could also result in dilution to the book value per share of our common stock. The preferred stock could also be utilized, under certain circumstances, as a method for raising additional capital or discouraging, delaying or preventing a change in control of our Company.

We have not paid dividends in the past and do not expect to pay dividends in the future. Any return on an investment will be limited to any appreciation in the value of our common stock.

We have never paid cash dividends on our common stock and do not anticipate doing so in the foreseeable future. Any payment of dividends on our common stock would depend on contractual restrictions, such as those contained in our SWK loan agreement, as well as our earnings, financial condition and other business and economic factors as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if our stock price appreciates.

Offers or availability for sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

The sale of substantial amounts of our common stock in the public market, or the perception that sales could occur, may cause the market price of our common stock to fall. Sales could occur upon the expiration of any statutory holding period, such as under Rule 144 under the Securities Act of 1933, as amended, applicable to outstanding shares, upon expiration of any lock-up periods applicable to outstanding shares, upon our issuance of shares upon the exercise of outstanding options or warrants, or upon our issuance of shares pursuant offerings of our equity securities. The availability for sale of a substantial number of shares of our common stock, whether or not sales have occurred or are occurring, also could make it more difficult for us to raise additional financing through the sale of equity or equity-related securities in the future when needed, on acceptable terms or at all.

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
10.1*	Asset Purchase Agreement, dated July 26, 2019, by and between Park Compounding, Inc. and Noice Rx, LLC.
10.2*	Loan Agreement, dated July 26, 2019, by and between Park Compounding, Inc. and Noice Rx, LLC.
10.3*	License Agreement, dated July 28, 2019, among Mayfield Pharmaceuticals, Inc., TGV-Health, LLC and TGV-Gyneconix, LLC.
10.4*	License Agreement, dated July 29, 2019, among Stowe Pharmaceuticals, Inc., TGV-Health, LLC and TGV-Ophthalmix, LLC.
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*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase
101.DEF*	XBRL Taxonomy Extension Definition Linkbase
101.LAB*	XBRL Taxonomy Extension Label Linkbase
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase

* Filed herewith.

** Furnished herewith.

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: November 13, 2019

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)

ASSET PURCHASE AGREEMENT

THIS ASSET PURCHASE AGREEMENT (this “**Agreement**”) is made as of July 26, 2019, by and between Noice Rx, LLC a Texas limited liability company (“**Buyer**”), and Park Compounding, Inc., a California corporation (“**Seller**”). Buyer and Seller are sometimes referred to individually in this Agreement as a “**Party**” and collectively as the “**Parties**.” Other capitalized terms used in this Agreement and not otherwise defined are defined in Article 8.

WHEREAS, Seller is engaged in the business of operating a compounding pharmacy (the “**Business**”).

WHEREAS, Seller wishes to sell and assign to Buyer, and Buyer wishes to purchase and assume from Seller, substantially all of the assets of the Business, on the terms and subject to the conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants and agreements hereinafter set forth and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

ARTICLE 1**PRINCIPAL TRANSACTION**

1.1 Sale and Purchase of the Purchased Assets. On the terms and subject to the conditions of this Agreement, at Closing, Seller will sell, transfer and convey to Buyer, and Buyer will purchase from Seller, all of Seller’s right, title and interest in and to the Purchased Assets, free and clear of all Encumbrances (other than Permitted Encumbrances).

(a) Purchased Assets. For purposes of this Agreement, “**Purchased Assets**” means, except for the Excluded Assets, all property, assets and rights of any kind and description, whether real, personal or mixed, tangible or intangible, wherever located, owned by Seller associated with the Business, including:

(i) all furniture, fixtures, equipment and other tangible personal property used, or held for use, in connection with the operation of the Business;

(ii) all Prescription Files, Governmental Authorizations, Healthcare Authorizations, and National Provider Identifier numbers, subject to applicable Laws;

(iii) all Assigned Contracts;

(iv) all pharmaceutical and non-pharmaceutical inventory that is located at the Leased Real Property and procured by Seller in the normal course of business;

(v) pre-paid expenses, deposits, claims for refunds, rebates and rights of offset, and claims against third Persons;

(vi) all Books and Records (excluding Seller's Organizational Documents);

(vii) all Owned Intellectual Property Assets (including telephone and telecopy numbers, e-mail addresses, trade names and company names); and

(viii) all goodwill associated with the Business.

(b) Excluded Assets. For purposes of this Agreement, "**Excluded Assets**" means:

(i) Seller's cash and cash equivalents;

(ii) accounts and notes receivable,

(iii) Seller's Organizational Documents;

(iv) all rights and claims in any Tax refunds or prepaid Taxes of Seller;

(v) all Insurance policies of Seller and any prepaid premiums or refunds related thereto;

(vi) all Seller Benefit Plans (and any related trusts or funding arrangements);

(vii) all Tax Returns of Seller (including working papers related thereto);

(viii) Seller's rights in any Contracts not included among the Assigned Contracts;

(ix) all assets related to the Medicare and Medicaid Programs;

(x) the rights of Seller under this Agreement and the other Transaction Documents;

(xi) all assets primarily used in Seller's ophthalmology business, exclusive of those used in and related to the autologous serum eye drops sales; and

(xii) all assets set forth on Schedule 1.1(b).

1.2 Assumed Liabilities; Excluded Liabilities. As additional consideration for the Purchased Assets, at Closing, Buyer will assume and agree to discharge, when due, the Assumed Liabilities. Except for the Assumed Liabilities, neither Buyer nor any of its Affiliates will assume or become liable for any liability or obligation of Seller.

(a) For purposes of this Agreement, “**Assumed Liabilities**” means: (A) executory obligations arising in the Ordinary Course of Business under the Assigned Contracts, but excluding obligations arising from any breach of any Assigned Contracts prior to Closing; (B) Permitted Encumbrances; (C) all trade accounts payable of Seller to third parties in connection with the Business that remain unpaid and are not delinquent as of the Closing Date and that either are reflected on the Financial Statements or arose in the Ordinary Course of Business consistent with past practice since the date of the Financial Statements; and (D) post-Closing Liabilities relating to Buyer’s operation of the Business.

(b) All liabilities and obligations of Seller not expressly included among the Assumed Liabilities are retained by Seller and are collectively referred to in this Agreement as the “**Excluded Liabilities.**” The “**Excluded Liabilities**” include all: (A) liabilities and obligations related to Excluded Assets; (B) pre-Closing claims (whether in tort, contract or otherwise); (C) obligations for borrowed money or contracts entered into by Seller that are not otherwise included in the Purchased Assets; (D) pre-Closing Taxes; (E) liabilities and obligations related to the provision of any goods or services reimbursed or reimbursable by any healthcare program of any Governmental Body (including the Medicare and Medicaid Programs and related supplier agreements and supplier numbers); and (F) refunds and other liabilities and obligations related to any overpayment.

1.3 Purchase Price. The aggregate purchase price of the Purchased Assets shall be equal to the principal amount of eight million dollars (\$8,000,000) (the “**Purchase Price**”).

1.4 Payment of Purchase Price. The Purchase Price shall be payable pursuant to the terms and conditions of a Secured Promissory Note, in the principal amount equal to the Purchase Price, substantially in the form attached hereto as Exhibit A (the “**Seller Note**”).

1.5 Purchase Price Allocation. The Purchase Price, including any adjustments thereto, and any other applicable amounts, will be allocated among the Purchased Assets and the restrictive covenants set forth in Section 4.5 in accordance with Section 1060 of the Code and the treasury regulations thereunder (and any similar provision of state, local, or non-U.S. law, as appropriate) as follows (the “**Allocation**”).

(a) Buyer shall deliver a draft of such Allocation to Seller within sixty (60) calendar days after the Closing Date for Seller to comment and review such draft Allocation. In the event Seller does not provide Buyer with comments within thirty (30) calendar days from receipt, such Allocation shall be deemed final by the Parties hereto. In the event that Seller provides comments within such thirty (30) day period, and the Parties hereto cannot agree on a final Allocation schedule within thirty (30) days after Buyer has delivered the allocation schedule to Seller, then the Parties shall jointly retain an mutually-agreeable firm of independent certified public accountants (the “**Independent Accountants**”) to review the disputed item(s) on the allocation schedule. Buyer and Seller shall cooperate with the Independent Accountants and shall promptly provide such Independent Accountants with such documents and information as may be reasonably requested. The determination by the Independent Accountants of such allocation shall be final and binding on the Parties. The costs and expenses of the Independent Accountants in undertaking such review and determination shall be shared equally by Seller and Buyer and, to the extent required by the Independent Accountants or any Party shall be paid at the time of engagement of the Independent Accountants.

(b) Buyer and Seller and their respective Affiliates shall report and file Tax Returns (including, but not limited to IRS Form 8594) in all respects and for all purposes consistent with such allocation, subject to any Purchase Price adjustment under this Agreement. Seller shall timely and properly prepare, execute, file and deliver all such documents, forms and other information as Buyer may reasonably request to prepare such allocation. Neither Buyer, Seller nor any other Party shall take any position (whether in audits, Tax Returns or otherwise) that is inconsistent with such allocation unless required to do so by applicable law. All values contained in such allocation shall be consistently reported by the parties hereto and their Affiliates for Tax purposes in accordance with the procedures reflected herein.

After Closing, the Parties will make consistent use of the Allocation for all Tax purposes and in all filings, declarations and reports with the IRS and any other applicable Governmental Body in respect thereof. The applicable Parties each will file an IRS Form 8594 "Asset Acquisition Statement Under Section 1060" at the time and in the manner as required by Treasury Regulation 1.1060-1 (and all other applicable Tax Returns required by applicable state or local law) consistent with the Allocation, and the Parties agree not to take any position inconsistent therewith for any Tax purpose.

1.6 Closing. Subject to the satisfaction or waiver of the conditions set forth in Article 5, the consummation of the transactions contemplated by this Agreement ("Closing") will take place remotely via exchange of signature pages to the Transaction Documents on the third Business Day following the satisfaction or waiver of the conditions set forth in Article 5 (other than those conditions which by their nature are to be satisfied at Closing, which conditions must be satisfied at Closing unless waived) or at any other place, time or date as may be mutually agreed by Buyer and Seller. The date on which Closing occurs is referred to as the "Closing Date." For Tax purposes, Closing will be deemed effective as of the close of business on the Closing Date.

1.7 Deliveries at Closing.

(a) Buyer Deliverables. At Closing, Buyer will deliver to Seller: (i) an executed copy of the Seller Note and any related documents required to perfect the security interest granted therein; (ii) certified copies of resolutions of Buyer, in a form reasonably acceptable to Seller, authorizing the consummation of the transactions contemplated by this Agreement; (iii) an executed instrument of assumption providing for Buyer's assumption of the Assumed Liabilities; (iv) an executed copy of a Transition Services Agreement, substantially in the form attached hereto as Exhibit B (the "**Transition Services Agreement**"); (v) deliver to Seller an executed copy of a Warrant, substantially in the form attached hereto as Exhibit C (the "**Warrant**"); and (vi) deliver all other agreements, certificates, instruments and documents as may be reasonably required of Buyer under this Agreement.

(b) **Seller Deliverables.** At Closing, Seller will: (i) deliver to Buyer possession of the Purchased Assets; (ii) deliver bills of sale and other assignments of the Purchased Assets, in forms reasonably acceptable to Buyer, executed by Seller and sufficient to transfer good and valid title to the Purchased Assets to Buyer; (iii) deliver all licenses, permits, registrations, authorizations, consents and approvals, in forms reasonably acceptable to Buyer, by any third Person, including any Governmental Authorizations and consents under Assigned Contracts, that are necessary for the consummation of the transactions contemplated by this Agreement or another Transaction Document; (iv) deliver evidence, in forms reasonably acceptable to Buyer, of the releases of all Encumbrances on the Purchased Assets, other than Permitted Encumbrances; (v) deliver a written assignment of the leasehold interest under the Real Property Lease, which shall be in form and substance acceptable to Buyer and executed by Seller; (vi) deliver certificates from Seller in the applicable form provided in Treasury Regulation Section 1.1445-2; (vii) deliver powers of attorney and/or management agreements, in a form approved by Buyer, allowing Buyer, to the extent permitted by applicable Law, to obtain from boards of pharmacy and any other applicable state or federal Governmental Body (the “**Pharmacy Permits**”) and from the United States Drug Enforcement Administration (the “**DEA Registrations**”) the authority to operate under licenses and registrations held by Seller for a period not to exceed ninety (90) days; (viii) to the extent permitted by applicable Law, an agreement to allow continued claims submission and/or assignment of claims for any Payment Programs; (ix) deliver to Buyer an executed copy of the Transition Services Agreement; (x) deliver to Buyer an executed copy of the Warrant; and (xi) deliver all other agreements, certificates, instruments and documents as may be reasonably required of Seller under this Agreement.

ARTICLE 2 REPRESENTATIONS AND WARRANTIES OF SELLER

Seller hereby makes the following representations and warranties as of the date of this Agreement and again on the Closing Date immediately preceding Closing to induce Buyer to enter into this Agreement and to consummate the transactions contemplated hereby. These representations and warranties will survive Closing for the periods specified in Section 7.6.

2.1 Organization. Seller is a corporation, duly organized, validly existing and in good standing under the Laws of the State of California. Seller have the requisite power and authority to conduct its Business as it is now being conducted, to own and use the Purchased Assets and to perform its obligations under its Contracts. Seller is duly qualified to do business as a foreign entity and is in good standing in each state or other jurisdiction in which either the ownership or use of its Purchased Assets or the nature of the activities conducted by it requires such qualification, except where the failure to be so qualified or in good standing would not have a Material Adverse Effect. Certified copies of Seller’s Organizational Documents have been delivered to Buyer.

2.2 Financial Statements and Financial Matters.

(a) Copies of the statement of operations of Seller at and for the fiscal year ended December 31, 2018 and interim period ended June 30, 2019 (the “**Financial Statements**”) were delivered to Buyer. The Financial Statements are complete and accurate in all respects and present fairly the financial condition of Seller at the dates indicated and Seller’s results of operations for the periods then ended. The Financial Statements (i) were prepared on a pro forma basis and included non-GAAP based adjustments to depict operations of Seller as a separate entity from Seller Parent, and (ii) are consistent with the Books and Records of Seller Parent’s consolidated audited financial statements prepared in accordance with GAAP (subject, in the case of the Interim Financial Statements, to the absence of footnotes and normal year-end adjustments consistent with prior periods).

(b) Except for obligations under Contracts (other than those arising from a breach by Seller of such Contracts) and the liabilities and obligations set forth on Schedule 2.2(b), Seller has no liabilities or obligations (whether known or unknown, absolute, accrued, contingent or otherwise), except for (i) liabilities and obligations reflected or reserved against on the Balance Sheet and (ii) current liabilities and obligations (other than those that arise from a breach of Contract or violation of a Law) incurred in the Ordinary Course of Business since the date of the Balance Sheet which are not materially different in nature or amount than those incurred in prior periods.

(c) Schedule 2.2(c) lists all of the outstanding Indebtedness of Seller and the principal balance thereof as of a recent date identified thereon.

2.3 Books and Records. The Books and Records of Seller have been made available to Buyer, are complete and accurate in all material respects and have been maintained in accordance with sound business practices. At Closing, the Books and Records of Seller included among the Purchased Assets will be delivered to Buyer.

2.4 Taxes.

(a) Seller has timely filed all Tax Returns that it was required to file. All such Tax Returns were correct and complete in all respects and were prepared in substantial compliance with all applicable Laws and regulations. All Taxes owed by Seller (whether or not shown or required to be shown on any Tax Return) have been paid. Seller currently is not the beneficiary of any extension of time within which to file any Tax Return. No claim has ever been made by a Governmental Body in a jurisdiction where Seller does not file Tax Returns that Seller is or may be subject to taxation by that jurisdiction. There are no Encumbrances, other than Permitted Encumbrances, on any of the assets of Seller that arose in connection with any failure (or alleged failure) to pay any Tax.

(b) Seller has withheld and paid all Taxes required to have been withheld and paid in connection with any amounts paid or owing to any employee, independent contractor, creditor, stockholder, or other third party, and all Forms W-2 and 1099 (and corresponding state and local forms) required with respect thereto have been properly completed and timely filed.

(c) Schedule 2.4 contains a list of each jurisdiction to which Taxes have been claimed to be or are payable by Seller and Schedule 2.4 lists all federal, state, local, and non-U.S. Tax Returns filed with respect to Seller for taxable periods ended on or after December 31, 2016, indicates those Tax Returns that have been audited, and indicates those Tax Returns that currently are the subject of audit. Seller have delivered to Buyer correct and complete copies of all income Tax Returns, examination reports, and statements of deficiencies assessed against or agreed to by Seller since January 1, 2016.

(d) Seller does not expect any Governmental Body to assess any additional Taxes for any period ending on or before the Closing Date. There are no audits of or other Proceedings pending with respect to a Tax Return of Seller, and there are no outstanding waivers of statutes of limitations regarding Taxes payable by Seller. There is no dispute or claim concerning any Tax liability of Seller either (i) claimed or raised by any Governmental Body in writing or (ii) as to which Seller has Knowledge based upon personal contact with any agent of such Governmental Body.

(e) Seller has not waived any statute of limitations in respect of Taxes or agreed to any extension of time with respect to a Tax assessment or deficiency.

(f) All Taxes incurred by Seller but not yet paid are, and on the Closing Date will be, reflected or reserved against on the Balance Sheet, other than Taxes incurred in the Ordinary Course of Business since the date of the Balance Sheet that are not materially different in nature or amount than those incurred in prior periods.

(g) Seller is not a party to a Contract, arrangement or plan that could result, separately or in the aggregate, in the payment of (i) an “excess parachute payment” within the meaning of Section 280G of the Code (or a corresponding provision of state, local or non-U.S. Tax law) or (ii) an amount that would not be fully deductible as a result of Section 162(m) of the Code (or a corresponding provision of state, local or non-U.S. Tax law).

(h) Seller is not a party to any Tax allocation or sharing agreement. Seller (i) has not been a member of an Affiliated Group filing a consolidated federal income Tax Return (other than a group the common parent of which was Seller) and (ii) has no liability for the Taxes of any Person under Treasury Regulation §1.1502-6 (or any similar provision of state, local, or non-U.S. law), as a transferee or successor, by contract, or otherwise.

(i) Seller will not be required to include any item of income in, or exclude any item of deduction from, taxable income for any taxable period (or portion thereof) ending after the Closing Date as a result of any:

(i) change in method of accounting for a taxable period (or portion thereof) ending on or prior to the Closing Date;

(ii) “closing agreement,” as described in Code Section 7121 (or any corresponding provision of state, local, or non-U.S. income Tax law);

(iii) Intercompany transaction within the meaning of Treasury Regulation §1.1502-13 or any excess loss account within the meaning of Treasury Regulation. §1.1502-19 (or any corresponding or similar provision or administrative rule of federal, state, local, or non-U.S. income Tax law);

(iv) installment sale or open transaction made on or prior to the Closing Date;

(v) prepaid amount received on or prior to the Closing Date; or

(vi) election under Code Section 108(i).

(j) Seller has not distributed stock of another Person, or has had its stock distributed by another Person, in a transaction that was purported or intended to be governed in whole or in part by Code Section 355 or Code Section 361.

(k) Seller is not a "foreign person" within the meaning of Section 1445 of the Code.

(l) No issue has been raised by written inquiry of any Governmental Body which would reasonably be expected to affect the Tax treatment of the Purchased Assets or the Business for any taxable period (or portion thereof) ending after the Closing Date

(m) No power of attorney with respect to any Tax matter is currently in force with respect to the Purchased Assets or the Business that would, in any manner, bind, obligate or restrict the Buyer.

(n) None of the Purchased Assets is an interest in an entity taxable as a corporation, partnership, trust or real estate mortgage investment conduit for federal income tax purposes.

(o) Seller has disclosed on its federal income Tax Returns all positions taken therein that would reasonably be expected to give rise to a substantial understatement of federal income Tax within the meaning of Code Section 6662. Seller is not and has not been a party to any "reportable transaction," as defined in Code Section 6707A(c)(1) and Treasury Regulation §1.6011-4(b)

2.5 Business Operations.

(a) Except as set forth on Schedule 2.5(a), since March 31, 2019: (i) the operations and affairs of Seller and the Business have been conducted only in the Ordinary Course of Business; (ii) no Restricted Event has occurred or is reasonably likely to occur; and (iii) no event has occurred or circumstance exists that has caused or would reasonably be expected to result in a Material Adverse Effect.

(b) Except as set forth on Schedule 2.5(b), no Affiliates or Related Persons of Seller is or has during the prior three years engaged in any transaction with Seller, whether directly or indirectly, as an owner, shareholder, creditor or agent of, or consultant or lender to a Person engaged in business with Seller, including as a supplier or purchaser of goods or services to or from Seller or the Business or any part of which is or was in actual or potential competition with Seller or the Business. Schedule 2.5(b) sets forth any Contracts between Seller, on one hand, and any of its Affiliates or Related Persons, on the other hand.

(c) The express warranties applicable to the services or products sold or to be sold by Seller are attached to Schedule 2.5(c). Except as set forth on Schedule 2.5(c), there is no claim outstanding or Proceeding pending or, to Seller's Knowledge, Threatened under any warranty of Seller or any supplier to Seller. Schedule 2.5(c) summarizes material warranty claims that have been asserted against Seller within the past three years, indicating for each claim whether it has been resolved or remains outstanding and, if resolved, the manner and cost of resolution. No warranty claim, individually or in the aggregate with other warranty claims, has had or would reasonably be expected to result in a material liability to Seller that is not reserved or accrued for on the Balance Sheet.

(d) Schedule 2.5(d) lists the names, account numbers and locations of all banks and other financial institutions at which Seller has an account or safe deposit box and the name of all Persons authorized to draft on or have access to any such accounts.

(e) Schedule 2.5(e) sets forth: (i) a list of (A) the top 10 payors of Seller by revenue (the “**Material Payors**”) and (B) the top 10 suppliers of Seller by cost (the “**Material Suppliers**”), in each case, for the 12-month period ended December 31, 2018; and (ii) the corresponding amount in dollars of sales or purchases (as applicable) made to or from the Material Payors and the Material Suppliers during such time periods. Since the Balance Sheet Date, no Material Payor or Material Supplier has canceled or otherwise terminated its relationship with Seller. Seller has not received any notice from any Material Payor or Material Supplier indicating that such Material Payor or Material Supplier may terminate or materially adversely modify its relationship with Seller and, to Seller’s Knowledge, no such termination or modification is anticipated.

(f) Neither Seller nor any of its Representatives acting on its behalf: (i) has used any company or other funds for unlawful contributions, payments or gratuities, or made any unlawful expenditures relating to political or administrative activity to officials of a Governmental Body or to any other Person, or established or maintained any unlawful or unrecorded funds in violation of applicable Law; (ii) accepted or received any unlawful contributions, payments, gifts or gratuities; (iii) made any unlawful payment to foreign or domestic government officials or employees or to foreign or domestic political parties or campaigns or violated any provision of the Foreign Corrupt Practices Act of 1977, as amended, or the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT ACT) Act of 2001, as amended or (iv) conducted business or engaged in a transaction with any Person (A) who was identified on the OFAC List at such time or (B) with whom a citizen of the United States was prohibited from engaging in such business or transaction by any trade embargo, economic sanction, executive order or Law.

2.6 Employees.

(a) Schedule 2.6(a) contains, as of a recent date specified therein, the following information (i) for each employee of Seller (including, as designated thereon, each employee on leave of absence or layoff status), the name, job title, hire date, current compensation paid or payable on an annualized basis, annual vacation days and accrued vacation, license or registration numbers of pharmacists and technicians with renewal dates, and any other information reasonably requested by Buyer to determine whether such employees are included in any government exclusion list, including the OIG List of Excluded Individuals/Entities (“**LEIE**”) and the General Service Administration (“**GSA**”) Exclusion List (collectively, the “**Exclusion Lists**”); (ii) for each independent contractor used by Seller at any time since January 1, 2018, the name of such independent contractor, type of services provided by such independent contractor and aggregate amount of consideration paid to such independent contractors by Seller during such time and (iii) for each temporary staffing personnel or temporary employee used by Seller at any time since January 1, 2018, the name of such temporary employee, type of services provided by them and aggregate amount of consideration paid to them by Seller during such time. Seller has not received written notice that an employee intends to terminate his or her employment relationship with Seller and, to Seller’s Knowledge, there is no reason to reasonably expect that any such employee is likely to refuse an offer of employment from Buyer. The employees of Seller are either United States citizens or permanent resident aliens. Except as set forth on Schedule 2.6(a), the employees of Seller are employed on an “at will” basis and are terminable by Seller without penalty or severance obligation. A copy of the current version of the policy manual and handbook provided to or governing the employees of Seller, and a copy of the application forms currently being used by Seller in connection with the hiring of new employees, have been delivered to Buyer.

(b) Seller is not now, nor in the past three years has it been, a party to a collective bargaining or similar labor Contract. With respect to Seller or the Business, there has not been in the last three years, there is not now pending or existing and, to Seller's Knowledge, there is not Threatened: (i) a union organizational activity, strike, slowdown, picketing, work stoppage, lockout or other labor dispute or Proceeding; (ii) an application, complaint, charge or other Proceeding filed with a Governmental Body regarding a labor or employment matter; or (iii) an application, petition or demand for recognition or certification of a collective bargaining agent. To Seller's Knowledge, no event has occurred or circumstance exists that would reasonably be expected to give rise to the matters described in clauses (i), (ii) or (iii).

(c) Seller is complying, and has complied in the last three years, in all material respects with applicable Law and its own policies relating to labor and employment matters, including those relating to fair employment practices, terms and conditions of employment, contractual obligations, equal employment opportunity, nondiscrimination, immigration, wages, hours, benefits, workers' compensation, the payment of social security and similar Taxes, employee termination (actual or constructive), occupational safety, plant closing, mass layoffs and changes in operations. Except as described on Schedule 2.6(c), there is not currently, nor has there been in the past three years, a Proceeding against Seller or one of its employees alleging harassment, discrimination or other similar conduct or an internal investigation of an allegation, charge or complaint against Seller or one of its employees alleging harassment, discrimination or other similar conduct.

(d) Except as set forth on Schedule 2.6(d), Seller is not a party to a Contract with a present or former director, officer, manager, employee (leased or otherwise), agent, consultant or independent contractor with respect to length, duration or condition of employment or engagement (or the termination thereof), salary, bonus, compensation, deferred compensation, health Insurance, severance, other form of remuneration or otherwise.

(e) Except as set forth on Schedule 2.6(e), there is no Proceeding pending or, to Seller's Knowledge, Threatened against or affecting Seller relating to the alleged violation of a Law pertaining to labor relations or employment matters. Seller has not committed an unfair labor practice, nor has there has been a complaint, claim, charge or other Proceeding of unfair labor practice filed or, to Seller's Knowledge, Threatened against Seller before the National Labor Relations Board or other Governmental Body. There has been no complaint, claim, charge or other Proceeding of discrimination filed or, to Seller's Knowledge, Threatened against Seller with the EEOC or other Governmental Body.

(f) Seller has made all required payments to its unemployment compensation reserve accounts with the appropriate Governmental Bodies of the states or other jurisdictions where it is required to maintain such accounts, and each such account has a positive balance.

(g) Within the twelve (12) months prior to the date of this Agreement, Seller has not implemented a plant closing or layoff of employees that could implicate the WARN Act or similar Law. Schedule 2.6(g) lists the employees of Seller who have been terminated or laid off, or whose hours of work have been reduced by more than 50%, in the twelve (12) months prior to the date of this Agreement.

2.7 Employee Benefit Plans. Schedule 2.7(a) lists all Seller Benefit Plans. All Seller Benefit Plans are provided by Seller Parent. Copies of all Seller Benefit Plan have been delivered to Buyer, including summary plan descriptions, summaries of material modifications and related Contracts (including descriptions of vacation, separation and other personnel policies). Each of Seller and Seller Parent is complying, and has complied in the last three years, in all material respects with its obligations under or relating to Seller Benefit Plan (including, if applicable, reporting, disclosure, prohibited transaction, IRS qualification, Section 409A of the Code, ERISA and funding obligations). No prohibited transaction (within the meaning of Section 406 of ERISA or Section 4975 of the Code) for which a statutory or administrative exemption does not exist has occurred with respect to Seller Benefit Plan. The consummation of the transactions contemplated by this Agreement will not result in a prohibited transaction described in Section 406 of ERISA or Section 4975 of the Code for which an exemption is not available. No Proceeding with respect to the administration or the investment of assets of Seller Benefit Plan (other than routine claims for benefits) is pending or, to Seller's Knowledge, Threatened.

2.8 Real Property.

(a) Seller has a valid leasehold interest in the real property leased by it and located at 9257 Research Drive, Irvine, California (the "**Leased Real Property**"), free and clear of all Encumbrances other than Permitted Encumbrances. True, correct and complete copies of each lease governing the Leased Real Property, together with all amendments thereto (a "**Real Property Lease**"), have been delivered to Buyer. Except as set forth on Schedule 2.8(b), Seller's right to use any Leased Real Property has not been sublet, assigned or otherwise granted to any third-party. Except as set forth on Schedule 2.8(b), there are no parties in possession of any of the Leased Real Property other than Seller. Each Real Property Lease is in full force and effect. Seller is not in breach of its obligations under any Real Property Lease, all payments due under the Real Property Leases are current, and no other party to any Real Property Lease is in breach of its obligations thereunder. The consummation of the transactions provided for in this Agreement will not create or constitute a default under any Real Property Lease.

(b) Seller do not use, occupy or operate any real property other than the Leased Real Property, and no other real property is necessary for the operation of the Business as currently conducted by Seller. Neither Seller nor any of the Leased Real Property is, or during the last three years has been, in violation in any material respect of a zoning regulation, building restriction, restrictive covenant, ordinance, plat, declaration or other Law or a Contract relating to the Leased Real Property.

(c) The Leased Real Property is not the subject of a condemnation action and, to Seller's Knowledge, no such action is Threatened. To Seller's Knowledge, there is no proposal under consideration by a Governmental Body to take or use any portion of the Leased Real Property. There is no pending or, to Seller's Knowledge, proposed special assessment affecting or which may affect the whole or any party of the Leased Real Property.

2.9 Other Assets.

(a) Except as set forth on Schedule 2.9(a), the Purchased Assets are, or as of Closing will be, free and clear of all Encumbrances other than Permitted Encumbrances. At Closing, Seller will deliver to Buyer good and valid title to all of the Purchased Assets free and clear of all Encumbrances other than Permitted Encumbrances. Schedule 2.9(a) identifies each lease (other than a Real Property Lease) of tangible property and assets that is included among the Purchased Assets (each a "**Personal Property Lease**" and collectively, the "**Personal Property Leases**"). The Purchased Assets (including rights under Contracts) are sufficient in form and quality so that following Closing Buyer will be able to continue to operate the Business as currently conducted by Seller. On the Closing Date, the tangible Purchased Assets will be located on the Leased Real Property or in one or more other locations identified on Schedule 2.9(a).

(b) The tangible personal property (other than inventory) included among the Purchased Assets: (i) is in good operating condition and repair, normal wear and tear excepted, is adequately serviced by required utilities and is adequate for the uses to which it is being put; (ii) is free of physical, mechanical and structural defect and does not need maintenance or repair, except for ordinary, routine maintenance and repair that is not material in nature or cost; and (iii) is sufficient for the continued conduct of the Business after Closing in substantially the same manner as conducted by Seller before Closing. Schedule 2.9(b) sets forth a list and general description of each item of tangible personal property (other than inventory) included in the Purchased Assets having a book value of more than \$10,000.

(c) Schedule 2.9(c) sets forth: (i) the Intellectual Property Assets owned by Seller, including trade names, trademarks, services marks, brand names and other business identifiers and logos (the "**Owned Intellectual Property Assets**"); (ii) the Intellectual Property Assets used but not owned by Seller, including all software (the "**Other Intellectual Property Assets**"); (iii) a list of all Contracts pursuant to which rights in the Owned Intellectual Property Assets are granted by Seller (the "**Outbound Intellectual Property Licenses**"); and (iv) a list of all Contracts pursuant to which rights in the Other Intellectual Property Assets are granted to Seller (the "**Inbound Intellectual Property Licenses**" and together with the Outbound Intellectual Property Licenses, the "**Intellectual Property Licenses**"). True, correct and complete copies of the Intellectual Property Licenses (and all amendments thereto) have been delivered to Buyer. Subject to the terms of the Outbound Intellectual Property Licenses, Seller exclusively owns the entire right, title and interest in and to the Owned Intellectual Property Assets free and clear of all rights, licenses, restrictions and Encumbrances (other than Permitted Encumbrances) and has the valid right to use the Other Intellectual Property Assets subject to existing Inbound Intellectual Property Licenses. Each item of the Owned Intellectual Property Assets registered with a Governmental Body is valid and subsisting, and all necessary registration, maintenance and renewal fees in connection with such Owned Intellectual Property Assets have been paid and all necessary documents and articles in connection with such Owned Intellectual Property Assets have been filed with the relevant Governmental Bodies. At Closing, Seller will transfer and convey to Buyer all right, title and interest in and to the Owned Intellectual Property Assets and Intellectual Property Licenses free and clear of any transfer or assignment fees or obligations owing to a third Person and all Encumbrances, other than Permitted Encumbrances.

(d) Except as set forth on Schedule 2.9(d), the operation of the Business by Seller has not infringed, violated, misappropriated or unlawfully used, and is not infringing, violating, misappropriating or unlawfully using, any Intellectual Property Asset of any other Person. Seller has not received any notice from any Person claiming that the operation of the Business by Seller violates, infringes or misappropriates the Intellectual Property Assets of any Person nor is there any basis therefor. There is, and has been, no pending, decided or settled Proceeding related to any Owned Intellectual Property Assets or Other Intellectual Property Assets (“**IP Dispute**”), nor, to Seller’s Knowledge, has any such IP Dispute been Threatened, challenging the legality, validity, enforceability or ownership of any Owned Intellectual Property Asset. To Seller’s Knowledge, no circumstances or grounds exist that would reasonably be expected to give rise to a valid IP Dispute. Seller has not sent any notice of any IP Dispute and, to Seller’s Knowledge, there exists no circumstance or grounds upon which Seller could reasonably assert any IP Dispute and, to Seller’s Knowledge, there is no infringement of or unlawful use by any other Person of any Owned Intellectual Property Asset. No Owned Intellectual Property Asset is subject to any outstanding Order restricting its use or any pending or, to Seller’s Knowledge, Threatened Proceeding. No Other Intellectual Property Asset is subject to any outstanding Order materially restricting its use by Seller in a manner currently used.

(e) Seller own or has a valid and enforceable license to use all Intellectual Property Assets used in or necessary to conduct the Business as currently conducted by Seller. Except for the Other Intellectual Property Assets licensed pursuant to Inbound Intellectual Property Licenses, all Intellectual Property Assets used by Seller or necessary to conduct the Business as presently conducted were created or developed solely by (i) Seller’s employees acting within the scope of their employment who have validly and irrevocably assigned all of their rights to such Intellectual Property Assets to Seller or (ii) other Persons, including any independent contractors or Persons acting under the direction or supervision of Seller’s employees or independent contractors, who have validly and irrevocably assigned all of their rights to such Intellectual Property Assets to Seller. Seller has taken all necessary steps to maintain and protect all of the Owned Intellectual Property Assets, including those required by applicable Law.

2.10 Litigation. Except as set forth on Schedule 2.10: (a) there is no Proceeding or Order pending with respect to Seller, the Business or any Purchased Asset; (b) to Seller’s Knowledge, no such Proceeding or Order has been Threatened; and (c) no event has occurred or circumstance exists that would reasonably be expected to give rise to or serve as a basis for such Proceeding or Order.

2.11 Authorization and Enforceability; No Conflict.

(a) Seller has the requisite capacity, power and authority to enter into and perform the Transaction Documents to which it or he is a party and to carry out the transactions contemplated thereby. The execution, delivery and performance by Seller of this Agreement and each of the other Transaction Documents to which it or he will be a party and the consummation by Seller of the transactions contemplated hereby and thereby have been duly and validly authorized by all necessary corporate, company or other action (as applicable). This Agreement and each other Transaction Document to which Seller is a signatory is binding upon it or him and is enforceable against it or him in accordance with the terms of this Agreement or such other Transaction Document, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium and similar laws affecting creditors' rights and remedies generally.

(b) The execution, delivery and performance of this Agreement and the other Transaction Documents and the consummation of the transactions contemplated hereby and thereby will not (i) contravene the Organizational Documents of Seller or result in a breach of, or constitute a default under, any Assigned Contract or any other Contract by which Seller is bound or affected; (ii) violate a Law or Order or give a Governmental Body the right to revoke, withdraw, suspend, cancel, terminate or modify a Governmental Authorization relating to Seller or the Business; (iii) result in the acceleration of a liability of Seller or adversely modify the terms of such liability; (iv) result in an Encumbrance being created or imposed upon Buyer or a Purchased Asset; or (v) except for filings under any Governmental Authorizations set forth on Schedule 2.11(b)(v) (the "**Regulatory Approvals**"), require any Governmental Authorization or other consent, approval, exemption or other authority or notice to a Governmental Body. The consents, approvals or authorizations of and declarations, filings or registrations with a Person required (including those required under the terms of a Contract to avoid a breach or default thereunder or to effectively convey such Contract to Buyer) in connection with Seller's execution, delivery and performance of this Agreement and the other Transaction Documents and the consummation of the transactions contemplated hereby or thereby are set forth on Schedule 2.11(b).

2.12 Contracts; Insurance.

(a) Each Assigned Contract is in full force and effect and is valid and enforceable in accordance with its terms. Seller and, to Seller's Knowledge, each other Person that is a party to such Assigned Contract has complied and is complying with the terms of such Assigned Contract in all material respects. To Seller's Knowledge, no event has occurred or circumstance exists that (with or without notice or lapse of time) would reasonably be expected to result in a material breach of such Assigned Contract. True, correct and complete copies of each Assigned Contract and each other Contract listed on Schedule 2.12(b) (in each case, together with any amendments thereto) have been delivered to Buyer.

(b) Schedule 2.12(b) lists each Contract to which Seller is a party that:

- (i) involves performance of services or delivery of goods or materials by or to Seller either of an amount or value in excess of in excess of \$100,000 during any 12-month period;
- (ii) commits Seller to make an expenditure in excess of \$100,000 during any 12-month period;
- (iii) was not entered into the Ordinary Course of Business;
- (iv) cannot be terminated by Seller upon less than 90 days' notice without penalty;
- (v) requires Seller to purchase its total requirements of a good or service from another Person or that includes a "take or pay" or similar provision;
- (vi) is a collective bargaining agreement or otherwise involves a labor union or other representative of a group of employees relating to wages, hours or conditions of employment;
- (vii) restricts Seller's or any of its Affiliate's business activity or limits the right or ability of Seller or any of its Affiliates to engage in any line of business or to compete with another Person;
- (viii) involves the grant of a power of attorney by Seller to another Person;
- (ix) relates to a joint venture, partnership, strategic alliance or similar arrangement or that involves a sharing of profits, losses, costs or liabilities with another Person;
- (x) is an employment or consulting agreement or involves engagement of an individual as an independent contractor;
- (xi) provides for payment to or by a Person based on sales, purchases, profits or other metrics other than direct payment for goods or services;
- (xii) is a distributor, broker, dealer, franchise, manufacturer's representative, agency, sales promotion, market research, marketing or advertising Contract;
- (xiii) provides for or otherwise involves a volume discount from vendors, rebates, marketing arrangements or other similar arrangements;
- (xiv) is a loan, credit or similar Contract or that otherwise relates to Indebtedness;
- (xv) grants a lien, security interest or other Encumbrance on a Purchased Asset;
- (xvi) is with a Governmental Body;

(xvii) involves or relates to the acquisition of a business or a material amount of assets, properties or securities of another Person (whether by merger, sale of stock, sale of assets, lease, license or otherwise);

(xviii) involves a warranty obligation of Seller;

(xix) creates or purports to create an exclusive or preferential relationship or arrangement (including a most favored nation pricing provision);

(xx) is with any customer or supplier of Seller identified on Schedule 2.5(e); or

(xxi) is material to the Business but is not an Assigned Contract.

(c) Schedule 2.12(c) lists the policies of Insurance, and for each policy indicates: (i) the name of the insurer; (ii) the deductible or self-insurance retention amount and the coverage limit; (iii) the type of Insurance; (iv) the policy number; (v) the expiration date; and (vi) pending claims under the policy. True, correct and complete copies of each such Insurance policy have been delivered to Buyer. Each policy of Insurance is in full force and effect and will remain in full force through the Closing Date. Premiums with respect to such policies of Insurance have been timely paid and the duties of the insureds under such policies have been fully discharged. Except as set forth on Schedule 2.12(c), Seller has not been refused Insurance by a carrier to which it has applied for Insurance within the past three years. Except as set forth on Schedule 2.12(c), in the past three years, the general liability and similar Insurance policies have been “occurrence” policies and not “claims made” policies.

2.13 Permits and Licenses; Compliance with Laws.

(a) Schedule 2.13 sets forth the Governmental Authorizations required or maintained to carry on the Business as now conducted. Each such Governmental Authorization has been timely obtained by Seller and is in full force and effect. Except as set forth on Schedule 2.13(a), no such Governmental Authorization will be voided, nullified or impacted by the consummation of the transactions contemplated by this Agreement. Except as set forth on Schedule 2.13(a), at Closing, unless specifically excluded by Buyer, all such Governmental Authorizations will be assigned, transferred and conveyed to Buyer and will remain in full force and effect after such assignment and transfer. Seller is not subject to nor, to Seller’s Knowledge, has it been Threatened with, any Losses as a result of a failure to comply with a Law, and no event has occurred or circumstance formerly existed or currently exists that (with or without notice or lapse of time) would reasonably be expected to give rise to such Losses. Seller is in compliance in all material respects with all Laws applicable to the conduct of the Business as currently conducted or the ownership and use of the Purchased Assets.

(b) Except as set forth on Schedule 2.13(b):

(i) Seller has not (A) received any written notice from any Governmental Body of any Threatened or pending violation, investigation, audit or inquiry into an alleged or suspected violation of any Law or result in the suspension, revocation or limitation or restriction of any Governmental Authorization, or (B) entered into any agreement or settlement with any Governmental Body with respect to its alleged non-compliance with, or violation of, any Law.

(ii) Seller has not received any written notice from any current or former employee of any alleged or suspected violation of any Law pertaining to any state or federal pharmacy law or other Healthcare Laws.

(iii) Seller and all of its current or former managers, officers and directors and professionally licensed employees and contractors who provide, or have provided, professional services to, or at, or in connection with the Business (“**Professional Personnel**”), are in compliance in all material respects with all Laws applicable to Governmental Programs and all Laws and guidance relating to health care fraud and abuse, including the Anti-Kickback Statute, 42 U.S. Code § 1320a-7b, 42 C.F.R. § 1001.952, the federal false coding statute, 42 U.S. Code § 1320a-7a, the federal physician self-referral prohibition, 42 U.S. Code § 1395nn, 42 C.F.R. § 411.351 et seq., and the False Claims Act, 31 U.S. Code § 3729 et seq. (collectively, “**Healthcare Laws**”).

(iv) Professional Personnel providing professional services, including but not limited to, pharmacists and pharmacy technicians, currently hold in good standing and unrestricted, any and all appropriate licensure, registration or certification required to perform services related to the Business (“**Professional Licenses**”).

(v) Seller (A) is not a party to any corporate integrity agreement or similar memorandum of understanding with any Governmental Body, (B) is not subject to any order, judgment, injunction, award, decree or writ handed down, adopted or imposed by any Governmental Body and (C) has not entered into any other Contract at the request of any Governmental Body that restricts the conduct of the Business or that impacts upon the management or operation of the Business (collectively, “**Regulatory Agreements**”). Seller has not received written notice from any Governmental Body that such Governmental Body is considering issuing or requesting any Regulatory Agreement.

(vi) To the extent Seller directly receives reimbursement under Titles XVIII and XIX of the Social Security Act (the “**Medicare and Medicaid Programs**”), the CHAMPUS/TRICARE programs and other reimbursement programs of any Governmental Body (each a “**Governmental Program**”), Seller is appropriately registered, accredited and/or certified for participation and reimbursement under the Medicare and Medicaid Programs. To the extent that Seller directly receives reimbursement under the Medicare and Medicaid Programs, Seller has all current provider numbers and is in compliance in all material respects with all provider agreements required under such Governmental Programs.

(vii) To the extent that Seller directly or indirectly receives payments under Private Programs, Seller has all provider agreements, certifications, credentials, and provider numbers that are required under such Private Programs.

(viii) There has been no Proceeding instituted against Seller or any of its Professional Personnel and in any way related to the Business, the Purchased Assets, or with respect to Pharmacy Permits, DEA Registrations, or certifications, provider agreements or provider numbers related to any Governmental Program (collectively, “**Healthcare Authorizations**”).

(ix) To the Knowledge of Seller, no event has occurred that, with the giving of notice, the passage of time, or both, would constitute reasonable grounds for a violation or exclusion order with respect to any Healthcare Authorization, or the revocation, withdrawal or suspension of any Healthcare Authorization, or the termination of the participation of Seller in any Payment Program.

(x) Neither Seller nor any of its Professional Personnel has been determined or alleged by a Governmental Body to have committed a violation of any Healthcare Laws or other Laws relating to the referral of patients or health care business in exchange for remuneration or to entities in which the referring Person has an ownership or financial relationship, in connection with such employment by, or activity on behalf of, Seller. Neither Seller nor any of its Professional Personnel are or were under investigation by a Governmental Body in connection with any of the foregoing.

(xi) Neither Seller nor any of its Professional Personnel (during the term of such individual's employment with Seller or while acting as an agent of Seller): (A) has been convicted of or indicted for any crime, for which debarment or similar punishment is mandated or permitted by any applicable Law, (B) has engaged in any activities that are prohibited, or cause for the imposition of penalties or mandatory or permissive exclusion, under 42 U.S.C. §§ 1320a-7, 1320a-7a, 1320a-7b, 1395nn or 1396b, 31 U.S.C. §§ 3729-3733, the federal CHAMPUS/TRICARE statute (or other Laws related to false or fraudulent claims), any Healthcare Law or any criminal Law relating to health care services or payments, or that are prohibited by rules of professional conduct, or (C) has received written notice that Seller or any of its Professional Personnel is under investigation with respect to any of the foregoing.

(xii) Seller has: (A) timely filed all reports and billings required to be filed prior to the date hereof with respect to all applicable Payment Programs (all of which reports and billings are complete and accurate in all material respects and have been prepared in compliance in all material respects with applicable Laws); (B) paid or caused to be paid all known and undisputed refunds, overpayments, discounts or adjustments that have become due pursuant to such reports and billings; and (C) will continue to timely file all reports and billings and comply with (B) of this subsection (b)(x)(ii) through the Closing Date.

(xiii) Seller has not claimed or received reimbursements from Payment Programs in excess of amounts permitted by applicable Law, and Seller has no liability or obligation of any kind, whether accrued, contingent, absolute, inchoate or otherwise, whether due or to become due, under any Payment Program for any refund, overpayment, discount or adjustment.

(xiv) There are no pending or, to the Knowledge of Seller, Threatened, appeals, adjustments, challenges, audits, inquiries, litigation or written notices of intent to audit with respect to such prior reports or billings, and Seller has not been audited, or otherwise examined by any Payment Programs.

(xv) No employee of Seller, either before or during such employment, has been excluded or suspended from participation in any Governmental Program, and no employee of Seller has been debarred, suspended or are otherwise ineligible to participate in any Governmental Program, or are otherwise included in any Exclusion List.

(xvi) To the Knowledge of Seller, no employee of Seller, either before or during such employment, has committed any offense that may reasonably serve as the basis for any such exclusion, suspension, debarment or other ineligibility.

(xvii) Seller has not arranged or contracted with any Person that is suspended, excluded or debarred from participation in, or otherwise ineligible to participate in, any Governmental Program.

(xviii) Seller has operated the Business in compliance in all material respects with all applicable Laws affecting contractors and subcontractors under Governmental Programs (including the Medicare and Medicaid Programs), and all manuals and other interpretations thereof promulgated by Governmental Programs, including the Social Security Act, Federal Acquisition Regulations, and the regulations, manuals, guidance, and other pronouncements of the United States Department of Health and Human Services and the Centers for Medicare and Medicaid Services.

(xix) Seller has not received any notice of any complaint filed against Seller under HIPAA or any other applicable patient privacy and data protection Law.

(xx) Seller has implemented physical, technical and administrative safeguards designed to ensure compliance in all material respects with (A) all Laws, including HIPAA, relating to the collection, use, privacy or protection of Personal Data and all additional or higher industry standards or requirements related to Personal Data, (B) all requirements applicable to a covered entity (as defined in HIPAA) to the extent applicable to Seller, (C) all requirements of all business associate agreements (as defined in HIPAA) entered into by Seller, and (D) Seller's privacy and security policies.

(xxi) Since January 1, 2016, Seller has not experienced any incident in which personally identifiable information or other protected information, including any Person's name, address, credit card information, health information, email address, date of birth, social security number or account information ("**Personal Data**"), has been or may have been stolen or improperly accessed or any other security breach, and Seller is not aware of any facts exist suggesting any of the foregoing has occurred, including, to the Knowledge of Seller, any breach of security or any written notices or complaints from any Person regarding any Personal Data

(xxii) Seller and Professional Personnel are complying, and have complied in the last three years, in all material respects with the Federal Food Drug and Cosmetic Act, the Telephone Consumer Protection Act and all Laws relating to the procurement, marketing and promotion of prescription drugs and all applicable Laws and any related guidance documents published by a Governmental Body.

2.14 Environmental Matters.

(a) Seller (i) has obtained and has held, during all applicable statute of limitations periods, and currently holds all Governmental Authorizations that are required under any Environmental Law to operate its Business and the Purchased Assets to their full physical capacity; and (ii) is, and has been during all applicable statute of limitations periods, in compliance in all material respects with all such Governmental Authorizations. There is no action pending or, to Seller's Knowledge, Threatened by any Government Body to revoke, limit or modify such Governmental Authorizations. Seller is, and during all applicable statute of limitation periods has been, in compliance in all material respects with all Environmental Laws. Seller has not been subject of any Proceedings relating to Environmental Laws or which could have resulted in Environmental Liabilities, and neither Seller nor any of its Affiliates has received written notice alleging that Seller or the Business is not, or has not been, in compliance with, or is liable under, any Environmental Law.

(b) The Leased Real Property is not listed on and, to Seller's Knowledge, is not being considered for listing on a list maintained under an Environmental Law of contaminated or potentially contaminated sites or a list maintained under an Environmental Law of sites where certain environmentally related activities occurred or are occurring. The Leased Real Property is not the subject of or, to Seller's Knowledge, is not being considered to be the subject of, an enforcement action under an Environmental Law.

(c) The Real Property is free of the presence of Hazardous Substances in the soil, subsurface strata, groundwater, surface water, air, buildings, fixtures, outdoor artificial surfaces and structures, piping, drains, sumps, pits, ditches and equipment in a quantity, concentration or condition that has resulted in or would reasonably be expected to result in an Environmental Liability and no Hazardous Substances have migrated, are migrating or will migrate on or off the Leased Real Property through any environmental medium other than pursuant to and in compliance with a Governmental Authorization issued under Environmental Law.

(d) No Hazardous Substance is or was used, generated, Released, emitted, transported, stored, treated or disposed on or off the Leased Real Property by Seller or, to Seller's Knowledge, any other Person.

(e) There are not now, and except as listed on Schedule 2.14(e) never have been, any above-ground or underground storage tanks or tank systems at, on or under any Real Property. Each such tank and tank system listed on Schedule 2.14(e) has been registered, operated and maintained in full compliance with Environmental Law and no such tank or tank system is or has been the source of a Release of a Hazardous Substance. All underground and above-ground storage tanks and tank systems which have been removed from the Leased Real Property were removed and closed in accordance with Environmental Law.

(f) True, correct and complete copies of each site assessment, audit or report about the Environment concerning any Real Property in the possession or control of Seller or any of its Affiliates has been delivered to Buyer. Seller has delivered to Buyer all documents in Seller's or any of its Affiliate's possession or control evidencing a land use restriction or institutional control relating to the Environment with respect to the Leased Real Property, the Business or a Purchased Asset.

2.15 Broker's Fees. Except as set forth on Schedule 2.15, neither Seller nor anyone acting on its behalf has incurred or will incur a liability or obligation to pay fees or commissions to a broker, finder or agent with respect to the transactions contemplated by this Agreement or any other Transaction Document for which Buyer or its Affiliates could be or become liable. Seller will be solely responsible for the fees and other amounts due legal counsel and other advisors engaged by Seller in connection with the transactions contemplated by this Agreement or another Transaction Document.

2.16 Accuracy of Statements. No representation or warranty made by Seller in this Agreement or other Transaction Document or any statement, certificate or schedule furnished to Buyer pursuant to this Agreement or other Transaction Document in connection with the transactions contemplated hereby or thereby contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained herein or therein not misleading. Buyer has been delivered a true, complete and correct copy of each document (together with all amendments thereto) required to have been provided to Buyer or attached to a schedule under this Agreement.

ARTICLE 3 REPRESENTATIONS AND WARRANTIES OF BUYER

Buyer makes the following representations and warranties as of the date of this Agreement and again on the Closing Date immediately preceding Closing to induce Seller to enter into this Agreement and consummate the transactions contemplated hereby. These representations and warranties will survive Closing for the periods specified in Section 7.7.

3.1 Organization and Good Standing. Buyer is a limited liability company duly organized, validly existing and in good standing under the Laws of the State of Texas. Buyer has the requisite corporate power and authority to conduct its business as it is now being conducted and to own and use its properties and assets.

3.2 Authorization and Enforceability; No Conflict.

(a) Buyer has the requisite company power and authority to enter into and perform the Transaction Documents to which it is a party and to carry out the transactions contemplated thereby. The execution, delivery and performance by Buyer of each Transaction Document to which it is a party has been duly authorized, approved and adopted by it. Each Transaction Document to which Buyer is a party is binding upon it and is enforceable against it in accordance with the terms of that Transaction Document, except as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium and similar laws affecting creditors' rights and remedies generally.

(b) The execution, delivery and performance by Buyer of the Transaction Documents to which it is a party and the consummation by Buyer of the transactions contemplated thereby will not (i) contravene the Organizational Document of Buyer or result in a breach of, or constitute a default under, any Contract to which Buyer is a party or by which its assets are bound or affected or (ii) violate a Law or Order.

3.3 Regulatory Matters. Schedule 3.3 sets forth the names of each of the officers, directors and managers of Buyer who will be identified in any applications for licenses, authorizations, consents and approvals (including, without limitation, the Regulatory Approvals and any other Governmental Authorizations) submitted by Buyer in connection with the consummation of the transactions contemplated by this Agreement.

3.4 No Third-Party Approval or Consent. Except for the Regulatory Approvals, no consent, authorization, order or approval of, or filing or registration with, any Governmental Body or other person is required for the execution and delivery by Buyer of this Agreement and any other agreements provided herein, and the consummation by Buyer of the transactions contemplated by this Agreement and such other agreements.

3.5 No Broker's Fees. Neither Buyer nor anyone acting on its behalf has incurred or will incur a liability or obligation to pay fees or commissions to a broker, finder or agent with respect to the transactions contemplated by this Agreement or any other Transaction Document for which Seller could become liable. Buyer will be solely responsible for the fees and other amounts due legal counsel and other advisors engaged by Buyer in connection with the transactions contemplated by this Agreement or another Transaction Document.

3.6 Accuracy of Statements. No representation or warranty made by Buyer in this Agreement or other Transaction Document or any statement, certificate or schedule furnished to Seller pursuant to this Agreement or other Transaction Document in connection with the transactions contemplated hereby or thereby contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained herein or therein not misleading.

3.7 Sufficiency of Funds. Buyer (i) has sufficient cash, available lines of credit, or other sources of funds to enable it to pay the Purchase Price pursuant to the terms of this Agreement; (ii) has the resources and capabilities (financial and otherwise) to perform its obligations hereunder and under the Seller Note and Warrant; and (iii) has not incurred any obligation, commitment, restriction or liability which could impair adversely affect its ability to perform its obligations hereunder and under the Seller Note and Warrant.

ARTICLE 4 COVENANTS AND AGREEMENTS

The applicable Parties hereby covenant and agree as follows:

4.1 Conduct Pending Closing.

(a) From the date of this Agreement to Closing, Seller will conduct its operations and affairs diligently and only in the Ordinary Course of Business, except for actions taken with Buyer's prior written consent necessary to prepare for the consummation of the transactions contemplated by this Agreement. Seller will exercise its commercially reasonable efforts to preserve intact the present business organization, including completing all applicable renewals and revalidations, personnel and goodwill of Seller and the Business and to comply with applicable Laws.

(b) Until Closing, Seller will not, and will cause its Affiliates and Representatives not to, directly or indirectly: (i) enter into or continue any negotiations, discussions or Contracts contemplating or relating to the acquisition by a Person other than Buyer of all or any part of the Purchased Assets, equity securities or other securities, properties, Assets or business of Seller or the Business (regardless of the form of the transaction); (ii) take an action that could interfere with or prevent the timely consummation of the transactions contemplated by this Agreement or another Transaction Document; or (iii) except for actions taken with Buyer's prior written consent necessary for the consummation of the transactions contemplated by this Agreement, take an action that would constitute a Restricted Event or that would be inconsistent with a representation, warranty, covenant or agreement set forth in this Agreement, as if such representation, warranty, covenant or agreement were made both before and after such action. If there is a breach of clause (i) of this Section 4.1(b) and the transactions contemplated by this Agreement are not consummated for any reason, in addition to other rights and remedies available to Buyer (which will remain available to Buyer notwithstanding anything else in this Agreement), Seller will, within three Business Days following written demand by Buyer, immediately reimburse Buyer for all fees and expenses actually paid or incurred by Buyer and its Affiliates in connection with the transactions contemplated by this Agreement, including fees of its Representatives.

(c) Buyer shall prepare and submit all applicable notices and change of ownership applications (at Buyer's sole expense) related to the Governmental Authorizations with each applicable Governmental Body necessary to continue to operate the Business in the same manner as Seller prior to Closing. Seller shall fully cooperate with Buyer and provide any documents or information required for Buyer to complete such submissions; provided, however, that Seller will have an opportunity to review such applications (which may be redacted to protect confidential or proprietary information, as determined by Buyer in its sole discretion) in advance of filing and will be afforded reasonable access to all communications with Governmental Bodies related to such applications and related consents, notices and approvals (which may also be redacted to protect confidential or proprietary information as determined by Buyer in its sole discretion).

4.2 Access and Investigation by Buyer; Customer Meetings. From the date of this Agreement to Closing, Seller will: (a) give Buyer and its Representatives full and free access to Seller's Books and Records, Assets and Representatives; and (b) promptly provide to Buyer and its Representatives copies of any information and documents relating to Seller, its Business or the Purchased Assets as Buyer or its Representatives may reasonably request. With the prior consent of Seller, Buyer and its Representatives will be given access to the employees and suppliers of Seller as designated by Buyer pursuant to an agreed upon protocol and format. Buyer and its Representatives will conduct themselves with respect to the access described in clause (a) above in a manner that does not unreasonably interfere with the normal operations of the Business.

4.3 Reasonable Best Efforts; Notices.

(a) Each Party will use its reasonable best efforts to fulfill, or cause to be fulfilled, the conditions required to be fulfilled by it or him to bring about the timely consummation of the transactions contemplated by this Agreement and the other Transaction Documents. Each Party will give prompt notice to the other Parties of the occurrence of any event or the failure of any event to occur that might preclude or interfere with the satisfaction of any condition precedent to the obligations of a Party under this Agreement or the timely consummation of the transactions contemplated by this Agreement or the other Transaction Documents. Without limiting the generality of the foregoing, Seller will promptly notify Buyer of any fact or circumstance that could constitute a breach of any of the representations and warranties in Article 2; *provided, however*, that any such notification will not be deemed to be part of the Disclosure Schedule for purposes of this Agreement, will not be deemed to modify or cure any breach of a representation or warranty in Article 2 or limit in any way Buyer's rights or remedies with respect to any such breach.

(b) Each Party will use reasonable best efforts to promptly make all filings and submissions required by Law, and promptly provide any additional information requested from any Governmental Body with respect to filings or submissions. Each Party will promptly inform the other Parties of any communication, and any proposed understanding, undertaking or agreement, with a Governmental Body in connection with any filing or submission related to the transactions contemplated by this Agreement.

(c) Notwithstanding Section 4.3(b) or any other provision of this Agreement to the contrary, (i) Seller will not, without Buyer's prior written consent, commit to any divestiture transaction or agree to any restriction on the Business, (ii) Buyer will not be required to contest or otherwise resist any administrative or judicial action or proceeding, including any proceeding by a private party, challenging any of the transactions contemplated by this Agreement as violating any antitrust or competition Law, and (iii) Buyer will not be required to offer, accept or agree (A) to dispose or hold separate any part of the Business, the Purchased Assets, or any other business, assets, operations or product lines of Buyer, (B) not to compete in any geographic area or line of business, or (C) to restrict the manner in which, or whether, Buyer or any of its Affiliates may carry on the Business or any other business in any part of the world.

(d) This Section 4.3 will not limit any applicable rights a Party may have to terminate this Agreement pursuant to Article 6 so long as such Party has complied in all material respects with its obligations under this Section 4.3.

4.4 Public Announcements. Following Closing, any public announcement concerning this Agreement and the transactions contemplated by this Agreement by Seller or any of its Affiliates or Representatives will be subject to the prior written approval of Buyer. Prior to Closing, no Party will make any such public announcement except as required by Law without the consent of the other Parties, such consent not to be unreasonably withheld, conditioned or delayed; provided, however, that Seller Parent may make an announcement related to the signing of this Agreement and its material terms, without such approval, as it believes are required pursuant to any listing agreement with any national securities exchange or stock market or applicable securities Laws, in which case Seller shall allow Buyer reasonable time to comment on such release or announcement in advance of such issuance. The Parties will issue a joint press release for the transactions contemplated herein at Closing.

4.5 Restrictive Covenants.

(a) Non-Competition. During the Restricted Period, Buyer will not, directly or indirectly: (i) compete or plan to compete with Seller, Seller Parent or any of their Affiliates in the business of providing healthcare or compounded pharmaceutical products or services in the ophthalmic market (the “**Buyer Restricted Business**”), (ii) participate in the ownership, management, financing or control of, or act as an employee, advisor, consultant or agent to, or furnish services, information or advice to, whether or not for consideration, a Person that competes or plans to compete in the Buyer Restricted Business, or (iii) take or encourage an action the purpose or effect of which is to evade the intent of this Section 4.5. Notwithstanding the foregoing, Buyer may (i) engage in the business of providing autologous serum eye drops and dispensing of commercially available non-compounded finished form FDA approved drugs or (ii) own, directly or indirectly, solely as an investment, securities of any Person if Buyer is not a controlling Person of, or a member of a group which controls, such Person and does not, directly or indirectly, own twenty-five percent (25%) or more of any class of securities of such Person. The geographic scope of the foregoing covenant is the United States of America.

(b) Non-Solicitation.

(i) During the period beginning on the Closing Date and ending three (3) years after the Closing Date, Seller will not, and will cause its Affiliates not to, directly or indirectly, (i) solicit for hire an employee of Buyer or any of its Affiliates, except pursuant to a general solicitation which is not directed specifically to any such employee, (ii) encourage, induce, seek to encourage or induce, or assist another Person to encourage, induce or seek to encourage or induce an employee, agent, independent contractor, customer, supplier or creditor of, or another Person having a business relationship with, Buyer or any of its Affiliates, to cease or adversely change its, his or her business relationship or dealings with Buyer or any such Affiliate or (iii) in any way deliberately interfere with the relationship between Buyer or its Affiliates and an employee, agent, independent contractor, customer, supplier or creditor of, or another Person having a business relationship with, Buyer or any such Affiliate.

(ii) During the period beginning on the Closing Date and ending three (3) years after the Closing Date, Buyer will not, and will cause its Affiliates not to, directly or indirectly, (i) solicit for hire an employee of Seller or any of its Affiliates, except pursuant to a general solicitation which is not directed specifically to any such employee, (ii) encourage, induce, seek to encourage or induce, or assist another Person to encourage, induce or seek to encourage or induce an employee, agent, independent contractor, customer, supplier or creditor of, or another Person having a business relationship with, Seller or any of its Affiliates, to cease or adversely change its, his or her business relationship or dealings with Seller or any such Affiliate or (iii) in any way deliberately interfere with the relationship between Seller or its Affiliates and an employee, agent, independent contractor, customer, supplier or creditor of, or another Person having a business relationship with, Seller or any such Affiliate.

(c) Confidentiality. From the date of this Agreement and forever afterward, Seller will not, and will cause its Affiliates not to, directly or indirectly, use or disclose to another Person any proprietary, secret or confidential information of or relating to the Business or Buyer or any of its Affiliates, other than such information that: (i) enters the public domain through no fault of Seller or any of its Affiliates; or (ii) is required by legal process or other applicable Law to be disclosed. If Seller or any of its Affiliates is required by legal process or other applicable Law to disclose such information, then Seller (or, if applicable, its Affiliate) will provide Buyer notice thereof a reasonable time before complying with the disclosure requirement so that Buyer (or, if applicable, its Affiliate) may seek an appropriate protective order, and Seller (as applicable) will (and, if applicable, will cause its Affiliates to) cooperate with the efforts of Buyer (or, if applicable, its Affiliate) to obtain the protective order.

(d) In the event of any breach or violation by Seller, Buyer or any of their respective Affiliates of any of the covenants set forth in this Section 4.5, the time period of such covenant will be tolled until such breach or violation is resolved. If a court of competent jurisdiction finds that the time period of any of the foregoing covenants is too lengthy or the geographic coverage or scope is too broad, the restrictive time period will be deemed to be the longest period and the geographic coverage and scope will be deemed to comprise the largest coverage and scope, in either instance, as is permissible under applicable Law. It is the Parties' intent, and a critical inducement to the Parties entering into this Agreement and the Transaction Documents and consummating the transactions contemplated hereby and thereby, and thus the Parties agree that the time period and the geographic coverage and scope of the covenants set forth in this Agreement are reasonable and necessary. If Seller, Buyer or any of their respective Affiliates breaches or Threatens to breach any of the foregoing covenants, the non-breaching Party and its Affiliates will be entitled to: (i) seek and receive specific performance and any other requested injunctive and other equitable relief in any court of competent jurisdiction, without the requirement of posting a bond or other security or proving the lack or inadequacy of a remedy at Law; and (ii) require such breaching Person to account for and pay over to the non-breaching Party any profits, monies, accruals, increments or other benefits derived or received by such Person as the result of any transactions constituting a breach of the provisions of this Section 4.5, in each case in addition to other rights and remedies that may be available under applicable Law or otherwise.

4.6 Further Assurances; Cooperation. Following Closing: (a) each Party will take such additional actions, execute and deliver such additional documents and do such other acts and things as another Party may reasonably request for the purpose of carrying out and documenting the intent of this Agreement and the other Transaction Documents; (b) Seller will reasonably cooperate with Buyer in its efforts to continue and maintain the relationships of Seller existing prior to Closing, including relationships with lessors, Governmental Bodies, customers, suppliers, employees, independent contractors, creditors and others; (c) Seller will not take any action that could tend to diminish the value of a Purchased Asset or the Business or that could interfere with the operation of the Business; and (d) Seller will not, and will cause its Affiliates not to, directly or indirectly, make or publish a negative or disparaging comment or remark regarding the Business, the Purchased Assets, Buyer or its Affiliates.

4.7 Tax Matters.

(a) Transfer Taxes. Any Taxes payable by reason of transfer and conveyance of the Purchased Assets will be paid entirely by Seller, and Seller shall indemnify, defend and hold the Buyer Indemnified Parties harmless from and against any and all Losses arising out of or relating to or resulting from the failure by Seller to timely pay such Taxes. Seller shall prepare and file all necessary Tax Returns and other documentation with respect to all such transfer Taxes as may be necessary to comply with the laws and regulations relating to such sales, use and/or transfer Taxes.

(b) Indemnification. Seller hereby agrees to indemnify, defend and hold the Buyer Indemnified Parties harmless from and against any and all Losses arising out of or relating to or resulting from: (i) all Taxes (or the non-payment thereof) of Seller, or relating or arising out of the operation of the Business, for all taxable periods ending on or before the Closing Date and the portion through the end of the Closing Date of any Straddle Period (such Taxes, “**Pre-Closing Taxes**” and such period, “**Pre-Closing Tax Period**”), (ii) all Taxes of any member of an affiliated, combined or unitary group of which Seller is or was a member on or prior to the Closing Date, including pursuant to Treasury Regulation §1.1502-6 or any analogous or similar state, local or foreign Law, and/or (iii) any Taxes of any other Person for which the Buyer Indemnified Parties or any of Seller is or may become liable as a transferee in equity or in law or by contract which Taxes relate to an event or transaction occurring on or before the Closing Date. For purposes of this Section 4.7(b), in the case of any Straddle Period, the determination of the amount of any Taxes based on or measured by income, receipts, or payroll for the Pre-Closing Tax Period shall be made by assuming that the Straddle Period consisted of two taxable years or periods, one which ended at the close of the Closing Date and the other which began at the beginning of the day following the Closing Date. Items of income, gain, deduction, loss or credit of Seller for the Straddle Period shall be allocated between such two taxable years or periods on a “closing of the books basis” by assuming that the books of Seller were closed at the close of the Closing Date; provided, however, that exemptions, allowances or deductions that are calculated on an annual basis, such as property Taxes and depreciation deductions, shall be apportioned between such two taxable years or periods on a daily basis. The determination of the amount of any other Taxes for a Straddle Period that relates to the Pre-Closing Tax Period shall be made by multiplying the amount of such Tax for the entire taxable period by a fraction the numerator of which is the number of days in the taxable period ending on the Closing Date and the denominator of which is the number of days in such Straddle Period.

(c) Tax Clearance Certificate. If requested by Buyer, Seller shall notify all of the taxing authorities in the jurisdictions that impose Taxes on Seller or where Seller has a duty to file Tax Returns of the transactions contemplated by this Agreement in the form and manner required by such taxing authorities, if the failure to make such notifications or receive any available tax clearance certificate (a “**Tax Clearance Certificate**”) could subject Buyer to any Taxes of Seller. If any taxing authority asserts that Seller is liable for any Tax, Seller shall promptly pay any and all such amounts and shall provide evidence to Buyer that such liabilities have been paid in full or otherwise satisfied.

(d) Assistance and Cooperation. After the Closing Date, each of Seller and Buyer shall (and shall cause their respective Affiliates to):

(i) timely sign and deliver such certificates or forms as may be necessary or appropriate to establish an exemption from (or otherwise reduce), or file Tax Returns or other reports with respect to, Taxes described in Section 4.7(a);

(ii) assist the other Party in preparing any Tax Returns which such other Party is responsible for preparing and filing in accordance with Section 4.7(d) and, in connection therewith, provide the other Party with any necessary powers of attorney;

(iii) cooperate fully, as and to the extent reasonably requested by the other Party, in preparing for and defending any audits of, or disputes with Taxing authorities regarding, any Tax Returns of Seller;

(iv) make available to the other Party, and to any Taxing authority as reasonably requested, all information, records, and documents relating to Taxes of Seller;

(v) furnish the other Party with copies of all correspondence received from any Taxing authority in connection with any Tax Proceeding, audit or information request; and

(vi) retain, or cause to be retained, for so long as any such taxable years or audits shall remain open for adjustments, any records or information which may be reasonably relevant to any such Tax Returns or audits, provided that such records and information are not required to be retained for a period in excess of seven (7) years from the close of taxable year to which such information may be relevant.

(e) Tax Proceedings and Audits.

(i) Notwithstanding anything to the contrary herein, Seller shall exclusively control (at their own expense) the contest of the portions of any audits, disputes, administrative, judicial or other Proceedings relating to income Taxes of Seller for the portion through the end of the Closing Date of any Straddle Period; provided, however, that Seller may not settle any such claim without the consent of Buyer, which shall not be unreasonably withheld or delayed.

(ii) Notwithstanding anything to the contrary herein, Seller and Buyer shall jointly control (each at its own expense) the contest of the portions of any audits, disputes, administrative, judicial or other Proceedings relating to Taxes other than income Taxes of Seller for the portion through the end of the Closing Date of any Straddle Period, and neither Seller nor Buyer may settle such claim without the consent of the other Party, which shall not be unreasonably withheld or delayed.

(iii) For the avoidance of doubt, Buyer shall control (at Seller's expense) the contest of the portion of any audits, disputes, administrative, judicial or other Proceedings relating to the Taxes of Seller for the portion of any Straddle Period beginning after the Closing Date and all periods beginning after the Closing Date.

(f) Tax Returns.

(i) Seller shall timely file or cause to be timely filed when due all Tax Returns that are required to be filed by or with respect to Seller on or prior to the Closing Date and such Tax Returns shall be filed in a manner consistent with past practice (to the extent in compliance with applicable law) and no position shall be taken, election made or method adopted that is inconsistent with positions taken, elections made or methods used in prior periods in preparing and filing similar Tax Returns (unless otherwise required by applicable law). In each case, Seller shall remit any Taxes due in respect of such Tax Returns.

(ii) Subject to Section 4.7(a), Buyer shall timely file or cause to be timely filed when due all Tax Returns that are required to be filed by or with respect to Seller after the Closing Date.

(g) Withholding Rights. Buyer shall be entitled to deduct and withhold from any amounts payable to Seller under this Agreement or any other Transaction Document such amounts as Buyer is required to deduct and withhold with respect to the making of such payment under the Code, or any provision of applicable Tax law and shall timely remit to the appropriate Taxing authority any and all amounts so deducted or withheld. To the extent that such amounts are so withheld or paid over to or deposited with the relevant Taxing authority by Buyer in accordance with the foregoing, such withheld amounts shall be treated for all purposes of this Agreement and the other Transaction Documents as having been paid to the applicable Seller in respect to which such deduction and withholding was made. To the extent required in connection with any withholding Taxes or obligations, or any applicable exemption therefrom with respect to the Transactions or the payment of the Purchase Price, Seller shall promptly provide documentation or certification reasonably requested by Buyer.

4.8 Payments Received. After Closing, Seller will hold and promptly remit to Buyer any cash, checks (with appropriate endorsements) or other property received by Seller following Closing which are included among the Purchased Assets or properly belongs to Buyer under this Agreement. Buyer may, upon reasonable notice, audit the Books and Records of Seller to ensure compliance with this Section 4.8. From and after Closing, Buyer may endorse the name of Seller on any check or other evidences of indebtedness received on account of any Purchased Asset.

4.9 Names. From and after the date of this Agreement, Seller will cease to use the trade names included among the Purchased Assets, any derivations thereof and any names confusingly similar to any of the foregoing, except in connection with Tax Returns and for similar purposes relating to periods prior to Closing. Within ten (10) days following Closing, Seller will take all necessary actions, including the filing of any documents to no longer use the name "Park Compounding" in any trade related materials.

4.10 Employee Matters; Benefit Plans.

(a) Seller will reasonably assist Buyer and its Affiliates in their efforts to hire the employees of Seller identified by Buyer, and Seller will not attempt to retain any such employees or encourage them to accept employment with another Person. Buyer may, at its option, offer employment to any of the employees of Seller pursuant to a protocol agreed to by the Parties, such employment to commence immediately after Closing. Subject to applicable Law, Seller will furnish to Buyer and its Representatives such information in Seller's personnel files as Buyer may reasonably request in connection with determining whether to offer employment to such employees. Seller will use reasonable efforts to assist Buyer in encouraging all employees of Seller who receive an offer of employment from Buyer or its Affiliates to accept such offer on the terms and conditions offered by Buyer or such Affiliate. Those employees of Seller that accept employment with Buyer or its Affiliates will be referred to as "**Transferred Employees.**"

(b) Seller will comply with all WARN Act requirements, if applicable, and terminate all employees (including but not limited to Transferred Employees) prior to the Closing. Seller will be responsible for all Losses relating to or arising out of the employment, engagement, remuneration or cessation of employment of Seller's employees hired by Buyer or its Affiliates immediately after Closing (and the dependents of such individuals) with respect to all periods prior to Closing, except to the extent any such Losses are included among the Assumed Liabilities. Seller will pay each Transferred Employee's earned or accrued wages, salary, commission, bonus, vacation pay, paid time off and other employee compensation and benefits related to his or her employment with Seller for all periods through Closing in a timely fashion and not later than the date such payment is required by Law or the provisions of Seller Benefit Plan or Contract under which such compensation is or becomes duly payable, except, in each case, to the extent such obligations are included among the Assumed Liabilities. Seller will be responsible for payment of all wages, salary, commission, bonus, vacation pay, paid time off and other employee compensation and benefits related to employment with Seller for all periods, before, on, and, if any, after Closing, with respect to the employees of Seller who are not hired by Buyer or any of its Affiliates.

(c) Neither Buyer nor any of its Affiliates will assume, or be deemed to have assumed, Seller Benefit Plan.

(d) No provision in this Section 4.10 will (i) create any third-party beneficiary or other rights in any employee or former employee (including any beneficiary or dependent thereof) of Seller or any other Person other than the Parties and their respective successors and permitted assigns, (ii) constitute or create or be deemed to constitute or create an employment agreement or otherwise alter the at-will nature of any employment relationship or (iii) constitute or be deemed to constitute an amendment to any Employee Benefit Plan sponsored or maintained by Seller, Buyer or any of their respective Affiliates.

4.11 Interim Financials. As promptly as practicable following each calendar month between the date of this Agreement and the Closing Date, Seller will deliver to Buyer periodic financial reports in the form that is consistent with the Financial Statements concerning the Business and, if available, unaudited statements of the financial position of the Business as of the last day of such calendar month and statements of income of the Business for the calendar month then ended. Seller covenant that such interim statements (a) will present fairly the financial condition of the Business and Seller as of their respective dates and the related results of their respective operations for the respective calendar month then ended and (b) will be prepared on a basis consistent with prior interim periods.

4.12 Discharge of Excluded Liabilities. Seller will timely discharge, or make adequate provisions for the timely discharge of, the Excluded Liabilities and other liabilities and obligations of Seller under this Agreement and the Transaction Documents.

4.13 Certain Assigned Contracts. To the extent that any Assigned Contract is not capable of being assigned to Buyer at Closing without the consent, waiver, confirmation or agreement of the other party thereto or any other Person which, in any case, has not been obtained, or if such assignment or attempted assignment would constitute a breach thereof or a violation of any Law, neither this Agreement nor any other Transaction Document will constitute an assignment or an attempted assignment of such Assigned Contract. If any Assigned Contract is not transferred to Buyer at Closing because a required third-party consent, waiver, confirmation or agreement has not been obtained, then this Agreement and the other Transaction Documents will constitute an equitable assignment by Seller to Buyer of all of Seller's rights, benefits, title and interest in and to such Assigned Contract, to the extent permitted by Law, and Buyer will be deemed to be Seller's agent for the purpose of performing, fulfilling and discharging Seller's rights and obligations arising after the Closing Date under such Assigned Contract. In furtherance of the foregoing, following Closing, until the completion of the transfer of all Assigned Contracts to Buyer, Seller will, and they will cause their respective Affiliates to, (i) provide to Buyer the benefits of each Assigned Contract, (ii) cooperate in reasonable and lawful arrangements designed to provide such benefits to Buyer, (iii) enforce, at the request of Buyer and for the account of Buyer, any rights of Seller arising from or related to such Assigned Contracts and (iv) promptly pay over and remit to Buyer without consideration any payments or other rights or benefits received by Seller or its Affiliates with respect to any such Assigned Contracts.

4.14 Prorations. All Proration Items that relate, in whole or in part, to periods on or prior to the Closing Date will be apportioned as of the Closing Date. The net amount of all Proration Items will be settled, if practicable, within 90 days following Closing. In the event that the amount of any of the Proration Items is not then known by Buyer and Seller, the proration will be made based upon the amount of the most recent cost of such Proration Item to Seller. Thereafter, Buyer and Seller each will provide to the other written notice, within ten (10) days after receipt, of each invoice relating to any Proration Item so estimated. Within ten (10) days thereafter, Buyer or Seller, as applicable, will make any payment to the other that is necessary to true up any proration based on the actual invoice.

4.15 Prescription Files. On the Closing Date, Seller will deliver the Prescription Files to Buyer, in an electronic format reasonably acceptable to Buyer in accordance with all applicable state and federal pharmacy regulations. Prior to the Closing Date, to the extent permitted by applicable Law, Seller will afford promptly to Buyer and its agents access to the Prescription Files (with an opportunity to make copies), during normal business hours and upon reasonable notice to Seller.

4.16 Data Transfer Requirements. Not less than ten (10) days prior to the Closing Date, Buyer and Seller will have agreed to a final approach for the conversion of Prescription Files (including e-commerce Prescription Files), such Prescription Files will have been converted in accordance with such agreed final approach, and a user interface test with respect to patient outreach, prescription transfer and transfer of prescription images will have been performed by Buyer and Seller immediately after such conversion, which test will have produced results reasonably acceptable to Buyer.

4.17 Controlled Substances Inventory. To the extent required by applicable Law, including United States Drug Enforcement Administration regulations, in connection with the transactions contemplated by this Agreement, Seller will undertake and deliver to Buyer, immediately prior to the Closing Date, an inventory of "controlled substances" located each location owned or leased by Seller or used by Seller used in connection with the Business.

4.18 HIPAA Privacy Standards.

(a) After the Closing Date, (i) Buyer will make the Prescription Files available for access and amendment to applicable Persons in accordance with HIPAA and other applicable Laws and (ii) Seller will respond, in accordance with HIPAA, to requests from applicable Persons for accounting of disclosure of protected health information for periods prior to the Closing Date.

(b) Buyer will maintain the Prescription Files and all protected health information transferred by Seller in accordance with HIPAA security standards governing electronic protected health information.

ARTICLE 5 CONDITIONS TO OBLIGATION TO CLOSE

5.1 Conditions to Obligation of Buyer. Buyer's obligation to consummate the transactions contemplated by this Agreement and the other Transaction Documents and to take the other actions required to be taken by Buyer at Closing is subject to the satisfaction, at or before Closing, as applicable, of each of the following conditions (any of which may be waived in writing by Buyer in its sole discretion, in whole or in part):

(a) Without regard to any reference to "**Material Adverse Effect**" or other materiality qualification contained therein, the representations and warranties set forth in Article 2, individually and collectively, must have been accurate as of the date of this Agreement and must be accurate as of the Closing Date as if made again on the Closing Date (except for a representation or warranty made as of a specific date or for a particular period, the accuracy of which will be determined as of such specific date or for such particular period) in all material respects;

(b) Seller must have performed and complied with, in all material respects, its covenants, agreements and obligations under each Transaction Document required to be performed or complied with before Closing;

(c) Seller must have delivered to Buyer, in form reasonably acceptable to Buyer: (i) a certificate dated as of the Closing Date certifying that the conditions set forth in Sections 5.1(a) and 5.1(b) have been satisfied and (ii) each of the Closing deliveries set forth in Section 1.7(b);

(d) There must not be a Proceeding or Order pending or Threatened or a Law in effect that would prevent the consummation of the transactions contemplated by this Agreement or another Transaction Document or that would be reasonably likely to result in Losses with respect to Buyer, the Business or any Purchased Asset if the transactions contemplated by this Agreement or the other Transaction Documents were consummated;

(e) No Material Adverse Effect must have occurred or be reasonably likely to occur following Closing;

(f) All licenses, authorizations, consents and approvals by any Person, including the Regulatory Approvals and any other Governmental Authorizations or consents under Assigned Contracts (including without limitation, all URAC accreditations) that are necessary for the consummation of the transactions contemplated by this Agreement or any other Transaction Document must have been received, in forms reasonably acceptable to Buyer, and be in full force and effect;

(g) Seller must have delivered to Buyer a certificate of non-foreign status pursuant to Treasury Regulations §1.1445-2(b) from Seller certifying that Seller is not a foreign person subject to withholding under Code Section 1445 and the Treasury Regulations promulgated thereunder; and

(h) All required filings, declarations and notices of, with or to any Person must have been timely and properly made or given and be in full force and effect.

5.2 Conditions to Obligations of Seller. The obligation of Seller to consummate the transactions contemplated by this Agreement and the other Transaction Documents and to take the other actions required to be taken by Seller at Closing is subject to the satisfaction, at or before Closing, as applicable, of each of the following conditions (any of which may be waived in writing by Seller in its sole discretion, in whole or in part):

(a) The representations and warranties set forth in Article 3, individually and collectively, must be accurate in all material respects as of the date of this Agreement and as of the Closing Date as if made again on the Closing Date;

(b) Buyer must have performed and complied with, in all material respects, its covenants, agreements and obligations under this Agreement required to be performed or complied with prior to Closing;

(c) Buyer must have delivered to Seller, in forms reasonably acceptable to Seller: (i) a certificate dated as of the Closing Date certifying that the conditions set forth in Sections 5.2(a) and 5.2(b) have been satisfied; and (ii) each of the Closing deliveries set forth in Section 1.7(a); and

(d) There must not be an Order entered or a Law enacted since the date of this Agreement that would prevent the consummation by Seller of the transactions contemplated by this Agreement or another Transaction Document.

ARTICLE 6
TERMINATION

6.1 Termination Events. This Agreement may be terminated upon mutual written consent of Buyer and Seller or by written notice given before or at Closing:

(a) By Buyer, on one hand, or Seller (acting through Seller), on the other hand, if a breach of a representation, warranty, covenant or agreement in this Agreement has been committed by the other that constitutes a failure of a condition contained in Article 5 if such breach occurred immediately prior to Closing and such breach has not been waived or cured to the reasonable satisfaction of the non-breaching Party within ten (10) days following the delivery of written notice of such breach;

(b) By Buyer, on one hand, or Seller (acting through Seller), on the other hand, if Closing has not occurred (other than through the failure of the Party seeking to terminate this Agreement or such Party's Affiliate to comply fully with his or its, as applicable, obligations under this Agreement) on or before August 26, 2019 or such later date as Buyer and Seller may agree in writing; or

(c) At any time by Buyer, on one hand, or Seller (acting through Seller), if (i) a Governmental Body has issued a final non-appealable Order enjoining or otherwise prohibiting the consummation of the transactions contemplated by this Agreement or (ii) a Law is enacted following the date of this Agreement preventing the consummation of the transactions contemplated by a Transaction Document.

6.2 Effect of Termination. The right of termination provided in Section 6.1 is in addition to any other rights and remedies a Party may have under this Agreement, applicable Laws or otherwise, and the exercise of a right of termination will not be deemed an election of remedies. If this Agreement is terminated pursuant to Section 6.1, all further obligations of the Parties to consummate the transactions contemplated by this Agreement and all obligations of the Parties under this Agreement will terminate; *provided, however*, that the obligations set forth in the last sentence of Section 4.1(b), this Section 6.2 and in Section 9.7, will survive any such termination; and *provided further*, that if this Agreement is terminated by a Party because of a breach of this Agreement by another Party or such other Party's Affiliate or because one or more of the conditions to the terminating Party's obligations under this Agreement is not satisfied as a result of a failure of another Party or such other Party's Affiliate to comply with its obligations under this Agreement, the terminating Party's right to pursue all available rights and remedies will survive termination.

ARTICLE 7
INDEMNIFICATION

7.1 Indemnification and Reimbursement by Seller. Seller will indemnify and hold harmless Buyer, its Affiliates and their respective Representatives ("Buyer Indemnified Parties"), and will reimburse Buyer Indemnified Parties, for all Losses arising from or relating to (a) any inaccuracy in or breach of any of the representations or warranties of Seller contained in this Agreement, (b) a breach of or failure to perform any of Seller's covenants or agreements in this Agreement, (c) an Excluded Liability or Excluded Asset, (d) Seller Transaction Expenses and (e) any Existing Litigation.

7.2 Indemnification and Reimbursement by Buyer. Buyer will indemnify and hold harmless Seller and its Affiliates and their Representatives ("Seller Indemnified Parties"), and will reimburse Seller Indemnified Parties, for all Losses arising from or relating to (a) any inaccuracy in or breach of any of the representations or warranties of Buyer contained in this Agreement, (b) a breach of or failure to perform any covenant or agreement of Buyer in this Agreement, and (c) a Purchased Asset or Assumed Liability.

7.3 Certain Indemnification Provisions.

(a) **Deductible.** Seller will not have any liability under this Article 7 until the aggregate amount of Losses incurred or suffered by Buyer Indemnified Parties arising under this Article 7 exceeds \$250,000 (the “**Deductible**”), at which time the indemnified party will be entitled to indemnification only for the amounts exceeding the Deductible; *provided, however*, that the Deductible will not apply to, and there will be first dollar indemnity for, all Losses arising from or relating to any inaccuracy in or breach of Sections 2.1, 2.11, 2.15, 3.1, 3.2, 3.4, or 3.5 (collectively, the “**Fundamental Representations**”), any Existing Litigation or an event of fraud, willful misconduct or intentional breach (collectively, the **Excluded Claims**”).

(b) **Cap.** The aggregate maximum liability of Seller under this Article 7, excluding any Losses arising from or relating to any Excluded Claim, will not exceed \$1,000,000 (the “**Cap**”). The aggregate maximum liability of Seller for Losses arising under this Article 7, including any Losses from or relating to any Excluded Claim, shall be the Purchase Price.

(c) **Loss Calculation.** For purposes of calculating Losses under this Article 7, any inaccuracy in or breach of any representation or warranty shall be determined without regard to any materiality, Material Adverse Effect or other similar qualification contained in or otherwise applicable to such representation or warranty.

(d) Payments by an Indemnifying Party pursuant to Section 7.1 or Section 7.2 in respect of any Losses shall be limited to the amount of any liability or damage that remains after deducting therefrom any insurance proceeds and any indemnity, contribution or other similar payment received or reasonably expected to be received by the Indemnified Party in respect of any such claim. The Indemnified Party shall use its commercially reasonable efforts to recover under insurance policies or indemnity, contribution or other similar agreements for any Losses prior to seeking indemnification under this Agreement.

(e) Payments by an Indemnifying Party pursuant to Section 7.1 or Section 7.2 in respect of any Losses shall be reduced by an amount equal to any Tax benefit realized or reasonably expected to be realized as a result of such Losses by the Indemnified Party.

(f) In no event shall any Indemnifying Party be liable to any Indemnified Party for any punitive, incidental, consequential, special or indirect damages, including loss of future revenue or income, loss of business reputation or opportunity relating to the breach or alleged breach of this Agreement, or diminution of value or any damages based on any type of multiple.

(g) Each Indemnified Party shall take, and cause its Affiliates to take, all reasonable steps to mitigate any Loss upon becoming aware of any event or circumstance that would be reasonably expected to, or does, give rise thereto, including incurring costs only to the minimum extent necessary to remedy the breach that gives rise to such Loss.

(h) Seller shall not be liable under this Article 7 for any Losses based upon or arising out of any inaccuracy in or breach of any of the representations or warranties of Seller contained in this Agreement if Buyer had knowledge of such inaccuracy or breach prior to the Closing.

7.3 Indemnification Procedures.

(a) Third-Party Proceedings.

(i) Promptly after receipt by a Person entitled to be indemnified under this Article 7 (an “**Indemnified Party**”) of notice of the commencement of a Proceeding against it, such Indemnified Party will, if a claim for indemnification is to be made against a Party (an “**Indemnifying Party**”) under this Article 7, give notice to the Indemnifying Party of the commencement of such Proceeding specifying with reasonable particularity (to the extent that such information is available) the factual basis for the indemnity claim and the amount of the indemnity claim if known. Any delay in providing such notice to the Indemnifying Party will not relieve the Indemnifying Party of any liability that it may have to an Indemnified Party, except to the extent that the defense of such action was materially and irreparably prejudiced by the delay.

(ii) If any Proceeding is brought against an Indemnified Party and it gives notice to the Indemnifying Party of the commencement of such Proceeding, the Indemnifying Party will be entitled to participate in such Proceeding and, subject to subsection (a)(iii) below, to the extent that it wishes and can demonstrate its financial capability to assume and diligently pursue such defense and the resolution thereof, to assume the defense of such Proceeding with counsel of its choice reasonably satisfactory to the Indemnified Party. Following a proper assumption of defense by an Indemnifying Party, as long as the Indemnifying Party diligently conducts such defense, it will not be liable for any subsequent fees of legal counsel or other expenses incurred by the Indemnified Party in connection with the defense of such Proceeding, other than reasonable costs incurred in investigation and providing requested assistance. If the Indemnifying Party assumes the defense of a Proceeding, (A) it will be conclusively established for purposes of this Agreement that the claims made in that Proceeding are within the scope of and subject to indemnification hereunder and (B) no compromise or settlement of such claims may be effected by the Indemnifying Party without the Indemnified Party’s written consent unless (1) there is no finding or admission of any violation of Laws or any violation of the rights of any Person and no effect on any other claims that may be made by or against the Indemnified Party and (2) the sole relief provided is monetary damages that are paid in full by the Indemnifying Party concurrently with the compromise or settlement. If notice is given to an Indemnifying Party of the commencement of any Proceeding and the Indemnifying Party does not within twenty (20) days, or such lesser period of time as required to meet any deadline for a response, properly exercise its election to assume the defense of such Proceeding, the Indemnifying Party will be bound by any determination made in such Proceeding or any compromise or settlement thereof reasonably effected by the Indemnified Party.

(iii) Notwithstanding the foregoing, if an Indemnified Party determines in good faith that (A) a Proceeding may adversely affect it or any of its Affiliates other than as a result of monetary damages for which it would be entitled to indemnification under this Agreement, (B) there are defenses available to it that may be unavailable to, or inconsistent with or contrary to the interests of the Indemnifying Party or (C) a Proceeding may result in Losses which would reasonably be expected to exceed the Cap, the Indemnified Party may, by notice to the Indemnifying Party, retain the exclusive right to defend, compromise or settle such Proceeding, but the Indemnifying Party will reserve the right to contest indemnification with respect to any determination, compromise or settlement of such Proceeding effected without its consent (which consent will not be unreasonably withheld, delayed or conditioned).

(iv) Except to the extent it would cause a waiver of a privilege, each Party will make available to the other Parties and the other Parties' Representatives all of its or his Books and Records relating to a third-party Proceeding, and each Party will render to the other Parties assistance as may be reasonably required to ensure the proper and adequate defense of such third-party Proceeding.

(v) Each Party hereby consents to the non-exclusive jurisdiction of any court or other forum in which a Proceeding is brought by a Person not a Party to this Agreement against any Indemnified Party for purposes of litigating a claim that an Indemnified Party may have under this Agreement against an Indemnifying Party with respect to such Proceeding or the matters alleged therein (including its right to indemnification).

(b) Other Claims. A claim for indemnification for any matter not involving a third-party Proceeding must be asserted by written notice to the Party or Parties from whom indemnification is sought, identifying the matter for which indemnification is sought, the estimated amounts of the claim if then calculable and the basic facts underlying the claim to the extent then known.

7.5 Adjusted Purchase Price. Any payment of a claim for indemnification under this Article 7 will be accounted for as an adjustment to the Purchase Price to the extent permitted under applicable Law.

7.6 Survival of Representations, Warranties, Covenants and Agreements. The representations, warranties, covenants and agreements made by any Party in this Agreement or another Transaction Document will survive Closing. The representations and warranties set forth in Article 2 and Article 3 will survive for twenty four (24) months following the Closing Date; provided, that the Fundamental Representations shall survive for the full period of all applicable statutes of limitation. Any claim for indemnification under Article 7 with respect to a breach of a representation or warranty set forth in Article 2 or Article 3 will toll the applicable survival period of such representation or warranty as it relates to such claim and any related claim.

7.7 Exclusive Remedies. Subject to Section 9.12, the Parties acknowledge and agree that their sole and exclusive remedy with respect to any and all claims for any breach of any representation, warranty, covenant, agreement or obligation set forth herein or otherwise relating to the subject matter of this Agreement, shall be pursuant to the indemnification provisions set forth in this Article VII. In furtherance of the foregoing, each Party hereby waives, to the fullest extent permitted under Law, any and all rights, claims and causes of action for any breach of any representation, warranty, covenant, agreement or obligation set forth herein or otherwise relating to the subject matter of this Agreement it may have against the other Parties hereto and their Affiliates and each of their respective Representatives arising under or based upon any Law, except pursuant to the indemnification provisions set forth in this Article VII. Nothing in this Section 7.7 shall limit any Person's right to seek and obtain any equitable relief to which any Person shall be entitled pursuant to Section 9.12.

ARTICLE 8
DEFINITIONS

For purposes of this Agreement, the following terms have the meanings specified in this Article 8:

“**Action**” means any claim, action, cause of action, demand, lawsuit, arbitration, inquiry, audit, notice of violation, proceeding, litigation, citation, summons, subpoena or investigation of any nature, civil, criminal, administrative, regulatory or otherwise, whether at law or in equity.

“**Affiliate**” means, as applied to any Person, any other Person who controls, is controlled by, or is under common control with, such Person. For purposes of this definition, “control” means the possession, directly or indirectly through one or more intermediaries, of the power to direct the management and policies of a Person, whether through the ownership of stock, by Contract or otherwise.

“**Affiliated Group**” means any affiliated group within the meaning of Code Section 1504(a) or any similar group defined under a similar provision of state, local, or non-U.S. law.

“**Agreement**” has the meaning set forth in the first paragraph of this Agreement.

“**Assets**” means all of the rights and assets of Seller.

“**Assigned Contracts**” mean those Contracts of Seller set forth on Exhibit 8.1.

“**Balance Sheet**” means the balance sheet of Seller included in the Financial Statements.

“**Balance Sheet Date**” means the date of the Balance Sheet.

“**Books and Records**” includes all data, documents, ledgers, databases, books, records, business plans, reports, records of sales, price calculation reports, customer and supplier lists, files, and Contracts and Organizational Documents.

“**Business**” has the meaning set forth in the second paragraph of this Agreement.

“**Business Day**” means any day that is not a Saturday, a Sunday or other day on which banks are required or authorized by Law to be closed in the State of California.

“**Buyer**” has the meaning set forth in the first paragraph of this Agreement.

“**CERCLA**” means the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended, 42 U.S.C. §§ 9601 et seq.

“**CHAMPUS/TRICARE**” means the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), which is now known as TRICARE.

“**Change of Control**” means, with respect to Buyer or Seller: (a) a sale of all or substantially all of the assets of Buyer or Seller, as applicable; (b) the acquisition of more than 50% of the voting power of the outstanding securities of Buyer or Seller, as applicable, by another entity by means of any transaction or series of related transactions (including, without limitation, reorganization, merger or consolidation) unless the stockholders of record of Buyer or Seller, as applicable, as constituted immediately prior to such acquisition will, immediately after such acquisition (by virtue of their continuing to hold such stock and/or their receipt in exchange therefor of securities issued as consideration for the outstanding stock of Buyer or Seller, as applicable) hold at least 50% of the voting power of the surviving or acquiring entity; or (c) any reorganization, merger or consolidation in which the corporation is not the surviving entity, excluding any merger effected exclusively for the purpose of changing the domicile of Buyer or Seller, as applicable.

“**Code**” means the United States Internal Revenue Code of 1986, as amended, and the regulations and rulings thereunder.

“**Contract**” means any agreement, contract, obligation, promise or undertaking (whether written or oral and whether express or implied) that is legally binding.

“**Current Assets**” means the current assets of the Business included in the line items set forth on Exhibit 1.4 and only to the extent acquired pursuant to the terms of this Agreement.

“**Current Liabilities**” means the current liabilities of the Business included in the line items set forth on Exhibit 1.4 and only to the extent assumed pursuant to the terms of this Agreement.

“**EEOC**” means United States Equal Employment Opportunity Commission.

“**Employee Benefit Plan**” means any “employee pension benefit plan” or “employee welfare benefit plan” as defined under ERISA (whether or not subject to ERISA), and any incentive compensation plan, benefit plan for retired employees, plan or Contract providing for payments subject to Section 409A of the Code, bonuses, commissions, pensions, profit-sharing, stock options, stock purchase rights, restricted stock, phantom stock, deferred compensation, Insurance relating to accidents, health or sickness, retirement benefits, vacation, severance, disability, compensation, employee assistance or counseling, educational assistance, §125/cafeteria/flexible benefits, adoption assistance, group legal, fringe benefit or payroll practice of any nature, covering any current or former (including retired) employees of a Person or under which such Person has any remaining liability or obligation, and any other employee compensation or benefit plan, agreement, policy, practice, commitment, contract or understanding (whether qualified or nonqualified, currently effective or terminated, written or unwritten) and any trust, escrow or other agreement related thereto.

“Encumbrance” means any charge, claim, community property interest, condition, equitable interest, mortgage, lien, option, warrant, purchase right, pledge, security interest, right of first refusal, marital or community property interest or restriction of any kind, including any restriction on use, voting (in the case of any security), transfer, receipt of income or exercise of any other attribute of ownership.

“Environment” means any and all soil, land surface or subsurface strata, surface waters (including navigable waters and ocean waters), groundwater, drinking water supply, stream sediments, ambient air (including indoor air), plant and animal life or any other environmental medium or natural resource.

“Environmental Claim” means any written notice, Proceeding, Order, lien, fine, obligation, penalty or, as to each, any settlement or judgment arising therefrom, by or from any Person alleging liability of whatever kind or nature (including liability or responsibility for the costs of enforcement proceedings, investigations, cleanup, governmental response, removal or remediation, natural resources damages, property damages, personal injuries, medical monitoring, penalties, contribution, indemnification and injunctive relief) arising out of, based on or resulting from: (a) the presence or Release of, or exposure to, any Hazardous Substances at or from the Leased Real Property or shipped from the Leased Real Property; (b) any actual or alleged non-compliance with any Environmental Law or term or condition of any environmental Governmental Authorization of Seller; or (c) ownership, lease, operation or use of the current or former Assets of the Business or the operation of the Business.

“Environmental Law” means any applicable Law, Order or binding agreement with any Governmental Body and any guidance and policy published by a Governmental Body as they exist as of the Closing and in the future: (a) relating to pollution (or the cleanup thereof) or the protection of natural resources, endangered or threatened species, human health or safety, or the Environment; or (b) concerning the presence of, exposure to or the management, manufacture, use, containment, storage, recycling, reclamation, reuse, treatment, generation, discharge, transportation, processing, production, disposal, remediation of, response to, or investigation of actual or suspected Hazardous Substances or property damage, natural resources damage or personal injury caused by any Hazardous Substances. The term “Environmental Law” includes the following, including their implementing regulations and any state or local analogs, all as amended: CERCLA; the Solid Waste Disposal Act, 42 U.S.C. §§ 6901 et seq.; the Federal Water Pollution Control Act of 1972, 33 U.S.C. §§ 1251 et seq.; the Toxic Substances Control Act of 1976, 15 U.S.C. §§ 2601, et seq.; the Emergency Planning and Community Right-to-Know Act of 1986, 42 U.S.C. §§ 1101 et seq.; the Clean Air Act of 1966, 42 U.S.C. §§ 7401 et seq.; and the Occupational Safety and Health Act of 1970, 29 U.S.C. §§ 652 et seq.

“Environmental Liability” means any Action, Order, lien, fine, penalty, or, as to each, any settlement or judgment arising from or relating to any violation of or liability or obligation under any Environmental Law or any Environmental Claim with respect to acts or omissions having occurred, or conditions in existence, on or before the Closing Date with respect to the continuation of such conditions, acts, omissions or their consequences after the Closing Date, including: (a) any environmental, health or safety matters or conditions (including on-site or off-site contamination, Occupational Safety and Health Law violations and regulation of chemical substances or products); and (b) any responsibility for response costs, natural resource damages, corrective action or actions to achieve compliance, including any cleanup, removal, containment or remediation or response action under applicable Environmental Law or Occupational Safety and Health Law (whether or not such cleanup has been ordered or requested by any Governmental Body or any other Person). The terms “removal,” “remedial,” and “response action” include the types of activities covered by CERCLA.

“**ERISA**” means the Employee Retirement Income Security Act of 1974, as amended, and any duly promulgated regulations and rulings thereunder.

“**ERISA Affiliate**” means any member of a controlled group of corporations under Section 414(b) of the Code of which Seller is or was a member, and any trade or business (whether or not incorporated) who is or was under common control with Seller under Section 414(c) of the Code, and all other entities which together with Seller is or was prior to the date hereof treated as a single employer under Section 414(m) or 414(o) of the Code.

“**GAAP**” means United States generally accepted accounting principles as consistently applied.

“**Governmental Authorization**” means any approval, consent, franchise, license, permit, registration, order, certificate, accreditation, variance, waiver or other authorization or similar right issued, granted, given or otherwise made available by or under the authority of any Governmental Body or pursuant to any Law, including all pending applications therefor or renewals thereof.

“**Governmental Body**” means any: (a) nation, state, county, city, town, village, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental agency, branch, department, official or entity and any court or other tribunal); (d) multi-national organization or body; (e) body exercising, or entitled or purporting to exercise, any administrative, executive, judicial, legislative, police, regulatory or Taxing authority; (f) organization or association that sponsors, authorizes or conducts any arbitration proceeding; (g) any for-profit or non-profit accreditation agencies; or (h) any arbitrator or panel of arbitrators, the decisions of which are enforceable in any court of law.

“**Hazardous Substances**” means any material, substance, chemical, waste, product, derivative, compound, mixture, solid, liquid, mineral or gas, in each case, whether naturally occurring or manmade, that is subject to regulation under any Law relating to or protecting the Environment, including any petroleum and petroleum-derived and refined petroleum products, radon, radioactive materials or wastes, asbestos in any form, lead or lead-containing materials, mold, hazardous wastes, hazardous waste constituents, urea formaldehyde insulation, polychlorinated biphenyls and CERCLA hazardous substances.

“**HIPAA**” means the Health Insurance Portability and Accountability Act of 1996, as amended, and the regulations promulgated thereunder.

“Indebtedness” means with respect to Seller any of the following: (a) obligations for borrowed money, including all principal, interest, premiums, fees, expenses, overdrafts and penalties with respect thereto; (b) obligations evidenced by bonds, debentures, notes or other similar instruments; (c) obligations to pay the deferred purchase price of property or services, except trade payables incurred in the Ordinary Course of Business; (d) obligations to reimburse any bank or other Person in respect of amounts paid under a letter of credit or similar instrument; (e) capitalized lease obligations; (f) other obligations which would be required to be shown as indebtedness on a balance sheet prepared in accordance with GAAP; and (g) indebtedness of any other Person of the type referred to in clauses (a) to (f) above directly or indirectly guaranteed by Seller or secured by any of the Purchased Assets, whether or not such indebtedness has been expressly assumed by Seller.

“Insurance” means all forms of insurance, including liability, crime, fidelity, life, fire, product liability, workers’ compensation, health, director and officer liability and other forms of insurance, owned, maintained or insuring any part of Seller, the Business, a Purchased Asset or employees of Seller.

“Intellectual Property Assets” means all: (a) United States and foreign trademark rights, business identifiers, trade dress, service marks, trade names and brand names, United States and foreign registrations and applications therefor and all goodwill associated with the foregoing; (b) United States and foreign copyrights, copyright registrations and copyright applications, and all other rights associated with the foregoing and the underlying works of authorship (including databases, software and mask works); (c) United States and foreign patents and patent applications, and all proprietary rights associated therewith; (d) inventions, mask works, mask work registrations, know-how, bills of material, discoveries, improvements, designs, trade secrets, confidential business information, and shop and royalty rights; (e) employee covenants and Contracts respecting intellectual property including invention rights, noncompetition, confidentiality and license Contracts; (f) internet domain names and websites; (g) computer software and firmware (including code, databases, user interfaces and documentation); and (h) other types of intellectual property rights and other intangible assets.

“IRS” means the United States Internal Revenue Service.

“Knowledge” means a Person’s actual awareness following reasonable inquiry of each employee and agent of such Person who would reasonably be expected to have knowledge of a particular fact, circumstance or other matter.

“Law” or **“Laws”** means any federal, state, local, municipal, foreign, international, multinational or constitution law, ordinance, principle of common law (including equitable principles), statute, code, regulation, rule or treaty.

“Losses” means losses, damages, liabilities, deficiencies, Actions, judgments, interest, awards, penalties, fines, costs or expenses of whatever kind, including reasonable attorneys’ fees and the cost of enforcing any right to indemnification hereunder and the cost of pursuing any insurance providers; *provided, however*, that “Losses” shall not include punitive, indirect, or special damages, lost profits or any damages or liability based on a multiple of profits, multiple of cash flow or similar valuation methodology, except in the case of fraud or to the extent actually awarded to a Governmental Authority or other third party.

“Material Adverse Effect” means a change, event or circumstance the effect of which, individually or in the aggregate, is both material and adverse to the property, business, operations, assets (tangible and intangible), financial condition, results of operation or prospects of the Business.

“Material Interest” means direct or indirect beneficial ownership (as defined in Rule 13D-3 under the Securities Exchange Act of 1934, as amended) of voting securities or other voting interests representing at least 20% of the outstanding voting power of a Person or capital stock or other equity interests or securities representing at least 20% of the outstanding equity or equity interests in a Person.

“Multi-Employer Retirement Plan” has the meaning set forth in Section 3(37)(A) of ERISA.

“Occupational Safety and Health Law” means any Law and any program or any Governmental Body designed to regulate or provide safe and healthful working conditions and to reduce occupational safety and health hazards, illness, disease, etc.

“OFAC List” means a list compiled by the Office of Foreign Asset Control, an office of the United States Department of Treasury.

“Order” means any award, decision, injunction, decree, consent decree, judgment, order, ruling, subpoena or verdict entered, issued, made or rendered by any Governmental Body.

“Ordinary Course of Business” means in accordance with the usage of trade prevailing in the industry in which the Business operates and in accordance with Seller’s historical and customary day-to-day practices with respect to the activity in question.

“Organizational Documents” means the organizational documents of a non-natural Person, including, as applicable, the charter, articles or certificate of incorporation, bylaws, articles of organization, operating agreement or similar governing documents, as amended, and all minute books and stock record books.

“Party” or **“Parties”** has the meaning set forth in the first paragraph of this Agreement.

“Payment Programs” means Governmental Programs and Private Programs.

“Pension Plan” means an employee pension benefit plan, as defined in Section 3(2) of ERISA, other than a Multi-Employer Plan, that is covered by Title IV of ERISA and that either: (a) is maintained or contributed to by Seller and/or any of its ERISA Affiliates for employees of Seller; or (b) has at any time preceding the date hereof, been maintained or contributed to by Seller and/or any of its ERISA Affiliates for employees of Seller.

“Permitted Encumbrances” means: (a) liens for Taxes not yet due and payable; (b) mechanics’, carriers’, workmen’s, repairmen’s or other like liens arising or incurred in the ordinary course of business consistent with past practice or amounts that are not delinquent and which are not, individually or in the aggregate, material to the Business or the Purchased Assets; (c) easements, rights of way, zoning ordinances and other similar encumbrances affecting Real Property which are not, individually or in the aggregate, material to the Business or the Purchased Assets, which do not prohibit or interfere with the current operation of any Real Property and which do not render title to any Real Property unmarketable; or (d) other than with respect to Owned Real Property, liens arising under original purchase price conditional sales contracts and equipment leases with third parties entered into in the ordinary course of business consistent with past practice which are not, individually or in the aggregate, material to the Business or the Purchased Assets.

“**Person**” means any individual, corporation (including any non-profit corporation), general or limited partnership, limited liability company, joint venture, estate, trust, association, organization, Governmental Body or other entity.

“**Pre-Closing Period**” means any taxable period ending on or prior to the Closing Date.

“**Pre-Closing Taxes**” means: (a) all Taxes of Seller for all Pre-Closing Periods; (b) all Taxes of Seller for all Pre-Closing Straddle Periods; (c) all Taxes of any member of an affiliated, consolidated, combined or unitary group of which Seller (or any predecessor thereof) is or was a member on or prior to the Closing Date, including pursuant to Treasury Regulations Section 1.1502-6 or any analogous or similar Law; and (d) all Taxes of any Person (other than Seller) imposed on Seller as a transferee or successor, by contract or pursuant to any Law, as a result of an event or transaction occurring on or prior to the Closing Date.

“**Prescription Files**” mean, with respect to Seller and the Business, all: (a) electronic, hard copy (and electronic images thereof) and faxed prescriptions (and electronic images thereof); (b) prescription files and records; (c) customer lists and patient profiles, including refill history, status reports, insurance coverages, and clinical and customer service notes and references; (d) files and records maintained electronically, including authentication credentials and other relevant information; (e) files and records of all “active patients” (including e-commerce customers) that received a prescription from the Business in the twelve (12) months prior to the Closing; and (f) files and records of patients that the Business is required to retain for a specific period in accordance with applicable Law.

“**Private Programs**” means any third-party payor (other than a Governmental Program) with which Seller, with respect to the Business, has a contract to provide services and to receive payment for such services.

“**Proceeding**” means any action, arbitration, written charge, written claim, written complaint, challenge, dispute, audit, hearing, investigation, litigation or suit (whether civil, criminal, administrative, investigative or informal) commenced, brought, conducted or heard by or before, or otherwise involving, any Governmental Body.

“**Proration Items**” means real and personal property Taxes, utility charges (including water, sewer, electric and gas), maintenance charges, rental or lease payments, equipment charges, charges under service Contracts including among the Assigned Contracts, and similar expenses related to the Purchased Assets.

“Related Person” means with respect to a natural Person: (a) each other member of such Person’s family; (b) any Person who is directly or indirectly controlled by any one or more members of such Person’s family; (c) any Person in which members of such Person’s family hold (individually or in the aggregate) a Material Interest; and (d) any Person with respect to which one or more members of such Person’s family serves as a director, officer, partner, manager, managing member, executor or trustee (or in a similar capacity). For purposes of this definition, the “family” of a natural Person includes (i) the natural Person; (ii) his or her spouse; (iii) any other natural Person who is related to the natural Person or his or her spouse within the second degree; and (iv) any other natural Person who resides with such natural Person.

“Release” means any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, disposing or migration in any part of the environment of Hazardous Substances.

“Representative” means, with respect to a particular Person, any director, officer, manager, managing member, employee, agent, consultant, advisor or other representative of such Person, including legal counsel, accountants and financial advisors.

“Restricted Event” means, with respect to Seller: (a) except in the Ordinary Course of Business or pursuant to existing Contracts, paying any bonus to or increasing the salary or other compensation of any director, officer, manager, employee or agent; (b) adopting or increasing payments to or benefits under any Employee Benefit Plan; (c) incurring or suffering any labor dispute or disturbance, other than routine individual grievances that are not material to the Business; (d) entering into, terminating or receiving notice of termination of any Government Authorization, license, royalty, noncompetition, joint venture, credit or other Contract or transaction that involves a total remaining commitment of more than \$50,000; (e) selling, leasing, licensing or otherwise disposing of any material asset, or incurring or suffering any Encumbrance on any property or asset; (f) canceling or waiving any claim or right, or writing down or writing off any accounts or notes receivable, in each case with a value in excess of \$50,000; (g) changing any accounting method or principle; (h) failing to cause any uncontested liability or obligation in excess of \$50,000 to be paid or satisfied when the same becomes due; (i) making any capital expenditure in excess of \$50,000; (j) incurring or suffering material damage to or destruction or loss of any of any material asset, whether or not covered by Insurance; (k) taking any action, or failing to act, other than in the Ordinary Course of Business; (l) failing to timely pay any supplier or other creditor in the Ordinary Course of Business; (m) licensing, selling or transferring any Owned Intellectual Property Assets; (n) amending or modifying any Contract set forth on the Disclosure Schedule or entering into any Contract that would be required to be set forth on the Disclosure Schedule if such Contracts was entered into immediately prior to the signing of this Agreement; (o) entering into a Contract or making a binding commitment to do any of the foregoing; (p) terminating, or permitting the termination or expiration of, any existing pharmacy license, permit, registration or certification, Medicare or Medicaid provider number or any other Governmental Authorization; (q) executing, modifying or canceling any Contract with a third-party payor; or (r) agreeing to or executing any settlement agreement or corporate integrity agreement with any Governmental Body, including the Office of Inspector General of the United States Department of Health and Human Services.

“Restricted Period” means, with respect to Buyer or Seller, the period beginning on the Closing Date and ending on the earlier of (a) five (5) years after the Closing Date or (b) the occurrence of a Change of Control with respect to Buyer or Seller, as applicable.

“**Seller**” has the meaning set forth in the first paragraph of this Agreement.

“**Seller Benefit Plan**” means each Employee Benefit Plan sponsored, co-sponsored, maintained or contributed to by Seller or an ERISA Affiliate of Seller or covering an employee of Seller.

“**Seller Transaction Expenses**” means all fees, expenses and Losses incurred by or on behalf of Seller in connection with the negotiation, preparation or execution of this Agreement, another Transaction Document or any documents or agreements contemplated hereby or the performance or consummation of the transactions contemplated hereby or thereby, including (a) brokers’ or finders’ fees, (b) fees and expenses of counsel, advisors, consultants, investment bankers, accountants, auditors, experts and other Representatives, (c) all bonuses, compensation or other payments to employees of Seller relating to the transactions contemplated by this Agreement or another Transaction Documents and (d) any assignment or transfer fees payable in connection with the assignment of the Assigned Contracts from Seller to Buyer.

“**Seller’s Knowledge**” means the Knowledge of each of the individuals set forth on Exhibit 8.3.

“**Seller Parent**” means Harrow Health, Inc., a Delaware corporation.

“**Social Security Act**” means the Social Security Act of 1935, as amended, and the regulations promulgated thereunder.

“**Straddle Period**” means any taxable year or period beginning on or before and ending after the Closing Date.

“**Tax**” or “**Taxes**” means any tax (including any income tax, gross receipts tax, capital gains tax, value-added tax, sales tax, use tax, property tax, business tax, license tax, payroll tax, employment tax, social security tax, unemployment tax, severance tax, environmental tax, gift tax, estate tax, franchise tax, net worth tax, escheat or unclaimed property tax, excise tax and business occupancy tax), levy, assessment, tariff, duty (including any customs duty), deficiency or other fee or any related charge or amount (including any fine, penalty, interest or addition thereto), imposed, assessed or collected by or under the authority of any Governmental Body or payable pursuant to any tax-sharing or tax-indemnity Contract or any other Contract relating to the sharing of payment of any tax, levy, assessment, tariff, duty, deficiency or fee.

“**Tax Return**” means any return (including any information return), declaration, claim for refund, report, statement, schedule, notice, form or other document or information filed with or submitted to, or required to be filed with or submitted to, any Governmental Body in connection with the determination, assessment, collection or payment of any Tax or in connection with the administration, implementation or enforcement of or compliance with any Law relating to any Tax.

“**Threatened**” means, as to any Proceeding or other matter, that a demand or statement has been made (orally or in writing), a notice has been given (orally or in writing) or an event has occurred or some other circumstance exists that would lead a prudent Person to conclude that such a Proceeding or other matter is reasonably likely to be asserted, commenced, taken or otherwise pursued in the future.

“**Transaction Documents**” means this Agreement, the Transition Services Agreement and all other Contracts to be executed and delivered by any Party or any of his or its Affiliates or Representatives in connection with the consummation of the transactions contemplated by this Agreement.

“**WARN Act**” means: (a) the Worker Adjustment and Retraining Notification (WARN) Act Pub. L. 100 379.102 stat. 890 (1988), as amended, codified at 29 U.S.C. 2101 et seq.; and (b) any state “mini” Warn Act.

“**Warranty Deed**” means a general warranty deed, in form and substance acceptable to Buyer, duly executed and acknowledged in recordable form by Seller, for the purpose of conveying the Owned Real Property to Buyer.

ARTICLE 9 MISCELLANEOUS

9.1 Binding Effect; Benefits; Assignment. All of the provisions of this Agreement and the other Transaction Documents executed by a Party will be binding upon, inure to the benefit of and be enforceable by and against that Party and its successors and authorized assigns. Except (a) as otherwise expressly provided in this Agreement or another Transaction Document or (b) from the provisions in Article 7 which is intended to be for the benefit of, and will be enforceable by, each Buyer Indemnified Party and Seller Indemnified Party, nothing in this Agreement or such other Transaction Document, express or implied, is intended to confer upon any Person other than the signatories thereto any rights or remedies under or by reason of this Agreement or such other Transaction Document. No Party will assign any of its rights or obligations under this Agreement or any other Transaction Document to any other Person without the prior written consent of the other Parties to this Agreement or other Transaction Documents, as applicable, and any such attempted or purported assignment will be null and void; *provided, however*, that Buyer may, without consent, assign all or part of its rights under this Agreement or other Transaction Documents to (a) one or more of its Affiliates or (b) any Person providing funded debt to Buyer or any Affiliate.

9.2 Entire Agreement. This Agreement, the exhibits and schedules to this Agreement (including the Disclosure Schedule) and the other Transaction Documents set forth the entire agreement and understanding of the Parties in respect of the transactions contemplated by this Agreement or other Transaction Documents, as applicable, and supersede all prior Contracts, term sheets, letters of intent, exclusivity agreements, and other arrangements and understandings relating to the subject matter hereof and thereof.

9.3 Amendment and Waiver. This Agreement may be amended, superseded or canceled, and any of its provisions may be waived, only by a written instrument executed by the Parties or, in the case of a waiver, by the Party waiving compliance. The failure of any Party at any time to require performance of any provision of this Agreement will in no manner affect the right of that Party at a later time to enforce the same or a different provision. No waiver by any Party of any condition or the breach of any provision of this Agreement, in any one or more instances, will be deemed to be or construed as a further or continuing waiver of the same or any other breach or provision of this Agreement.

9.4 Governing Law. This Agreement will be governed by and construed in accordance with the Law of the State of Delaware as applicable to Contracts made and to be performed in the State of California, without regard to conflicts of laws principles.

9.5 Notices. All notices, requests, demands and other communications required or permitted to be given pursuant to this Agreement must be in writing and will be deemed to have been duly given on the day of delivery if delivered by hand, on the day of transmission if sent by facsimile with confirmation (or on the next Business Day if not sent on a Business Day), on the first Business Day following deposit with a nationally recognized overnight mail service, delivery charges prepaid, or on the third Business Day following first class mailing, with postage prepaid:

If to Buyer:

with a copy to:

Noice Rx, LLC

If to Seller:

with a copy to:

Harrow Health, Inc.
12264 El Camino Real, Suite 350
San Diego, California 92130
Attention: Andrew Boll

Quarles & Brady LLP
Renaissance One, Two N. Central Ave.
Phoenix, Arizona 85004
Attention: Kevin Walsh

A Party may change its or his address, telephone number or facsimile number by prior written notice to the other Parties provided in accordance with this Section 9.5.

9.6 Counterparts. This Agreement may be executed by facsimile, digital or other electronic signature and in one or more counterparts, each of which will be deemed an original and together will constitute a single instrument.

9.7 Like Kind Exchange. Seller or one of its Affiliates may wish to sell or purchase a portion or all of the Purchased Assets and other assets to be sold under this Agreement as part of a tax-deferred, like-kind exchange as provided under Section 1031 of the Code. Buyer agrees to cooperate with Seller in such exchange provided that neither Buyer nor any of its Affiliates will be required to incur any obligation, liability, cost or expense with respect to any such exchanges.

9.8 Expenses. Except as otherwise expressly provided in this Agreement, each Party will pay its own expenses, costs and fees (including legal and other professional fees and costs) incurred in connection with the negotiation, preparation, execution and delivery of this Agreement and the other Transaction Documents and the consummation of the transactions contemplated hereby and thereby.

9.9 Headings; Construction; Time of Essence. The headings of the articles, sections and paragraphs in this Agreement have been inserted for convenience of reference only and will not restrict or otherwise modify any of the terms or provisions of this Agreement. Unless expressly provided otherwise, each reference in this Agreement to a “Section” or an “Article” means a Section or Article, respectively, of this Agreement. Unless expressly provided otherwise, the words “including,” “include” or “includes,” or other similar words, whenever used in this Agreement will be deemed to be immediately followed by the words “without limitation”. With regard to all dates and time periods set forth or referred to in this Agreement, time is of the essence. References in this Agreement to any gender include references to all genders, and references to the singular include references to the plural and vice versa. Neither this Agreement nor any other Transaction Document (nor any uncertainty or ambiguity herein or therein) will be construed against any Party under any rule of construction or otherwise. No Party will be considered the drafter of this Agreement or any other Transaction Document. This Agreement and the other Transaction Documents have been reviewed, negotiated and accepted by all Parties and their attorneys and will be construed and interpreted according to the ordinary meaning of the words so as fairly to accomplish the purposes and intentions of the Parties. All references to dollars in this Agreement or any other Transaction Document are to United States Dollars.

9.10 Severability. Whenever possible, each provision of this Agreement and each other Transaction Document will be interpreted in such manner as to be effective and valid under applicable Laws, but in case any one or more of the provisions contained in this Agreement or other Transaction Document is, for any reason, held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other provision of this Agreement or other Transaction Document, as applicable, and this Agreement or other Transaction Document will be construed as if such invalid, illegal or unenforceable provision or provisions had never been contained herein or therein unless the deletion of such provision or provisions would result in such a material change as to cause completion of the transactions contemplated hereby or thereby to be unreasonable. If the deemed deletion of the invalid, illegal or unenforceable provision or provisions is reasonably likely to have a material adverse effect on a Party, all Parties will endeavor in good faith to replace the invalid, illegal or unenforceable provisions with valid provisions the economic effect of which comes as close as practicable to that of the invalid, illegal or unenforceable provisions.

9.11 Waiver of Jury Trial. EACH PARTY HEREBY KNOWINGLY AND WILLINGLY WAIVES ITS OR HIS RIGHTS TO DEMAND A JURY TRIAL IN ANY ACTION OR PROCEEDING INVOLVING THIS AGREEMENT, ANY OTHER TRANSACTION DOCUMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY. EACH PARTY REPRESENTS AND WARRANTS THAT IT OR HE HAS REVIEWED THIS WAIVER WITH ITS OR HIS LEGAL COUNSEL AND HAS KNOWINGLY AND VOLUNTARILY WAIVED ITS OR HIS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL. IN THE EVENT OF LITIGATION, THIS AGREEMENT MAY BE FILED AS A WRITTEN CONSENT TO TRIAL BY THE COURT.

9.12 Specific Performance. The Parties acknowledge and agree that irreparable harm for which monetary damages would not be an adequate remedy would occur in the event of a breach of any of the terms or provisions of this Agreement. Accordingly, the Parties agree that, in addition to other remedies, each of the Parties will be entitled to specific performance without the necessity of providing the inadequacy of monetary damages as a remedy and to obtain injunctive relief against any such breaches or threatened breaches of this Agreement. The Parties agree and acknowledge that (i) by seeking the remedies provided for in this [Section 9.12](#), a Party will not in any respect waive its or his right to seek any other form of relief that may be available to such Party under this Agreement, including monetary damages in the event that this Agreement has been terminated or in the event that the remedies provided for in this [Section 9.12](#) are not available or otherwise are not granted and (ii) nothing contained in this [Section 9.12](#) will require any Party to institute any Proceeding for (or limit any Party’s right to institute any Proceeding for) specific performance under this [Section 9.12](#) before properly exercising any termination right under [Article 6](#) (and pursuing any other remedies under this Agreement after such termination) nor will the commencement of any Proceeding pursuant to this [Section 9.12](#) or anything contained in this [Section 9.12](#) restrict or limit any Party’s right to properly terminate this Agreement in accordance with the terms of [Article 6](#) or pursue any other remedies under this Agreement that may be available then or thereafter. Each of the Parties agrees that it or he will not oppose the granting of an injunction, specific performance and other equitable relief on the basis that the other Parties have an adequate remedy at Law or an award of specific performance is not an appropriate remedy for any reason at Law or equity. Any Party seeking an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement will not be required to provide any bond or other security in connection with any such order or injunction.

[Signature page to follow]

IN WITNESS WHEREOF, the Parties have executed this Asset Purchase Agreement as of the date stated in the first paragraph of this Asset Purchase Agreement.

BUYER:

NOICE RX, LLC

By: /s/ Robert Haywood

Name: Robert Haywood

Title: President/Manager

SELLER:

PARK COMPOUNDING, INC.

By: /s/ Andrew Boll

Name: Andrew Boll

Title: CFO

SECURED PROMISSORY NOTE

Loan Amount: U.S. \$8,000,000.00**Date: July 26, 2019**

1. FUNDAMENTAL PROVISIONS. In addition to other defined terms set forth elsewhere in this Secured Promissory Note (this "Note"), the following terms are used as defined terms in this Note:

Holder: Park Compounding, Inc., a California corporation
12264 El Camino Real, Suite 350
San Diego, CA 92130

Maker: Noice Rx, LLC

Loan: The loan from Holder to Maker in the Principal Amount stated below, in connection with Maker's purchase of substantially all of the assets of Holder.

Principal Amount: Eight Million Dollars (U.S. \$8,000,000.00).

Base Interest Rate: Nine and One-Half Percent (9.5%) per annum.

Default Interest Rate: Fifteen Percent (15%) per annum.

Interest Accrual Date: September 15, 2019.

First Payment Date: October 15, 2019.

Maturity Date: March 15, 2025.

Daily Late Charge: \$100.00.

Prepayment Fee: None.

Business Day: Any day of the year other than Saturday, Sunday or legal holidays in the United States.

Purchase Agreement: The Asset Purchase Agreement, dated July 26, 2019, by and between Maker and Holder, as amended, restated, or replaced from time to time.

Warrant: The Warrant, dated on or about the date hereof, identified in Section 1.7(a) of the Purchase Agreement, executed by the Maker, as amended, restated, or replaced from time to time.

Security Agreement: The Security Agreement dated on or about the date hereof, executed by and among the Holder and Maker.

Loan Documents: The Purchase Agreement, this Note, the Warrant, the Security Agreement and any and all other documents executed in connection with the Loan, as such documents are amended, restated, or replaced from time to time.

2. PROMISE TO PAY. For value received, Maker promises to pay Holder at its address above or such other place as Holder may from time to time designate in writing, the Principal Amount, together with interest accruing on the unpaid principal balance hereof at the Base Interest Rate (or at the Default Interest Rate from and after an Event of Default) from the Interest Accrual Date through and including the Maturity Date (and continuing until the Loan is paid in full), on the basis of the actual number of days elapsed in a year of 365 days as more fully set forth in Section 3 below. All payments to be made by Maker to Holder are deemed received by Holder's actual receipt of same.

3. PAYMENTS OF INTEREST AND PRINCIPAL; LATE CHARGES.

A. Commencing on the First Payment Date, Maker will pay Holder principal plus accrued interest and fees in the amounts set forth Exhibit A attached hereto.

B. If not sooner paid, all unpaid principal, accrued and unpaid interest and any other amounts due hereunder or under the other Loan Documents is due and payable on or before three o'clock, p.m. (3:00 p.m.) PT on the Maturity Date.

C. If any payment to be made by Maker hereunder becomes due on a day that is not a Business Day, such payment must be made on the next succeeding Business Day.

D. If any balance of interest and/or principal remains unpaid after the date such payment is due, then, in addition to the remedies available to Holder under Section 9 of this Note and the remedies available under the other Loan Documents, the following applies: (i) the entire outstanding principal balance of this Note, together with all past due interest thereon and all other amounts due under the Loan Documents (including, without limitation, any unpaid late charges) bears interest at the Default Interest Rate, computed from the date of the last interest payment until all past due amounts are paid, subject to the limitations contained in Section 14 hereof; and (ii) the Daily Late Charge will be added to the delinquent amount for each day the payment is overdue beginning on the day after the payment due date and continuing through and including the day such delinquent payment is received to compensate Holder for the expense of handling the delinquency.

E. All payments due hereunder must be made: (i) without deduction of any present or future taxes, levies, imposts, deductions, charges or withholdings, which amounts must be paid by Maker; and (ii) without any other set off. Maker will pay the amounts necessary such that the gross amount of the principal and interest received by Holder is not less than that required by this Note.

4. PREPAYMENT. This Note may be prepaid in whole, or in part, without penalty or other charge to Maker at any time.

5. LAWFUL MONEY. Principal, interest, and any other amounts due to Holder under this Note and the other Loan Documents must be paid in lawful money of the United States of America.

6. APPLICATION OF PAYMENTS. Absent the occurrence of an Event of Default hereunder or under any of the other Loan Documents, any payments received by Holder pursuant to the terms hereof will be applied first to sums, other than principal and interest, due to Holder pursuant to the Loan Documents, next to the payment of all interest accrued to the date of such payment, and the balance, if any, to the payment of principal. After the occurrence of an Event of Default hereunder or under any of the Loan Documents, any payments received by Holder (including any prepaid interest that has not yet been earned) will be applied to the amounts specified in this Section 6 in such order as Holder may, in its sole discretion, elect. If at any time any payment made by Maker under this Note is rescinded or must otherwise be restored or returned upon the insolvency, bankruptcy or reorganization of Maker or otherwise, Maker's obligation to make such payment shall be reinstated as though such payment had not been made.

7. SECURITY. This Note and the obligations hereunder are secured by a first priority lien on, and security interest in and to, the Collateral, as such term is defined in the Security Agreement.

8. EVENTS OF DEFAULT. The occurrence of any of the following is deemed to be an event of default ("Event of Default") hereunder:

A. Any failure to pay any principal or interest under this Note as and when the same becomes due and payable, and such failure is not cured within five (5) days after written notice the date on which payment is due.

B. Any failure or neglect to perform or observe any other term, provision, or covenant of this Note or the other Loan Documents, and such failure or neglect either cannot be remedied or, if it can be remedied, it continues unremedied for a cure period of fifteen (15) days after written notice of such default is given to Maker by Holder.

C. Maker fails to pay when due any of its indebtedness (other than indebtedness arising under this Note) or any interest or premium thereon when due (whether by scheduled maturity, acceleration, demand or otherwise) and such failure continues after the applicable grace period, if any, specified in the agreement or instrument relating to such indebtedness.

D. (i) Maker commences any case, proceeding or other action (A) under any law relating to bankruptcy, insolvency, reorganization, or other relief of debtors, seeking to have an order for relief entered with respect to it, or seeking to adjudicate it as bankrupt or insolvent, or seeking reorganization, arrangement, adjustment, winding-up, liquidation, dissolution, composition or other relief with respect to it or its debts or (B) seeking appointment of a receiver, trustee, custodian, conservator or other similar official for it or for all or any substantial part of its assets, or Maker makes a general assignment for the benefit of its creditors; (ii) there is commenced against Maker any case, proceeding or other action of a nature referred to in the foregoing clause (i) which (A) results in the entry of an order for relief or any such adjudication or appointment or (B) remains undismitted, undischarged or unbonded for a period of thirty (30) days; (iii) there is commenced against Maker any case, proceeding or other action seeking issuance of a warrant of attachment, execution or similar process against all or any substantial part of its assets which results in the entry of an order for any such relief which has not been vacated, discharged, or stayed or bonded pending appeal within thirty (30) days from the entry thereof; or (iv) Maker is generally not, or shall be unable to, or admits in writing its inability to, pay its debts as they become due.

9. REMEDIES. Upon the occurrence of an Event of Default, then the entire outstanding principal balance of this Note, together with all accrued and unpaid interest thereon, and all other amounts payable by Maker under this Note and the other Loan Documents, will, at Holder's option, immediately become due and payable. Upon the occurrence of an Event of Default (and so long as such Event of Default continues without cure), the entire outstanding principal balance of this Note, together with all accrued and unpaid interest thereon, all other amounts due under this Note and the other Loan Documents (including, without limitation, any unpaid late charges), and any judgment for such principal, interest, and other amounts, bear interest at the Default Interest Rate from the date of the last interest payment until paid, subject to the limitations contained in Section 14 hereof. Maker acknowledges that it would be extremely difficult or impracticable to determine Holder's actual damages resulting from any late payment or default, and such interest at the Default Rate is a reasonable estimate of those damages and does not constitute a penalty. In addition to the foregoing remedies, upon the occurrence of an Event of Default, Holder is entitled to exercise any and all other remedies set forth in this Note and the other Loan Documents, or at law or in equity, and such remedies shall be cumulative and concurrent, and may be pursued singly, successively or together in Holder's discretion. No delay or omission on the part of Holder in exercising any right under this Note or under any of the other Loan Documents operates as a waiver of such right.

10. WAIVERS. Maker, endorsers, guarantors, and sureties of this Note hereby waive diligence, demand for payment, presentment for payment, protest, notice of nonpayment, notice of protest, notice of intent to accelerate, notice of acceleration, notice of dishonor, and notice of nonpayment, and all other notices or demands of any kind (except notices specifically provided for in the Loan Documents) and expressly agree that, without in any way affecting the liability of Maker, endorsers, guarantors, or sureties of this Note, Holder may extend any Maturity Date or the time for payment of any installment due hereunder, otherwise modify the Loan Documents, accept additional security, release any person liable, and release any security or guaranty without giving notice to or obtaining the consent of such endorsers, guarantors or sureties. Maker, endorsers, guarantors, and sureties waive, to the full extent permitted by law, the right to plead any and all statutes of limitations as a defense.

11. NO CHANGE, DISCHARGE, TERMINATION, OR WAIVER. No provision of this Note may be changed, discharged, terminated, or waived except in a writing signed by the party against whom enforcement of the change, discharge, termination, or waiver is sought. No failure on the part of Holder to exercise, and no delay by Holder in exercising, any right or remedy under this Note, under the other Loan Documents or under applicable law operates as a waiver thereof.

12. ATTORNEYS' FEES AND COSTS. In the event of any dispute arising out of or related to this Agreement, the prevailing Party is entitled to recover its reasonable attorneys' fees and costs associated with that dispute.

13. SEVERABILITY. If any provision of this Note is unenforceable, the enforceability of the other provisions are not be affected and remain in full force and effect.

14. INTEREST RATE LIMITATION. Maker will pay an effective rate of interest that is the sum of the interest rate provided for herein, together with any additional rate of interest resulting from any other charges of interest or in the nature of interest paid or to be paid in connection with the Loan, including, without limitation, any fees or charges to be paid by Maker pursuant to the provisions of this Note and the other Loan Documents. None of the terms and provisions contained herein or in any of the Loan Documents will be construed to create a contract for the use, forbearance, or detention of money requiring payment of interest at a rate in excess of the maximum interest rate permitted to be charged by the laws of the State of California. In the event Holder collects monies which are deemed to constitute interest which would otherwise increase the effective interest rate on this Note to a rate in excess of the maximum rate permitted to be charged by the laws of the State of Delaware, all such sums deemed to constitute interest in excess of such maximum rate will, at the option of Holder, be credited to the payment of other amounts payable under the Loan Documents (other than interest) or returned to Maker.

15. NUMBER AND GENDER. In this Note the singular includes the plural and the masculine includes the feminine and neuter gender, and vice versa.

16. HEADINGS. Headings at the beginning of each numbered section of this Note are intended solely for convenience and are not to be considered in interpreting the terms of this Note.

17. CHOICE OF LAW, JURISDICTION AND VENUE. This Note is governed by and construed in accordance with the laws of the State of Delaware without giving effect to conflict of laws principles. Any action or proceeding with respect to this Note or the other Loan Documents must be brought in a court of competent jurisdiction located in San Diego County, California.

18. INTEGRATION. This Note and the other Loan Documents contain the complete understanding and agreement of Maker and Holder, and supersede all prior representations, warranties, agreements, arrangements, understandings, and negotiations concerning the subject matter hereof.

19. BINDING EFFECT. The Loan Documents will be binding upon, and inure to the benefit of, Holder, Maker, and their respective successors and permitted assigns. Maker may not assign or delegate its rights or obligations under this Note or the other Loan Documents. This Note may be assigned or transferred by Holder to any person.

20. TIME OF THE ESSENCE. Time is of the essence with regard to each provision of the Loan Documents as to which time is a factor.

21. SURVIVAL. The representations, warranties, and covenants of Maker in the Loan Documents survive the execution and delivery of the Loan Documents and the making of the Loan.

22. MISCELLANEOUS PROVISIONS.

A. Partial Payment. Nothing in this Note will be construed as an obligation on the part of Holder to accept, at any time, less than the full amount then due hereunder, or as a waiver or limitation of Holder's right to compel prompt performance.

B. Notices. All notices required or permitted to be given hereunder must be in writing, and be delivered either: (i) by United States mail, certified or registered, postage prepaid; (ii) by personal hand delivery; or (iii) by recognized overnight courier. Notice is deemed given when delivered if hand delivered, two (2) Business Days after such notice is deposited in the United States mail if sent by mail, or one (1) Business day after such notice is deposited with the overnight courier if delivered by overnight courier. Such notices must be sent to the address set forth at the beginning of this Note, or to such other address as such party may, from time to time, designate in writing.

[Signature Page to Follow]

IN WITNESS WHEREOF, this Secured Promissory Note has been executed by Maker as of the day, month and year first written above.

MAKER: Noice Rx, LLC

By: /s/ Robert Haywood

Name: Robert Haywood

Its: President/Manager

EXHIBIT A
PAYMENT SCHEDULE

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this “Agreement”) dated as of July 28, 2019 (the “Effective Date”), is entered into between TGV-Health, LLC, a Delaware limited liability company (“TGV-H”) and TGV-Gyneconix, LLC, a Delaware limited liability company (“TGV- G”), each with a place of business at 101 Avenue of the Americas, New York, New York 10013 (TGV-G together with TGV-H, collectively “TGV”), on the one hand, and Mayfield Pharmaceuticals, Inc., a Delaware corporation (“Mayfield”), with a place of business at 12264 El Camino Real, Suite 350, San Diego, California 92130, on the other. The parties hereby agree as follows:

1. Definitions. For the purposes of this Agreement, the following terms shall have the respective meanings set forth below, and grammatical variations of such terms shall have corresponding meanings:

1.1 “Act” means the United States Federal Food, Drug and Cosmetic Act, as amended from time to time, and the regulations promulgated thereunder.

1.2 “Affiliate” means, with respect to any Person, any other Person which directly or indirectly controls, is controlled by, or is under common control with, such Person. A Person shall be regarded as in control of another Person if it owns, or directly or indirectly controls, more than fifty percent (50%) of the voting stock or other ownership interest of the other Person, or if it directly or indirectly possesses the power to direct or cause the direction of the management and policies of the other Person by any means whatsoever. Notwithstanding the foregoing, for purposes of this Agreement, neither Mayfield nor Harrow Health, Inc. shall be Affiliates of the other or of the other’s Affiliates.

1.3 “cGMP” means those current Good Manufacturing Practices required by the FDA to be followed in connection with the manufacture, handling, storage and control of pharmaceutical products in the United States, as set forth in the Act and any regulations related thereto.

1.4 “Commercially Reasonable Efforts” means, with respect to any objective regarding a Product and at any particular time, that degree of effort, expertise and financial resources commonly used in the pharmaceutical industry by a company of a similar size as Mayfield is at such time to achieve such objective for a product that has a clinical indication and market potential similar to such Product which is at a similar stage in development or product life as such Product taking into account, without limitation, commercial, legal and regulatory factors, target product profiles, product labeling, the regulatory environment and competitive market conditions and the efficacy of the Product.

1.5 “Dental Field” means the prevention, diagnosis or treatment of dental disease, state or condition (whether acute or chronic).

1.6 “Derived” or “derived” means acquired, obtained, conceived, reduced to practice, developed, created, synthesized, designed, derived or resulting from, based upon or otherwise generated (whether directly or indirectly, or solely or jointly with others, or in whole or in part).

1.7 “Development Costs” means the fully-burdened costs to Mayfield and its Affiliates incurred or accrued in connection with the research, development, pre-clinical and clinical studies, production and regulatory approval through submission of the first NDA for Product.

1.8 “Diligence Period” means, on a Product-by-Product basis, the period beginning on the Effective Date and ending on the earlier of (a) the last day of the twelve (12)- month period that the weighted average Net Sales price for such Product in the United States is less than fifty percent (50%) of the weighted average Net Sales price for such Product in the United States during the twelve (12)-month period immediately following the First Commercial Sale of such Product in the United States and (b) the date a generic product that is bioequivalent of such Product obtains the same or greater market share in the United States as such Product for treatment of any indication.

1.9 “Exclusive Sublicensee” means the Third Party sublicensee described in the first sentence of Section 4.7.

1.10 “FDA” means the Food and Drug Administration of the United States, or any successor thereto.

1.11 “Field of Use” means the prevention, diagnosis or treatment of any gynecological disease, state or condition (whether acute or chronic and regardless of delivery system or means of application) including without limitation caused by infections or inflammation, but excluding (a) surgical methods of treatment, (b) all diseases, states or conditions other than those set forth above and (c) the Dental Field, the Respiratory Field, the Wound Field, the Ophthalmic Field and the Otic Field.

1.12 “Field-Specific Patent Rights” means (a) all patents and patent applications within the Licensed Patent Rights that solely claim specific formulations of Mul- 1867 (but not solely Mul-1867), methods or uses, in each case, in the Field of Use; (b) all patents issuing therefrom (including utility models and design patents and certificates of invention); (c) all reissues, reexaminations, inter partes reviews, renewals, restorations, extensions and supplementary protection certificates of any of the foregoing patent applications or patents; (d) all confirmation patents, registration patents or patents of addition based on any of the foregoing patents; and (e) all foreign counterparts of any of the foregoing, or as applicable portions thereof.

1.13 “First Commercial Sale” means, with respect to any Product, the first sale of such Product by Mayfield, its Sublicensees or its or their respective Affiliates after all applicable marketing and pricing approvals (if any) have been granted by the applicable governing health authority.

1.14 “GAAP” means United States generally accepted accounting principles.

1.15 “Improvement Data” means IND-enabling data and results (a) from toxicology and/or pharmacokinetics studies performed by or on behalf of Mayfield; (b) that are specific to active pharmaceutical ingredient synthesis for Mul-1867 prepared by or on behalf of Mayfield.

1.16 “Improvement Patent Rights” means, collectively, (a) all patents and patent applications hereafter owned by Mayfield, a Sublicensee, or its or their respective Affiliates (including provisional patent applications), together with all divisionals, continuations and continuations-in-part that claim priority to, or common priority with, the foregoing; (b) all patents issuing therefrom (including utility models and design patents and certificates of invention); (c) all reissues, reexaminations, inter partes reviews, renewals, restorations, extensions and supplementary protection certificates of any of the foregoing patent applications or patents; (d) all confirmation patents, registration patents or patents of addition based on any of the foregoing patents; and (e) all foreign counterparts of any of the foregoing, or as applicable portions thereof; in each case, (i) that use or are supported by data and information derived from the use of Mul-1867 (sub)licensed hereunder and (ii) only to the extent they relate to Mul-1867 or its manufacture or use; but excluding the Licensed Patent Rights.

1.17 “IND” means an Investigational New Drug application required to commence human clinical testing of a product submitted to the FDA.

1.18 “Initial Capital Investment” means Mayfield’s receipt of aggregate proceeds (including both cash and conversion and/or cancellation of outstanding indebtedness or convertible securities) from the sale of Mayfield’s securities in one or more transactions following Mayfield’s incorporation of not less than fifteen million dollars (\$15,000,000).

1.19 “Knowledge of TGV” or “TGV’s Knowledge” means the actual knowledge of any director, officer, member or employee of TGV.

1.20 “Licensed IP Rights” means the Licensed Patent Rights, the Licensed Know-How Rights and all other intellectual property rights related to the Technology owned by, or licensed to (with the right to grant sublicenses), TGV or any of its Affiliates, whether existing as of the Effective Date or derived at any time after the Effective Date.

1.21 “Licensed Know-How Rights” means all trade secret and other know-how rights related to the Technology owned by, or licensed to (with the right to grant sublicenses), TGV or any of its Affiliates, whether existing as of the Effective Date or derived at any time after the Effective Date.

1.22 “Licensed Patent Rights” means, collectively, (a) all patents and patent applications owned by, or licensed to (with the right to grant sublicenses), TGV or any of its Affiliates (including provisional patent applications) in any jurisdiction that claim or cover the Technology (whether existing on or any time after the Effective Date), including those listed on Exhibit A, together with all divisionals, continuations and continuations-in-part that claim priority to, or common priority with, the foregoing; (b) all patents issuing therefrom (including utility models and design patents and certificates of invention); (c) all reissues, reexaminations, inter partes reviews, renewals, restorations, extensions and supplementary protection certificates of any of the foregoing patent applications or patents; (d) all confirmation patents, registration patents or patents of addition based on any of the foregoing patents; and (e) all foreign counterparts of any of the foregoing, or as applicable portions thereof.

1.23 “Mayfield Shares” means the combined shares of common stock of Mayfield issued to TGV-H or TGV-G pursuant to, and on the terms of, the Stock Issuance Agreement, and the shares of common stock of Mayfield issued to Zvi Ben-Zvi on the same date as the Stock Issuance Agreement.

1.24 “Mul-1867” means the composition referred to by TGV as “Mul-1867” and is more specifically described in the patents and patent applications listed on Exhibit A, together with all modifications, improvements and components thereof, whether existing as of the Effective Date or derived after the Effective Date.

1.25 “NDA” means a New Drug Application submitted to the FDA for marketing approval of a Product for use in the Field of Use.

1.26 “Net Sales” means, with respect to any Product, the gross sales price of such Product invoiced by Mayfield, its Sublicensees, and its and their respective Affiliates (collectively, the “Mayfield Group”) to customers who are not Affiliates (or are Affiliates but are the end users of such Product), less: (a) credits, allowances, discounts and rebates to, and chargebacks from the account of, such customers actually granted in the ordinary course of business; (b) freight and insurance costs in transporting Product in the ordinary course of business; (c) cash, quantity and trade discounts, rebates and other price reductions for Product; (d) sales, use, value-added and other direct Taxes if separately charged or invoiced (but not including Taxes based on the Mayfield Group’s profits); (e) customs duties, tariffs, surcharges and other governmental charges incurred in exporting or importing Product if separately invoiced; and (f) an allowance for uncollectible or bad debts determined in accordance with GAAP not to exceed three percent (3%) of Net Sales of such Product for the applicable quarterly reporting period prior to giving effect to this subsection (f). No deductions shall be made for commissions paid to individuals, whether they be with independent or affiliated sale agencies or regularly employed by the Mayfield Group, and on its payroll, or for the cost of collections.

1.27 “Non-Royalty Sublicense Income” means the cash consideration amounts received by Mayfield or its Affiliate from an Exclusive Sublicensee in consideration for the grant of an exclusive sublicense described in the first sentence of Section 4.7; provided, however, that Non-Royalty Sublicense Income excludes amounts received: (a) as bona fide reimbursement (i) for out of pocket costs incurred to prosecute and maintain the Licensed IP Rights or (ii) for fully-burdened costs incurred that are attributable to the research and/or development of the subject matter of the Licensed IP Rights and/or Products; (b) as bona fide loans (unless forgiven); (c) for securities sold to the Exclusive Sublicensee at fair market value; and (d) as running royalties (including any amounts paid based upon sales or profits from the sales of Product). To the extent that Non-Royalty Sublicense Income represents an unallocated combined payment for both a sublicense of Licensed IP Rights as well as other intellectual property, undertakings or subject matter, for purposes of calculating payments due to TGV, Non- Royalty Sublicense Income shall be reasonably allocated by mutual written agreement of the parties between the Licensed IP Rights and such other intellectual property, undertakings or subject matter, based on their relative value.

1.28 “Ophthalmic Field” means the prevention, diagnosis or treatment of any ophthalmic or eye-related disease, state or condition (whether acute or chronic).

1.29 “Otic Field” means the prevention, diagnosis or treatment of any otic or ear-related disease, state or condition (whether acute or chronic).

1.30 “Person” means any individual, partnership, firm, corporation, association, trust, unincorporated organization or other entity, as well as any syndicate or group of any of the foregoing.

1.31 “Phase I Clinical Trial” means a human clinical trial conducted on a limited number of study subjects for the purpose of gaining evidence of the safety and tolerability of, and information regarding, pharmacokinetics and potential pharmacological activity for a product or compound, as described in 21 C.F.R. § 312.21(a).

1.32 “Phase II Clinical Trial” means a human clinical trial conducted on study subjects with the disease or condition being studied for the principal purpose of achieving a preliminary determination of efficacy or appropriate dosage ranges, as further described in 21 C.F.R. § 312.21(b).

1.33 “Phase III Clinical Trial” means a pivotal human clinical trial the results of which could be used to establish safety and efficacy of a product as a basis for an NDA or that would otherwise satisfy requirements of 21 CFR 312.21(c).

1.34 “Product” means any product, in any form or formulation, comprising Mul-1867 that is useful in the Field of Use.

1.35 “Respiratory Field” means the use of Mul-1867 to treat respiratory diseases including, but not limited to cystic fibrosis, or any use of Mul-1867 in an inhalation dosage form.

1.36 “Stock Issuance Agreement” means the stock issuance agreement between the parties dated on the Effective Date.

1.37 “Sublicensee” means a Third Party to whom Mayfield or its Affiliate has granted a sublicense, immunity or other right under the Licensed Patent Rights to offer to sell, sell or otherwise commercialize one or more Products, provided such sublicense has not expired or been terminated.

1.38 “Successful Completion” means, with respect to a clinical trial for a Product for the treatment of an indication, completion of all patient enrollment, treatment and testing for such clinical trial in accordance with its applicable processes and delivery to the sponsor of the final report(s) for such clinical trial, where the results of such clinical trial are reasonably determined by the sponsor to be sufficient to progress such Product for the next phase of clinical testing in humans for such indication.

1.39 “Tax” or “Taxes” means any and all federal, state, local and foreign taxes, assessments and other governmental charges, duties, impositions and liabilities that are specific to the sale of the Products, including taxes based upon or measured by gross receipts, income, profits, sales, use and occupation, and value added, ad valorem, transfer, franchise, and property taxes together with all interest, penalties and additions imposed with respect to such amounts.

1.40 “Technology” means Mul-1867 and Product, together with all compositions, components and formulations thereof and all uses and methods of manufacture of the foregoing, whether existing as of the Effective Date or derived at any time after the Effective Date.

1.41 “Third Party” means any Person other than Mayfield, TGV or their respective Affiliates.

1.42 “Valid Claim” means either (a) a claim of an issued and unexpired patent included within the Licensed Patent Rights, which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise, or (b) a claim of a pending patent application included within the Licensed Patent Rights, which claim was filed in good faith, has not been pending for more than ten (10) years from the filing date from which such claim takes priority and has not been abandoned or finally disallowed without the possibility of appeal or refiling of such application.

1.43 “Wound Field” means the treatment of non-gynecological break or injury of the soft tissue and the skin.

2. Representations and Warranties.

2.1 Mutual Representations and Warranties. Each party represents and warrants to the other party as follows:

2.1.1 Organization. Such party is duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is organized.

2.1.2 Authorization and Enforcement of Obligations. Such party (a) has the requisite power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder; and (b) has taken all requisite action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such party, and constitutes a legal, valid, binding obligation, enforceable against such party in accordance with its terms.

2.1.3 Consents. All necessary consents, approvals and authorizations of all governmental authorities and other persons or entities required to be obtained by such party in connection with this Agreement have been obtained.

2.1.4 No Conflict. The execution and delivery of this Agreement and the performance of such party’s obligations hereunder (a) do not and will not conflict with or violate any requirement of applicable laws, regulations or orders of governmental bodies; and (b) do not and will not conflict with, or constitute a default under, any contractual obligation of such party.

2.2 TGV Representations and Warranties. TGV hereby represents, warrants and covenants to Mayfield as follows: (a) TGV-H is the sole owner of the Licensed IP Rights; (b) TGV has the right to grant the licenses and other rights purported to be granted herein and has not granted to any Third Party any license or other interest in the Licensed IP Rights within the Field of Use; (c) neither TGV-G nor TGV-H shall transfer, convey or assign any of the Licensed IP Rights useful within the Field of Use to any Person unless such Person agrees in writing to the applicable terms and conditions of this Agreement; (d) TGV shall promptly notify Mayfield in writing of any transfer, conveyance or assignment of any of the Licensed IP Rights; (e) to the best of each of TGV-H's and TGV-G's respective knowledge, neither TGV-H nor TGV-G is aware of any Third Party patent, patent application or other intellectual property rights that would be infringed (i) by practicing any process or method or by making, using or selling any composition which is claimed or disclosed in the Licensed Patent Rights or which constitutes Licensed Know-How Rights within the Field of Use, or (ii) by making, using or selling Product in the Field of Use; (f) neither TGV-H nor TGV-G is aware of any infringement or misappropriation by a Third Party of any Licensed IP Rights within the Field of Use; (g) all data and information provided by TGV hereunder shall be complete and accurate; and (h) all personnel (employees, consultants, contractors, etc.) involved in the research, development or commercialization of the Technology have entered into, or prior to commencing such involvement, will enter into, valid and enforceable intellectual property assignment agreements with TGV related to the Technology, and, to the extent ownership does not vest originally in TGV by operation of law, such personnel irrevocably assign to TGV all of their respective right, title and interest in and to the Technology, all associated records, and all intellectual property rights in and to the foregoing.

2.3 Mayfield Warranties. Mayfield warrants that it shall undertake its development (i.e., research, clinical and regulatory) and commercialization (i.e., manufacturing, distribution and marketing) obligations in compliance with all applicable laws and regulations (including but not limited to, and to the extent applicable, the Act and the Drug Supply Chain Security Act).

3. License Grant/Obligations.

3.1 License to Mayfield. Subject to the terms and conditions of this Agreement, and subject to satisfaction of the first milestone under Section 4.2, TGV hereby grants to Mayfield an exclusive (including with respect to TGV), non-transferable (except in connection with a permitted assignment of this Agreement), worldwide license under the Licensed IP Rights to develop, make, have made, use, offer for sale, sell and import Products for use in the Field of Use. Mayfield shall have the right to grant sublicenses within the Field of Use, through multiple tiers, to Third Parties and Affiliates.

3.2 Availability of Technology and Licensed IP Rights. TGV shall provide Mayfield (and its permitted designees) with a copy of all data and information available to TGV relating to the Technology and/or Licensed IP Rights. TGV shall provide Mayfield, free of charge, based on TGV's current knowledge, such technical assistance as may be reasonably necessary or useful for Mayfield to exploit such data and information, including without limitation (a) consulting services reasonably necessary to transfer the Mul-1867 molecule chemistry to an active pharmaceutical ingredient manufacturing entity and (b) consulting services reasonably necessary to transfer the formulation of a Mul-1867 topical formulation used to produce the pre-clinical data for Mul-1867 in the Field of Use.

3.3 Technical Assistance. During the term of this Agreement and in addition to the technical assistance described in Section 3.2, TGV shall provide such technical assistance to Mayfield as Mayfield reasonably requests regarding the Technology and/or Licensed IP Rights pursuant to and on the terms of a separate consulting agreement between Mayfield and either TGV, Victor Tets and/or Georgy Tets (the “Consulting Agreement”).

3.4 Improvements.

3.4.1 Improvement Patent Rights. Subject to the terms and conditions of this Agreement, Mayfield hereby grants to TGV a non-exclusive, worldwide, perpetual license under the Improvement Patent Rights for all uses other than to develop, make, have made, use, offer for sale, sell and import Products within the Field of Use. TGV shall have the right to grant sublicenses outside of the Field of Use, through multiple tiers, to other licensees (whether Third Parties or Affiliates) of the Licensed Patent Rights. The foregoing license is conditioned on TGV obtaining similar grantback licenses (together with the right to sublicense to Mayfield) from any and all Affiliates and Third Parties (together with their respective sublicensees and their sublicensees’ respective Affiliates) that enter into an agreement with TGV for rights under the Licensed Patent Rights or to develop and commercialize products comprising Mul-1867, and if TGV fails to obtain all such grantback licenses, then the foregoing license (together with any sublicenses granted by TGV) shall be void.

3.4.2 Improvement Data. Subject to the terms and conditions of this Agreement, subject to the payment provisions of this Section 3.4.2, Mayfield hereby grants to TGV a non-exclusive, worldwide, perpetual license to use and incorporate Improvement Data solely into an IND for development of products comprising Mul-1867 outside of the Field of Use. TGV shall have the right to grant sublicenses to other licensees (whether Third Parties or Affiliates) of the Licensed Patent Rights. TGV shall provide prompt written notice to Mayfield of any decision to incorporate such Improvement Data into any such IND (whether by TGV, an Affiliate of TGV or any Third Party). Thereafter, Mayfield shall provide TGV with a statement of its to-date Development Costs, and TGV shall pay Mayfield an amount equal to fifty percent (50%) thereof within fifty (50) days after initiating a Phase III Clinical Trial (by administering product to a first human subject) under such IND outside the Field of Use.

3.5 No Implied Licenses. Only licenses and rights expressly granted herein shall be of legal force and effect. No license or other right shall be created hereunder by implication, estoppel, or otherwise.

3.6 Mayfield Diligence. Mayfield shall use Commercially Reasonable Efforts (whether alone or with or through its Sublicensees and its or their respective Affiliates) to research, develop and commercialize one or more Products in the United States at all times during the Diligence Period for such Product. In addition, the parties shall meet and confer, either in person or by teleconference or videoconference, quarterly to discuss the development and commercialization of Product. Subject to the terms and conditions of this Agreement, Mayfield shall not prohibit any contract manufacturing organization that it engages to produce an active pharmaceutical ingredient of Mul-1867 for a Product (“CMO”) from being similarly engaged by TGV for production of an active pharmaceutical ingredient of Mul-1867 for a product (other than a Product), subject to the confidentiality and other terms between Mayfield and such CMO.

3.7 Allocation of Responsibilities.

3.7.1 Product Development. As between the parties, Mayfield shall be solely responsible, including financially responsible, for developing a Product suitable for submission as an IND within the Field of Use. TGV will provide technical assistance as set forth in Section 3.3 above.

3.7.2 Pre-Clinical and Clinical Responsibility. As between the parties, Mayfield shall be solely responsible, including financially responsible, for conducting the pre-clinical IND studies, Phase I Clinical Trials, Phase II Clinical Trials and Phase III Clinical Trials, in each case, for Product within the Field of Use.

3.7.3 Regulatory Responsibility. As between the parties, Mayfield shall be solely responsible for all regulatory filings and all costs associated with regulatory responsibilities for Product within the Field of Use, including preparation of the regulatory filings, the application filing fees for the IND and NDA (and foreign regulatory filings), site facility fees and periodic updates as is required by the relevant regulatory authority. In addition, as between the parties, Mayfield shall be solely responsible for the handling of all post approval matters including adverse events and pharmacovigilance matters to the extent solely related to Product within the Field of Use. Upon either party's request, the parties shall negotiate and enter into a pharmacovigilance agreement regarding Mul-1867 consistent with industry practices, and TGV shall require all other licensees of rights to develop and commercialize products comprising Mul-1867 to enter into substantially similar pharmacovigilance agreements.

3.7.4 Manufacturing. As between the parties, Mayfield shall be solely responsible for the manufacturing of the Products for use within the Field of Use, including qualification of the active pharmaceutical ingredient, the manufacturing facility, all associated methods and testing required for release, manufacturing, packaging and tracking of the Products for use within the Field of Use. Products released by Mayfield shall not be adulterated or misbranded within the meaning of the Act and, as between the parties, Mayfield shall be solely responsible for handling any recalls of Product released by Mayfield.

3.7.5 Marketing and Distribution. As between the parties, Mayfield shall be solely responsible for distribution, marketing and promotion of the Products within the Field of Use. Mayfield shall have sole discretion on determining the selling price of the Products within the Field of Use. All promotion of the Products shall strictly be within the Field of Use.

4. Financial Terms.

4.1 Stock Issuance. On the Effective Date, Mayfield shall issue to TGV certain shares of common stock of Mayfield pursuant to, and on the terms and conditions of, the Stock Issuance Agreement.

4.2 Milestone Payments. Within fifty (50) days following the first achievement of each of the following milestone events, Mayfield shall give written notice thereof to TGV and shall pay to TGV the corresponding non-refundable and noncreditable one-time milestone payments, except that the first Milestone Event shall be paid within thirty (30) days following its achievement:

Milestone Event	Milestone Payment
Mayfield achievement of Initial Capital Investment	\$ 300,000
Successful Completion of a Phase I Clinical Trial intended to support a Product in the Field of Use by Mayfield, a Sublicensee, or one of their respective Affiliates	\$ 400,000
Successful Completion of a Phase II Clinical Trial intended to support a Product in the Field of Use by Mayfield, a Sublicensee, or one of their respective Affiliates	\$ 400,000
FDA acceptance of an NDA submitted by Mayfield, a Sublicensee, or one of their respective Affiliates	\$ 400,000
FDA approval of either a second indication or a new dosage form for a Product submitted in an NDA by Mayfield, a Sublicensee, or one of their respective Affiliates that is not included in the original NDA as filed	\$ 750,000
First regulatory approval of a Product for any indication within the Field of Use pursuant a regulatory application submitted by Mayfield, a Sublicensee, or one of their respective Affiliates in any one of the following countries: Japan, Canada, Europe (EMEA, UK, France or Germany), Australia, Mexico or Brazil	\$ 400,000
Second regulatory approval of a Product for any indication within the Field of Use pursuant a regulatory application submitted by Mayfield, a Sublicensee, or one of their respective Affiliates in any one of the following countries: Japan, Canada, Europe (EMEA, UK, France or Germany), Australia, Mexico or Brazil	\$ 200,000

4.3 Royalty. Subject to the terms and conditions of this Agreement, on a Product-by-Product and country-by-country basis, Mayfield shall pay to TGV, on a quarterly basis, a royalty of three percent (3%) of Net Sales of any Product during the term of this Agreement (the "Royalty"); provided, however, that if the manufacture, use, offer for sale, sale, or import of a particular Product in a particular country would not infringe a Valid Claim (if such Valid Claim were in an issued patent and not licensed to Mayfield) or is not subject to a period of regulatory exclusivity, or if the Product is subject to generic competition (i.e., same active ingredient, same dosage form, same strength and same indication) in such particularly country then the applicable Royalty with respect to such Product in such country shall be reduced by one-half (½) to one and one-half percent (1½%) of Net Sales.

4.4 Royalty Reports and Payments. Within thirty (30) days after the end of each calendar quarter during the term of this Agreement, or, after the earlier of (i) the first sale of common stock of Mayfield to the general public pursuant to a registration statement filed with and declared effective by the Securities and Exchange Commission under the Securities Act of 1933 (as amended) and (ii) Mayfield first becoming subject to the reporting obligations under the Securities and Exchange Act of 1934 (as amended), within forty-five (45) days after the end of each calendar quarter during the term of this Agreement, Mayfield shall deliver to TGV a report setting forth for such calendar quarter (a) the calculation of the applicable Royalty; (b) the payments due under this Agreement for the sale of each Product; and (c) the applicable exchange rate as determined below. Mayfield shall remit the total payments due for the sale of Products during such calendar quarter at the time such report is made. No such reports or payments shall be due for any Product prior to the First Commercial Sale of such Product. With respect to Net Sales received in United States dollars, all amounts shall be expressed in United States dollars. With respect to Net Sales received in a currency other than United States dollars, all amounts shall be expressed both in the currency in which the amount is invoiced (or received as applicable) and in the United States dollar equivalent. The United States dollar equivalent shall be calculated using the average of the exchange rate (local currency per US\$1) published in The Wall Street Journal, Western Edition, under the heading "Currency Trading" on the last business day of each month during the applicable calendar quarter. All amounts paid to TGV shall be in United States dollars.

4.5 Payment Provisions.

4.5.1 Payment Terms. The Royalty shown to have accrued by each report provided for under Section 4.4 shall be due on the date such report is due. Payment of the Royalty in whole or in part may be made in advance of such due date.

4.5.2 Exchange Control. If at any time legal restrictions prevent the prompt remittance of part or all of the Royalty with respect to any country in which a Product is sold, Mayfield shall have the right, in its sole discretion, to make such payments by depositing the amount thereof in local currency to TGV's account in a bank or other depository institution in such country. If the payment rate specified in this Agreement should exceed the permissible rate established in any country, the payment rate for sales in such country shall be adjusted to the highest legally permissible or government-approved rate.

4.5.3 Withholding Taxes. Mayfield shall be entitled to deduct the amount of any withholding Taxes, value-added Taxes or other Taxes, levies or charges with respect to such amounts, other than United States taxes, payable by Mayfield, its Sublicensees or its or their respective Affiliates, or any Taxes required to be withheld by Mayfield, its Sublicensees or its or their respective Affiliates, to the extent Mayfield, its Sublicensees or its or their respective Affiliates pay to the appropriate governmental authority on behalf of TGV such Taxes, levies or charges. Mayfield shall use reasonable efforts to minimize any such Taxes, levies or charges required to be withheld on behalf of TGV by Mayfield, its Sublicensees or its or their respective Affiliates. Mayfield promptly shall deliver to TGV proof of payment of all such Taxes, levies and other charges, together with copies of all communications from or with such governmental authority with respect thereto.

4.6 Audits. Upon the written request of TGV and not more than once in each calendar year except if a prior audit in such calendar year revealed an Underpayment (as defined below), Mayfield shall permit an independent certified public accounting firm of nationally recognized standing selected by TGV and reasonably acceptable to Mayfield, at TGV's expense, to have access during normal business hours to such of the financial records of Mayfield as may be reasonably necessary to verify the accuracy of the Royalty reports hereunder for the eight (8) calendar quarters immediately prior to the date of such request (other than records for which TGV has already conducted an audit under this Section), which shall include, but not be limited to, review of fair market value calculations of bundled products,. If such accounting firm concludes that additional amounts were owed during the audited period, Mayfield shall pay such additional amounts within thirty (30) days after the date TGV delivers to Mayfield such accounting firm's written report so concluding. The fees charged by such accounting firm shall be paid by TGV; provided, however, if the audit discloses that the Royalty payable by Mayfield for such period is more than one hundred ten percent (110%) of the Royalty actually paid for such period (an "Underpayment"), then Mayfield shall pay the reasonable fees and expenses charged by such accounting firm. TGV shall cause its accounting firm to retain all financial information subject to review under this Section 4.6 in strict confidence; provided, however, that Mayfield shall have the right to require that such accounting firm, prior to conducting such audit, enter into an appropriate non-disclosure agreement with Mayfield regarding such financial information. The accounting firm shall disclose to TGV only whether the reports are correct or not and the amount of any discrepancy. No other information shall be shared. TGV shall treat all such financial information as Mayfield's confidential information, and shall not disclose such financial information to any Third Party or use it for any purpose other than as specified in this Section 4.6.

4.7 Non-Royalty Sublicense Income. If Mayfield enters into any agreement with a Third Party that includes a worldwide, exclusive (including with respect to Mayfield) sublicense ("Worldwide Sublicense") under all or substantially all of the Licensed IP Rights to develop, make, have made, use, offer for sale, sell and import all Products for use in the Field of Use, Mayfield shall give prompt written notice to TGV thereof. Within thirty (30) days after receipt of such written notice from Mayfield, TGV shall have the right, at its option but only in the event permitted by applicable law or regulation, to exchange the Mayfield Shares for an additional sublicense royalty stream as set forth below by giving express written notice to Mayfield thereof. If TGV timely exercises its such option as set forth above, then (a) within ten (10) days after the date of such notice, TGV shall duly convey, transfer and assign to Mayfield all right, title and interest in and to shares of common stock of Mayfield equal to the number of the Mayfield Shares (together with any and all new, substituted or additional securities issued in respect of the Mayfield Shares upon any stock split, stock dividend, recapitalization, merger, consolidation or similar events), free and clear of all encumbrances, liens and claims, including by duly executing and delivery such assignments and other instruments and agreements as reasonably requested by Mayfield, and (b) Mayfield shall, within fifty (50) days after the receipt of any Non-Royalty Sublicense Income, provide written notice thereof to TGV and remit to TGV an amount equal to five percent (5%) of such Non-Royalty Sublicense Income. For purposes of this Section 4.7, the term "Worldwide Sublicense" shall mean an exclusive sublicense or series of exclusive sublicenses executed on the same date with the same Third Party where the United States is included within the sublicensed territory. TGV shall have the right to audit the records of Mayfield to confirm the accuracy of the amount of the Non-Royalty Sublicense Income pursuant to the terms of Section 4.6.

5. Indemnification.

5.1 Indemnification by TGV. Subject to the provisions of this Section 5, TGV shall indemnify, defend and hold harmless Mayfield, its Affiliates, and its and their respective officers, directors, agents, stockholders and representatives, from and against any and all losses, liabilities, damages and expenses (including without limitation reasonable attorneys' fees and costs) (collectively, "Losses") resulting from any claim, demand, action or proceeding by any Third Party (each a "Claim") the extent resulting from or arising out of:

5.1.1 the actual or alleged breach of any representations, warranties or covenants of TGV in this Agreement; or

5.1.2 the actual or alleged negligence, gross negligence or willful misconduct of TGV, its Affiliates or their respective agents or representatives.

5.2 Indemnification by Mayfield. Subject to the provisions of this Section 5, Mayfield shall indemnify and hold harmless TGV, its Affiliates, and its and their respective officers, directors, agents, stockholders and representatives, from and against any and all Losses resulting from any Claim to the extent resulting from or arising out of:

5.2.1 the actual or alleged breach of any representations, warranties or covenants of Mayfield in this Agreement;

5.2.2 the actual or alleged negligence, gross negligence or willful misconduct of Mayfield, its Affiliates or their respective agents or representatives; or

5.2.3 the development or exploitation of Product by or on behalf of Mayfield, its Sublicensees or their respective Affiliates, customers or end-users.

5.3 Procedure. A party seeking indemnification (the "Indemnitee") shall promptly notify the other party (the "Indemnifying Party") in writing of a claim or suit; provided that an Indemnitee's failure to give such notice or delay in giving such notice shall not affect such Indemnitee's right to indemnification under this Section 5 except to the extent that the Indemnifying Party has been prejudiced by such failure or delay. The Indemnifying Party shall have the right to control the defense of all indemnification claims hereunder. The Indemnitee shall have the right to participate at its own expense in the claim or suit with counsel of its own choosing. The Indemnifying Party shall consult with the Indemnitee in good faith with respect to all non-privileged aspects of the defense strategy. The Indemnitee shall cooperate with the Indemnifying Party as reasonably requested, at the Indemnifying Party's sole cost and expense. The Indemnifying Party shall not settle any claim or suit without the Indemnitee's prior written consent, which consent shall not be unreasonably withheld.

6. Confidentiality.

6.1 Confidential Information. During the term of this Agreement, and for a period of five (5) years following the expiration or earlier termination hereof, each party shall maintain in confidence all information of the other party that is disclosed by the other party and identified as, or acknowledged to be, confidential at the time of disclosure (the "Confidential Information"), and shall not use, disclose or grant the use of the Confidential Information except on a need-to-know basis to those directors, officers, affiliates, employees, permitted actual or prospective licensees, permitted actual or prospective assignees and agents, consultants, clinical investigators or contractors, to the extent such disclosure is reasonably necessary in connection with performing its obligations or exercising its rights under this Agreement. For purposes of this Section, all Technology shall constitute the Confidential Information of both parties. To the extent that disclosure is authorized by this Agreement, prior to disclosure, the disclosing party shall obtain agreement of any such Person to hold in confidence and not make use of the Confidential Information for any purpose other than those permitted by this Agreement. Each party shall notify the other promptly upon discovery of any unauthorized use or disclosure of the other party's Confidential Information.

6.2 Terms of this Agreement. Except as otherwise provided in this Section 6, neither party shall disclose any terms or conditions of this Agreement to any Third Party without the prior consent of the other party; provided, however, that a party may disclose the terms or conditions of this Agreement, (a) on a need-to-know basis to its legal and financial advisors to the extent such disclosure is reasonably necessary, and (b) to a Third Party in connection with (i) an equity investment in such party, (ii) a merger, consolidation or similar transaction by such party, (iii) a permitted (sub)license under this Agreement, or (iv) the sale of all or substantially all of the assets of such party. Notwithstanding the foregoing, prior to execution of this Agreement, the parties have agreed upon the substance of information that can be used to describe the terms of this transaction, and each party may disclose such information, as modified by mutual agreement from time to time, without the other party's consent.

6.3 Permitted Disclosures. The confidentiality obligations contained in this Section 6 shall not apply to the extent that (a) a party is required (i) in the reasonable opinion of such party's legal counsel, to disclose information by applicable law, regulation, rule (including rule of a stock exchange or automated quotation system), order of a governmental agency or a court of competent jurisdiction or legal process, including tax authorities, or (ii) to disclose information to any governmental agency for purposes of obtaining approval to test or market a product, provided in either case that, to the extent practicable, such party shall provide written notice thereof to the other party and sufficient opportunity to object to any such disclosure or to request confidential treatment thereof; or (b) a party can demonstrate that (i) the information was or became public knowledge, other than as a result of actions of such party in violation hereof; or (ii) the information was disclosed to the recipient on an unrestricted basis from a source unrelated to any party to this Agreement and not under a duty of confidentiality to the other party. Notwithstanding anything to the contrary herein, Mayfield may disclose the terms and conditions of this Agreement to any Person with whom Mayfield has, or is proposing to enter into, a business relationship, as long as such Person has entered into a confidentiality agreement with Mayfield.

6.4 Injunctive Relief. Each party acknowledges that it will be impossible to measure in money the damage to the other party if such party fails to comply with the obligations imposed by this Section 6, and that, in the event of any such failure, the other party may not have an adequate remedy at law or in damages. Accordingly, each party agrees that injunctive relief or other equitable remedy, in addition to remedies at law or damages, is an appropriate remedy for any such failure and shall not oppose the granting of such relief on the basis that the disclosing party has an adequate remedy at law. Each party agrees that it shall not seek, and agrees to waive any requirement for, the securing or posting of a bond in connection with the other party seeking or obtaining such equitable relief.

7. Patents.

7.1 Patent Prosecution and Maintenance.

7.1.1 Prosecution by TGV. As between the parties, TGV shall control, at its own expense, the preparation, filing, prosecution and maintenance of the Licensed Patent Rights consistent with prudent business practices and shall consider in good faith the interests of Mayfield and its Affiliates and Sublicensees. With respect to each patent application and patent within the Field-Specific Patent Rights, TGV shall (a) provide Mayfield with each patent application to be filed by TGV reasonably in advance of filing and incorporate reasonable comments by Mayfield thereon; (b) provide Mayfield with a copy of any patent application filed by TGV promptly after such filing; (c) coordinate with Mayfield regarding patent strategy, provide Mayfield with copies of all correspondence and communications received regarding such patent applications and patents and implement reasonable comments by Mayfield in connection therewith; (d) provide Mayfield with copies of all correspondence and communications sent regarding such patents and patent applications; and (e) notify Mayfield of any interference, opposition, reexamination request, nullity proceeding, appeal or other similar action regarding such patents and patent applications, review it with Mayfield as reasonably requested, and implement reasonable comments by Mayfield thereon. TGV shall determine in what countries the Field-Specific Patent Rights will be filed and shall notify Mayfield of such countries. In the event that Mayfield wishes for TGV to file in additional countries, TGV shall have thirty (30) days to decide on whether to add such countries as its responsibility (and at its cost) and if it declines to do so, it shall notify Mayfield and TGV shall file such applications, but (i) Mayfield shall reimburse TGV for the costs associated with the additional country filings, (ii) TGV shall assign to Mayfield all right, title and interest in and to such patent or patent application, (iii) such patent or patent application shall no longer be within the Licensed Patent Rights and (iv) TGV shall assist Mayfield, upon request and to the extent commercially reasonable, in connection with the continued prosecution and maintenance thereof, at the sole expense of Mayfield. With respect to each patent application and patent within the Licensed Patent Rights that are not Field-Specific Patent Rights but can be exploited in the Field of Use, TGV shall deliver to Mayfield reasonably complete drafts of all material submissions, correspondence, filings and responses to patent authorities related to such Licensed Patent Rights, including without limitation patent applications and amendments, give Mayfield a reasonable opportunity to comment thereon prior to their submission, and consider in good faith such comments.

7.1.2 Abandonment. TGV shall not abandon any patent or patent application within the Field-Specific Patent Rights without providing to Mayfield written notice thereof reasonably in advance of any such abandonment. If TGV decides to abandon any such patent or patent application, then TGV shall provide reasonable prior written notice to Mayfield thereof. Mayfield shall have the right to assume control of such patent or patent application at its sole expense by providing TGV written notice thereof within thirty (30) days after receipt of the notice to abandon, whereupon (a) TGV shall assign to Mayfield all right, title and interest in and to such patent or patent application, (b) such patent or patent application shall no longer be within the Licensed Patent Rights and (c) TGV shall assist Mayfield, upon request and to the extent commercially reasonable, in connection with the continued prosecution and maintenance thereof, at the sole expense of Mayfield.

7.1.3 Transfer of Improvement Patents. Mayfield shall not enter into any agreement with a Third Party that is not a Sublicensee or permitted assignee described in Section 9.3 (such Third Party, an "Unaffiliated Third Party") to sell, convey, transfer or assign the Improvement Patent Rights without first giving to TGV the first right to negotiate with Mayfield for the purchase of such Improvement Patent Rights on the terms of this Section 7.1.3. If Mayfield desires to sell, convey, transfer or assign such Improvement Patent Rights to an Unaffiliated Third Party, then Mayfield shall provide prompt written notice thereof to TGV. If, within thirty (30) days after receipt of such notice, TGV provides written notice to Mayfield of its exercise of such right of first negotiation, then the parties shall negotiate in good faith, for a period not to exceed sixty (60) days, regarding terms and conditions of a mutually acceptable agreement therefor. If TGV fails to provide Mayfield timely written notice of its exercise of such right of first negotiation, or if the parties fail to reach mutual agreement and enter into a written agreement to sell, convey, transfer and assign such Improvement Patent Rights to TGV prior to the expiration of such sixty (60)-day period, then thereafter Mayfield shall have the right to enter into any agreement with any Unaffiliated Third Party, and TGV shall have no rights, regarding the sale, conveyance, transfer and/or assignment of such Improvement Patent Rights.

7.2 Notification of Infringement. Each shall promptly notify the other party of any substantial and continuing infringement known to such party of any Licensed Patent Rights in the Field of Use and shall provide the other party with the available evidence, if any, of such infringement.

7.3 Enforcement and Defense of Patent Rights in the Field of Use.

7.3.1 Field-Specific Patent Rights. As between the parties, Mayfield shall have the sole right, at its expense and in its sole discretion, to control the enforcement and defense of the Field-Specific Patent Rights. TGV shall reasonably assist Mayfield, upon request and at Mayfield's sole expense, in connection therewith.

7.3.2 Other Licensed Patent Rights. Except as set forth otherwise in this Agreement, as between the parties, TGV shall have the sole right, at its expense and in its sole discretion, to control the enforcement and defense of the Licensed Patent Rights other than the Field-Specific Patent Rights (“Other Licensed Patent Rights”). Mayfield shall reasonably assist TGV, upon request and at TGV’s sole expense, in connection therewith. In the event of any substantial and continuing infringement of such Licensed Patent Rights in a country by a Third Party in the Field of Use, if TGV fails to abate such infringement or to file an action to abate such infringement within ninety (90) days after a written request from Mayfield to do so, or if TGV discontinues the prosecution of any such action after filing without abating such infringement, then until such time as such infringement is abated, the royalty rate in such country shall be reduced to zero.

7.3.3 Combined Patent Rights. Subject to this Section 7.3.3, in the event of litigation that will involve both Field-Specific Patent Rights and Other Licensed Patent Rights, the parties shall work together to develop the strategy for the litigation. In the event of a litigation that results from a generic filing (either ANDA or 505(b)(2) filing) seeking approval of a generic product for the same indication as the Mayfield commercially marketed Product (“Hatch-Waxman Litigation”), regardless of the Licensed Patent Rights involved in such litigation, Mayfield shall have the sole right, at its expense and in its sole discretion, to control the litigation (including without limitation the enforcement and defense of any of the Licensed Patent Rights), but shall not stipulate to the invalidity or unenforceability of the Other Licensed Patent Rights without obtaining TGV’s prior written consent. If the litigation involves both Field-Specific Patent Rights and Other Licensed Patent Rights but is not Hatch-Waxman Litigation, as between the parties Mayfield shall be responsible for and shall have the sole right to control the litigation.

7.4 Recoveries. With respect to any action to enforce the Licensed Patent Rights to abate any infringement of the Licensed Patent Rights in the Field of Use or in any Hatch-Waxman Litigation, all monies recovered upon the final judgment or settlement of any such action shall be applied as follows: (a) first, to reimburse the costs and expenses (including reasonable attorneys’ fees and costs) of Mayfield and TGV; (b) second (to the extent that damages are awarded for lost sales or lost profits from the sale of Products), to Mayfield and TGV in shares that reflect the damages incurred by each party; and (c) the remainder to the account of Mayfield.

8. Term and Termination.

8.1 Term. The term of this Agreement shall continue until expiration of all payment obligations hereunder.

8.2 Termination by Mayfield. Mayfield may terminate this Agreement, in its sole discretion, upon thirty (30) days prior written notice of termination to TGV.

8.3 Termination for Cause or Financial Hardship.

8.3.1 Cause. TGV may terminate this Agreement upon or after the material breach of this Agreement by Mayfield if Mayfield has not cured such breach within ninety (90) days after receipt of express written notice thereof by TGV; provided, however, if any default is not capable of being cured within such ninety (90) day period and Mayfield is diligently undertaking to cure such default as soon as commercially feasible thereafter under the circumstances, TGV shall have no right to terminate this Agreement under this provision. Mayfield may terminate this Agreement upon or after the material breach of this Agreement by TGV if TGV has not cured such breach within ninety (90) days after receipt of express written notice thereof by Mayfield; provided, however, if any default is not capable of being cured within such ninety (90) day period and TGV is diligently undertaking to cure such default as soon as commercially feasible thereafter under the circumstances, Mayfield shall have no right to terminate this Agreement under this provision.

8.3.2 Financial Hardship. If either party applies for or consents to the appointment of a receiver, trustee or liquidator for all or a substantial part of its assets; admits in writing its inability to pay its debts generally as they mature; makes a general assignment for the benefit of creditors; is adjudicated as bankrupt; submits a petition or an answer seeking an arrangement with creditors; takes advantage of any insolvency law except as a creditor; submits an answer admitting the material allegations of a petition in bankruptcy or insolvency proceeding; has an order, judgment or decree entered by any court of competent jurisdiction approving a petition seeking reorganization of such party or appointing a receiver, trustee or liquidator for such party, or for all or a substantial part of any of its assets and such order, judgment or decree shall continue unstayed and in effect for a period of ninety (90) consecutive days; files a voluntary petition of bankruptcy or fails to remove an involuntary petition in bankruptcy filed against it within ninety (90) days of the filing thereof, the other party may terminate this Agreement immediately upon providing written notice to the first party.

8.4 Termination if an IND is not Filed within 48 Months. TGV may terminate this agreement in the event that an IND for a Product has not been filed within forty-eight (48) months after the Effective Date.

8.5 Termination for Lack of Minimum Annual Royalty. In the event that, commencing with the date that is two years after the First Commercial Sale of the first Product in the United States and ending with the date when there is a generic version of the Product available in the United States, the annual royalties paid by Mayfield is less than fifty thousand dollars (\$50,000), TGV shall have the right to terminate this Agreement by providing sixty (60) days' prior written notice of termination to Mayfield unless Mayfield pays TGV within such sixty (60)-day period the difference between fifty thousand dollars (\$50,000) and the amount of royalties actually paid for such year.

8.6 Effect of Expiration or Termination. Expiration or termination of this Agreement shall not relieve the parties of any obligation accruing prior to such expiration or termination, and the provisions of Sections 3.4, 4.2 (to the extent that a milestone has been achieved prior to termination), 5, 6, this 8.6 and 9 survive the expiration or termination of this Agreement. Upon any termination of this Agreement, TGV shall grant a direct license to any Sublicensee of Mayfield hereunder having the same scope as such sublicense and on terms and conditions no less favorable to such Sublicensee than the terms and conditions of this Agreement, provided that such Sublicensee is not in default of any applicable obligations under this Agreement and agrees in writing to be bound by the terms and conditions of such direct license and provided that such Sublicensee is not a direct competitor of TGV.

8.7 Effect of Termination Except for Breach by TGV. In the event that this Agreement is terminated by Mayfield pursuant to Section 8.2 or by TGV pursuant to Section 8.3 or 8.4, Mayfield shall assign to TGV all of its rights in and to (a) all compositions, samples, data and information specific to the Technology derived by Mayfield hereunder, (b) all results of experimentation and testing and other know-how specific to the Technology derived by Mayfield hereunder, (c) all Improvement Patent Rights owned by Mayfield that are specific to the Technology, and (d) all regulatory filings, regulatory applications and regulatory approval for Mul-1867 owned by Mayfield. Such assignment is subject to TGV agreeing to pay Mayfield an amount equal to one and one-half percent (1½%) of net sales (determined using a definition equivalent to “Net Sales” hereunder) of products comprising Mul-1867, until such payments total the full amount of Mayfield’s Development Costs. Payment from TGV to Mayfield shall occur within thirty (30) days after the end of each calendar quarter for which TGV achieves such net sales, and TGV shall deliver to Mayfield together with such payment a report equivalent to the royalty report under Section 4.4. Mayfield shall have a right to audit TGV equivalent to TGV’s right to audit Mayfield under Section 4.6. In addition, in the event that termination occurs while a Phase I Clinical Trial, Phase II Clinical Trial or Phase III Clinical Trial is ongoing, TGV shall have the right, but not the obligation to accept assignment of the associated clinical study agreement. If TGV declines to accept assignment of the clinical study agreement, as between the parties, Mayfield shall be responsible for any provisions in the clinical study agreement relating to termination of the study, including payment of all amounts required for termination.

8.8 Effect of Termination for Breach by TGV. In the event that this Agreement is terminated by Mayfield pursuant to Section 8.3, the provisions of Section 3.1 through 3.3 shall additionally survive such termination, except that the rights and licenses granted to Mayfield hereunder shall become fully paid-up and royalty free.

9. Miscellaneous.

9.1 Public Announcements. Neither party shall make any public announcements concerning matters concerning this Agreement or the negotiation thereof without the prior written consent of the other party unless such disclosure is required by law, in which case the announcing party shall provide the other party with reasonable notice of such disclosure.

9.2 No Consequential Damages. NOTWITHSTANDING ANYTHING TO THE CONTRARY HEREIN, EXCEPT WITH RESPECT TO A BREACH OF SECTION 6 OR WITH RESPECT TO A PARTY’S OBLIGATIONS TO INDEMNIFY, DEFEND AND HOLD HARMLESS PURSUANT TO SECTION 5, NEITHER PARTY SHALL BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER FORESEEABLE OR NOT, ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES.

9.3 Assignment. Neither party shall assign its rights or obligations under this Agreement without the prior written consent of the other party; provided, however, that a party may, without such consent, assign this Agreement and its rights and obligations hereunder (a) to any Affiliate, or (b) in connection with the transfer or sale of all or substantially all of its business to which this Agreement relates, or in the event of its merger, consolidation, change in control or similar transaction. Any permitted assignee shall assume all obligations of its assignor under this Agreement. Any purported assignment in violation of this Section 9.3 shall be void.

9.4 Severability. Any provision of this Agreement which is illegal, invalid or unenforceable shall be ineffective to the extent of such illegality, invalidity or unenforceability, without affecting in any way the remaining provisions hereof.

9.5 Relationship of the Parties. For all purposes of this Agreement, TGV and Mayfield shall be deemed to be independent entities and anything in this Agreement to the contrary notwithstanding, nothing herein shall be deemed to constitute TGV and Mayfield as partners, joint ventures, co-owners, an association or any entity separate and apart from each party itself, nor shall this Agreement constitute any party hereto an employee or agent, legal or otherwise, of the other party for any purposes whatsoever. Neither party is authorized to make any statements nor representations on behalf of the other party or in any way obligate the other party, except as expressly authorized in writing by the other party. Anything in this Agreement to the contrary notwithstanding, no party hereto shall assume nor shall be liable for any liabilities or obligations of the other party, whether past, present or future.

9.6 Headings. The headings set forth at the beginning of the various Articles of this Agreement are for reference and convenience and shall not affect the meanings of the provisions of this Agreement.

9.7 Governing Law; Exclusive Jurisdiction. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without regard to the conflicts of law principles thereof. Each of the parties hereto irrevocably consents to the exclusive jurisdiction and venue of any federal court located in the District of the State of Delaware or state court in Wilmington, Delaware having jurisdiction, in connection with any matter based upon or arising out of this Agreement or the matters contemplated herein, agrees that process may be served upon them in any manner authorized by laws of the State of Delaware for such persons and waives and covenants not to assert or plead any objection which they might otherwise have to such jurisdiction, venue and such process.

9.8 Entire Agreement; Amendment. This Agreement, together with the Exhibits hereto, and each additional document, instrument or other agreement to be executed and delivered pursuant hereto, including the Stock Issuance Agreement and the Consulting Agreement constitute all of the agreements of the parties with respect to, and supersede all prior agreements and understandings relating to the subject matter of, this Agreement or the transactions contemplated by this Agreement. This Agreement may not be modified or amended except by a written instrument specifically referring to this Agreement signed by the parties hereto.

9.9 Waiver. No waiver by one party of the other party's obligations, or of any breach or default hereunder by any other party, shall be valid or effective, unless such waiver is set forth in writing and is signed by the party giving such waiver; and no such waiver shall be deemed a waiver of any subsequent breach or default of the same or similar nature or any other breach or default by such other party.

9.10 Notices. Any consent, notice or report required or permitted to be given or made under this Agreement by a party to the other party shall be in writing, delivered by any lawful means to such other party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor and (except as otherwise provided in this Agreement) shall be effective upon receipt by the addressee.

If to TGV: TGV-Health, LLC
101 Avenue of the Americas
New York, New York 10013
Attention: President/Chief Executive Officer

and

TGV-Gyneconix, LLC
101 Avenue of the Americas
New York, New York 10013
Attention: President/Chief Executive Officer

With a copy to: Polsinelli
100 S. Fourth Street, Suite 1000
St. Louis, MO 63102
Attention: Kathryn J. Doty, Esq.

If to Mayfield: Mayfield Pharmaceuticals, Inc.
12264 El Camino Real, Suite 350
San Diego, California 92130
Attention: Chief Executive Officer

9.11 Counterparts. This Agreement may be executed in separate counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[SIGNATURE PAGE FOLLOWS.]

IN WITNESS WHEREOF, each party has caused a duly authorized representative to execute and deliver this License Agreement as of the Effective Date.

TGV-Health, LLC

By: /s/ George Tets
Name: George Tets
Title: Chief Executive Officer

TGV-Gyneconix, LLC

By: /s/ George Tets
Name: George Tets
Title: Chief Executive Officer

Mayfield Pharmaceuticals, Inc.

By: /s/ Mark Baum
Name: Mark L. Baum
Title: Executive Director

[Signature Page to License Agreement - 1]

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this “Agreement”) dated as of July 29, 2019 (the “Effective Date”), is entered into between TGV-Health, LLC, a Delaware limited liability company (“TGV-H”) and TGV-Ophthalmix, LLC, a Delaware limited liability company (“TGV- O”), each with a place of business at 101 Avenue of the Americas, New York, New York 10013 (TGV-O together with TGV-H, collectively “TGV”), on the one hand, and Stowe Pharmaceuticals, Inc., a Delaware corporation (“Stowe”), with a place of business at 12264 El Camino Real, Suite 350, San Diego, California 92130, on the other. The parties hereby agree as follows:

1. Definitions. For the purposes of this Agreement, the following terms shall have the respective meanings set forth below, and grammatical variations of such terms shall have corresponding meanings:

1.1 “Act” means the United States Federal Food, Drug and Cosmetic Act, as amended from time to time, and the regulations promulgated thereunder.

1.2 “Affiliate” means, with respect to any Person, any other Person which directly or indirectly controls, is controlled by, or is under common control with, such Person. A Person shall be regarded as in control of another Person if it owns, or directly or indirectly controls, more than fifty percent (50%) of the voting stock or other ownership interest of the other Person, or if it directly or indirectly possesses the power to direct or cause the direction of the management and policies of the other Person by any means whatsoever. Notwithstanding the foregoing, for purposes of this Agreement, neither Stowe nor Harrow Health, Inc. shall be Affiliates of the other or of the other’s Affiliates.

1.3 “Applicable Percentage” means, with respect to a particular time, the percentage represented by (a) the number of Stowe Shares at such time (as reflected by any new, substituted or additional securities issued in respect of the Stowe Shares upon any stock split, stock dividend, recapitalization, merger, consolidation or similar events), divided by (b) the total number of fully-diluted shares of capital stock outstanding (on an as-converted basis) as of such time.

1.4 “cGMP” means those current Good Manufacturing Practices required by the FDA to be followed in connection with the manufacture, handling, storage and control of pharmaceutical products in the United States, as set forth in the Act and any regulations related thereto.

1.5 “Commercially Reasonable Efforts” means, with respect to any objective regarding a Product and at any particular time, that degree of effort, expertise and financial resources commonly used in the pharmaceutical industry by a company of a similar size as Stowe is at such time to achieve such objective for a product that has a clinical indication and market potential similar to such Product which is at a similar stage in development or product life as such Product taking into account, without limitation, commercial, legal and regulatory factors, target product profiles, product labeling, the regulatory environment and competitive market conditions and the efficacy of the Product.

1.6 “Dental Field” means the prevention, diagnosis or treatment of dental disease, state or condition (whether acute or chronic).

1.7 “Derived” or “derived” means acquired, obtained, conceived, reduced to practice, developed, created, synthesized, designed, derived or resulting from, based upon or otherwise generated (whether directly or indirectly, or solely or jointly with others, or in whole or in part).

1.8 “Development Costs” means the fully-burdened costs to Stowe and its Affiliates incurred or accrued in connection with the research, development, pre-clinical and clinical studies, production and regulatory approval through submission of the first NDA for Product.

1.9 “Diligence Period” means, on a Product-by-Product basis, the period beginning on the Effective Date and ending on the earlier of (a) the last day of the twelve (12)- month period that the weighted average Net Sales price for such Product in the United States is less than fifty percent (50%) of the weighted average Net Sales price for such Product in the United States during the twelve (12)-month period immediately following the First Commercial Sale of such Product in the United States and (b) the date a generic product that is bioequivalent of such Product obtains the same or greater market share in the United States as such Product for treatment of any indication.

1.10 “Exclusive Sublicensee” means the Third Party sublicensee described in the first sentence of Section 4.7.

1.11 “FDA” means the Food and Drug Administration of the United States, or any successor thereto.

1.12 “Field of Use” means the Ophthalmic Field and, if the option under Section 4.8 is exercised, the Otic Field, but excluding (a) non-ophthalmic and non-otic surgical methods of treatment, (b) all diseases, states or conditions other than those set forth above and (c) the Dental Field, the Gynecology Field and the Wound Field.

1.13 “Field-Specific Patent Rights” means (a) all patents and patent applications within the Licensed Patent Rights that solely claim specific formulations of Mul- 1867 (but not solely Mul-1867), methods or uses, in each case, in the Field of Use; (b) all patents issuing therefrom (including utility models and design patents and certificates of invention); (c) all reissues, reexaminations, inter partes reviews, renewals, restorations, extensions and supplementary protection certificates of any of the foregoing patent applications or patents; (d) all confirmation patents, registration patents or patents of addition based on any of the foregoing patents; and (e) all foreign counterparts of any of the foregoing, or as applicable portions thereof.

1.14 “First Commercial Sale” means, with respect to any Product, the first sale of such Product by Stowe, its Sublicensees or its or their respective Affiliates after all applicable marketing and pricing approvals (if any) have been granted by the applicable governing health authority.

1.15 “GAAP” means United States generally accepted accounting principles.

1.16 “Gynecology Field” means the prevention, diagnosis or treatment of any gynecological disease, state or condition (whether acute or chronic and regardless of delivery system or means of application) including without limitation caused by infections or inflammation.

1.17 “Improvement Data” means IND-enabling data and results (a) from toxicology and/or pharmacokinetics studies performed by or on behalf of Stowe; (b) that are specific to active pharmaceutical ingredient synthesis for Mul-1867 prepared by or on behalf of Stowe.

1.18 “Improvement Patent Rights” means, collectively, (a) all patents and patent applications hereafter owned by Stowe, a Sublicensee, or its or their respective Affiliates (including provisional patent applications), together with all divisionals, continuations and continuations-in-part that claim priority to, or common priority with, the foregoing; (b) all patents issuing therefrom (including utility models and design patents and certificates of invention); (c) all reissues, reexaminations, inter partes reviews, renewals, restorations, extensions and supplementary protection certificates of any of the foregoing patent applications or patents; (d) all confirmation patents, registration patents or patents of addition based on any of the foregoing patents; and (e) all foreign counterparts of any of the foregoing, or as applicable portions thereof; in each case, (i) that use or are supported by data and information derived from the use of Mul-1867 (sub)licensed hereunder and (ii) only to the extent they relate to Mul-1867 or its manufacture or use; but excluding the Licensed Patent Rights.

1.19 “IND” means an Investigational New Drug application required to commence human clinical testing of a product submitted to the FDA.

1.20 “Initial Capital Investment” means Stowe’s receipt of aggregate proceeds (including both cash and conversion and/or cancellation of outstanding indebtedness or convertible securities) from the sale of Stowe’s securities in one or more transactions following the Effective Date of not less than ten million dollars (\$10,000,000) within twenty-four (24) months after the Effective Date at a pre-money valuation of Stowe equal to or greater than eighteen million dollars (\$18,000,000); provided however up to three million dollars (\$3,000,000) of such amount may be raised at a pre-money valuation that is less than eighteen million dollars (\$18,000,000) as follows: the first four hundred thousand dollars (\$400,000) at a pre-money valuation of at least eleven million seven hundred thousand dollars (\$11,700,000) and up to an additional two million six hundred thousand dollars (\$2,600,000) at a pre-money valuation of at least nine million dollars (\$9,000,000).

1.21 “Knowledge of TGV” or “TGV’s Knowledge” means the actual knowledge of any director, officer, member or employee of TGV.

1.22 “Licensed IP Rights” means the Licensed Patent Rights, the Licensed Know-How Rights and all other intellectual property rights related to the Technology owned by, or licensed to (with the right to grant sublicenses), TGV or any of its Affiliates, whether existing as of the Effective Date or derived at any time after the Effective Date.

1.23 “Licensed Know-How Rights” means all trade secret and other know-how rights related to the Technology owned by, or licensed to (with the right to grant sublicenses), TGV or any of its Affiliates, whether existing as of the Effective Date or derived at any time after the Effective Date.

1.24 “Licensed Patent Rights” means, collectively, (a) all patents and patent applications owned by, or licensed to (with the right to grant sublicenses), TGV or any of its Affiliates (including provisional patent applications) in any jurisdiction that claim or cover the Technology (whether existing on or any time after the Effective Date), including those listed on Exhibit A, together with all divisionals, continuations and continuations-in-part that claim priority to, or common priority with, the foregoing; (b) all patents issuing therefrom (including utility models and design patents and certificates of invention); (c) all reissues, reexaminations, inter partes reviews, renewals, restorations, extensions and supplementary protection certificates of any of the foregoing patent applications or patents; (d) all confirmation patents, registration patents or patents of addition based on any of the foregoing patents; and (e) all foreign counterparts of any of the foregoing, or as applicable portions thereof.

1.25 “Mul-1867” means the composition referred to by TGV as “Mul-1867” and is more specifically described in the patents and patent applications listed on Exhibit A, together with all modifications, improvements and components thereof, whether existing as of the Effective Date or derived after the Effective Date.

1.26 “NDA” means a New Drug Application submitted to the FDA for marketing approval of a Product for use in the Field of Use.

1.27 “Net Sales” means, with respect to any Product, the gross sales price of such Product invoiced by Stowe, its Sublicensees, and its and their respective Affiliates (collectively, the “Stowe Group”) to customers who are not Affiliates (or are Affiliates but are the end users of such Product), less: (a) credits, allowances, discounts and rebates to, and chargebacks from the account of, such customers actually granted in the ordinary course of business; (b) freight and insurance costs in transporting Product in the ordinary course of business; (c) cash, quantity and trade discounts, rebates and other price reductions for Product; (d) sales, use, value-added and other direct Taxes if separately charged or invoiced (but not including Taxes based on the Stowe Group’s profits); (e) customs duties, tariffs, surcharges and other governmental charges incurred in exporting or importing Product if separately invoiced; and (f) an allowance for uncollectible or bad debts determined in accordance with GAAP not to exceed three percent (3%) of Net Sales of such Product for the applicable quarterly reporting period prior to giving effect to this subsection (f). No deductions shall be made for commissions paid to individuals, whether they be with independent or affiliated sale agencies or regularly employed by the Stowe Group, and on its payroll, or for the cost of collections.

1.28 “Non-Royalty Sublicense Income” means the cash consideration amounts received by Stowe or its Affiliate from an Exclusive Sublicensee in consideration for the grant of an exclusive sublicense described in the first sentence of Section 4.7; provided, however, that Non-Royalty Sublicense Income excludes amounts received: (a) as bona fide reimbursement (i) for out of pocket costs incurred to prosecute and maintain the Licensed IP Rights or (ii) for fully-burdened costs incurred that are attributable to the research and/or development of the subject matter of the Licensed IP Rights and/or Products; (b) as bona fide loans (unless forgiven); (c) for securities sold to the Exclusive Sublicensee at fair market value; and (d) as running royalties (including any amounts paid based upon sales or profits from the sales of Product). To the extent that Non-Royalty Sublicense Income represents an unallocated combined payment for both a sublicense of Licensed IP Rights as well as other intellectual property, undertakings or subject matter, for purposes of calculating payments due to TGV, Non- Royalty Sublicense Income shall be reasonably allocated by mutual written agreement of the parties between the Licensed IP Rights and such other intellectual property, undertakings or subject matter, based on their relative value.

1.29 “Ophthalmic Field” means the prevention, diagnosis or treatment of any ophthalmic or eye-related disease, state or condition (whether acute or chronic).

1.30 “Otic Field” means the prevention, diagnosis or treatment of any otic or ear-related disease, state or condition (whether acute or chronic).

1.31 “Person” means any individual, partnership, firm, corporation, association, trust, unincorporated organization or other entity, as well as any syndicate or group of any of the foregoing.

1.32 “Phase I Clinical Trial” means a human clinical trial conducted on a limited number of study subjects for the purpose of gaining evidence of the safety and tolerability of, and information regarding, pharmacokinetics and potential pharmacological activity for a product or compound, as described in 21 C.F.R. § 312.21(a).

1.33 “Phase II Clinical Trial” means a human clinical trial conducted on study subjects with the disease or condition being studied for the principal purpose of achieving a preliminary determination of efficacy or appropriate dosage ranges, as further described in 21 C.F.R. § 312.21(b).

1.34 “Phase III Clinical Trial” means a pivotal human clinical trial the results of which could be used to establish safety and efficacy of a product as a basis for an NDA or that would otherwise satisfy requirements of 21 CFR 312.21(c).

1.35 “Product” means any product, in any form or formulation, comprising Mul-1867 that is useful in the Field of Use.

1.36 “Respiratory Field” means the use of Mul-1867 to treat respiratory diseases including, but not limited to cystic fibrosis, or any use of Mul-1867 in an inhalation dosage form.

1.37 “Stock Issuance Agreement” means the stock issuance agreement between the parties dated on the Effective Date.

1.38 “Stowe Shares” means the combined shares of common stock of Stowe issued to TGV-H or TGV-O pursuant to, and on the terms of, the Stock Issuance Agreement, and the shares of common stock of Stowe issued to Zvi Ben-Zvi on the same date as the Stock Issuance Agreement.

1.39 “Sublicensee” means a Third Party to whom Stowe or its Affiliate has granted a sublicense, immunity or other right under the Licensed Patent Rights to offer to sell, sell or otherwise commercialize one or more Products, provided such sublicense has not expired or been terminated.

1.40 “Successful Completion” means, with respect to a clinical trial for a Product for the treatment of an indication, completion of all patient enrollment, treatment and testing for such clinical trial in accordance with its applicable processes and delivery to the sponsor of the final report(s) for such clinical trial, where the results of such clinical trial are reasonably determined by the sponsor to be sufficient to progress such Product for the next phase of clinical testing in humans for such indication.

1.41 “Tax” or “Taxes” means any and all federal, state, local and foreign taxes, assessments and other governmental charges, duties, impositions and liabilities that are specific to the sale of the Products, including taxes based upon or measured by gross receipts, income, profits, sales, use and occupation, and value added, ad valorem, transfer, franchise, and property taxes together with all interest, penalties and additions imposed with respect to such amounts.

1.42 “Technology” means Mul-1867 and Product, together with all compositions, components and formulations thereof and all uses and methods of manufacture of the foregoing, whether existing as of the Effective Date or derived at any time after the Effective Date.

1.43 “Third Party” means any Person other than Stowe, TGV or their respective Affiliates.

1.44 “Valid Claim” means either (a) a claim of an issued and unexpired patent included within the Licensed Patent Rights, which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise, or (b) a claim of a pending patent application included within the Licensed Patent Rights, which claim was filed in good faith, has not been pending for more than ten (10) years from the filing date from which such claim takes priority and has not been abandoned or finally disallowed without the possibility of appeal or refiling of such application.

1.45 “Wound Field” means the treatment of, break or injury of the soft tissue and the skin.

2. Representations and Warranties.

2.1 Mutual Representations and Warranties. Each party represents and warrants to the other party as follows:

2.1.1 Organization. Such party is duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is organized.

2.1.2 Authorization and Enforcement of Obligations. Such party (a) has the requisite power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder; and (b) has taken all requisite action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such party, and constitutes a legal, valid, binding obligation, enforceable against such party in accordance with its terms.

2.1.3 Consents. All necessary consents, approvals and authorizations of all governmental authorities and other persons or entities required to be obtained by such party in connection with this Agreement have been obtained.

2.1.4 No Conflict. The execution and delivery of this Agreement and the performance of such party's obligations hereunder (a) do not and will not conflict with or violate any requirement of applicable laws, regulations or orders of governmental bodies; and (b) do not and will not conflict with, or constitute a default under, any contractual obligation of such party.

2.2 TGV Representations and Warranties. TGV hereby represents, warrants and covenants to Stowe as follows: (a) TGV-H is the sole owner of the Licensed IP Rights; (b) TGV has the right to grant the licenses and other rights purported to be granted herein and has not granted to any Third Party any license or other interest in the Licensed IP Rights within the Field of Use; (c) neither TGV-O nor TGV-H shall transfer, convey or assign any of the Licensed IP Rights useful within the Field of Use to any Person unless such Person agrees in writing to the applicable terms and conditions of this Agreement; (d) TGV shall promptly notify Stowe in writing of any transfer, conveyance or assignment of any of the Licensed IP Rights; (e) to the best of each of TGV-H's and TGV-O's respective knowledge, neither TGV-H nor TGV-O is aware of any Third Party patent, patent application or other intellectual property rights that would be infringed (i) by practicing any process or method or by making, using or selling any composition which is claimed or disclosed in the Licensed Patent Rights or which constitutes Licensed Know-How Rights within the Field of Use, or (ii) by making, using or selling Product in the Field of Use; (f) neither TGV-H nor TGV-O is aware of any infringement or misappropriation by a Third Party of any Licensed IP Rights within the Field of Use; (g) all data and information provided by TGV hereunder shall be complete and accurate; and (h) all personnel (employees, consultants, contractors, etc.) involved in the research, development or commercialization of the Technology have entered into, or prior to commencing such involvement, will enter into, valid and enforceable intellectual property assignment agreements with TGV related to the Technology, and, to the extent ownership does not vest originally in TGV by operation of law, such personnel irrevocably assign to TGV all of their respective right, title and interest in and to the Technology, all associated records, and all intellectual property rights in and to the foregoing.

2.3 Stowe Warranties. Stowe warrants that it shall undertake its development (i.e., research, clinical and regulatory) and commercialization (i.e., manufacturing, distribution and marketing) obligations in compliance with all applicable laws and regulations (including but not limited to, and to the extent applicable, the Act and the Drug Supply Chain Security Act).

3. License Grant/Obligations.

3.1 License to Stowe. Subject to the terms and conditions of this Agreement, and subject to Stowe's achievement of the Initial Capital Investment, TGV hereby grants to Stowe an exclusive (including with respect to TGV), non-transferable (except in connection with a permitted assignment of this Agreement), worldwide license under the Licensed IP Rights to develop, make, have made, use, offer for sale, sell and import Products for use in the Field of Use. Stowe shall have the right to grant sublicenses within the Field of Use, through multiple tiers, to Third Parties and Affiliates.

3.2 Availability of Technology and Licensed IP Rights. TGV shall provide Stowe (and its permitted designees) with a copy of all data and information available to TGV relating to the Technology and/or Licensed IP Rights. TGV shall provide Stowe, free of charge, based on TGV's current knowledge, such technical assistance as may be reasonably necessary or useful for Stowe to exploit such data and information, including without limitation (a) consulting services reasonably necessary to transfer the Mul-1867 molecule chemistry to an active pharmaceutical ingredient manufacturing entity and (b) consulting services reasonably necessary to transfer the formulation of a Mul-1867 topical formulation used to produce the pre-clinical data for Mul-1867 in the Field of Use.

3.3 Technical Assistance. During the term of this Agreement and in addition to the technical assistance described in Section 3.2, TGV shall provide such technical assistance to Stowe as Stowe reasonably requests regarding the Technology and/or Licensed IP Rights pursuant to and on the terms of a separate consulting agreement between Stowe and either TGV, Victor Tets and/or Georgy Tets (the "Consulting Agreement").

3.4 Improvements.

3.4.1 Improvement Patent Rights. Subject to the terms and conditions of this Agreement, Stowe hereby grants to TGV a non-exclusive, worldwide, perpetual license under the Improvement Patent Rights for all uses other than to develop, make, have made, use, offer for sale, sell and import Products within the Field of Use. TGV shall have the right to grant sublicenses outside of the Field of Use, through multiple tiers, to other licensees (whether Third Parties or Affiliates) of the Licensed Patent Rights. The foregoing license is conditioned on TGV obtaining similar grantback licenses (together with the right to sublicense to Stowe) from any and all Affiliates and Third Parties (together with their respective sublicensees and their sublicensees' respective Affiliates) that enter into an agreement with TGV for rights under the Licensed Patent Rights or to develop and commercialize products comprising Mul-1867, and if TGV fails to obtain all such grantback licenses, then the foregoing license (together with any sublicenses granted by TGV) shall be void.

3.4.2 Improvement Data. Subject to the terms and conditions of this Agreement, subject to the payment provisions of this Section 3.4.2, Stowe hereby grants to TGV a non-exclusive, worldwide, perpetual license to use and incorporate Improvement Data solely into an IND for development of products comprising Mul-1867 outside of the Field of Use. TGV shall have the right to grant sublicenses to other licensees (whether Third Parties or Affiliates) of the Licensed Patent Rights. TGV shall provide prompt written notice to Stowe of any decision to incorporate such Improvement Data into any such IND (whether by TGV, an Affiliate of TGV or any Third Party). Thereafter, Stowe shall provide TGV with a statement of its to-date Development Costs, and TGV shall pay Stowe an amount equal to fifty percent (50%) thereof within fifty (50) days after initiating a Phase III Clinical Trial (by administering product to a first human subject) under such IND outside the Field of Use.

3.5 No Implied Licenses. Only licenses and rights expressly granted herein shall be of legal force and effect. No license or other right shall be created hereunder by implication, estoppel, or otherwise.

3.6 Stowe Diligence. Stowe shall use Commercially Reasonable Efforts (whether alone or with or through its Sublicensees and its or their respective Affiliates) to research, develop and commercialize one or more Products in the United States at all times during the Diligence Period for such Product. In addition, the parties shall meet and confer, either in person or by teleconference or videoconference, quarterly to discuss the development and commercialization of Product. Subject to the terms and conditions of this Agreement, Stowe shall not prohibit any contract manufacturing organization that it engages to produce an active pharmaceutical ingredient of Mul-1867 for a Product (“CMO”) from being similarly engaged by TGV for production of an active pharmaceutical ingredient of Mul-1867 for a product (other than a Product), subject to the confidentiality and other terms between Stowe and such CMO.

3.7 Allocation of Responsibilities.

3.7.1 Product Development. As between the parties, Stowe shall be solely responsible, including financially responsible, for developing a Product suitable for submission as an IND within the Field of Use. TGV will provide technical assistance as set forth in Section 3.3 above.

3.7.2 Pre-Clinical and Clinical Responsibility. As between the parties, Stowe shall be solely responsible, including financially responsible, for conducting the pre- clinical IND studies, Phase I Clinical Trials, Phase II Clinical Trials and Phase III Clinical Trials, in each case, for Product within the Field of Use.

3.7.3 Regulatory Responsibility. As between the parties, Stowe shall be solely responsible for all regulatory filings and all costs associated with regulatory responsibilities for Product within the Field of Use, including preparation of the regulatory filings, the application filing fees for the IND and NDA (and foreign regulatory filings), site facility fees and periodic updates as is required by the relevant regulatory authority. In addition, as between the parties, Stowe shall be solely responsible for the handling of all post approval matters including adverse events and pharmacovigilance matters to the extent solely related to Product within the Field of Use. Upon either party’s request, the parties shall negotiate and enter into a pharmacovigilance agreement regarding Mul-1867 consistent with industry practices, and TGV shall require all other licensees of rights to develop and commercialize products comprising Mul-1867 to enter into substantially similar pharmacovigilance agreements.

3.7.4 Manufacturing. As between the parties, Stowe shall be solely responsible for the manufacturing of the Products for use within the Field of Use, including qualification of the active pharmaceutical ingredient, the manufacturing facility, all associated methods and testing required for release, manufacturing, packaging and tracking of the Products for use within the Field of Use. Products released by Stowe shall not be adulterated or misbranded within the meaning of the Act and, as between the parties, Stowe shall be solely responsible for handling any recalls of Product released by Stowe.

3.7.5 Marketing and Distribution. As between the parties, Stowe shall be solely responsible for distribution, marketing and promotion of the Products within the Field of Use. Stowe shall have sole discretion on determining the selling price of the Products within the Field of Use. All promotion of the Products shall strictly be within the Field of Use.

4. Financial Terms.

4.1 Stock Issuance. On the Effective Date, Stowe shall issue to TGV certain shares of common stock of Stowe pursuant to, and on the terms and conditions of, the Stock Issuance Agreement.

4.2 Milestone Payments. Within the dates as set forth in the below table, following the first achievement of each of the following milestone events, Stowe shall give written notice thereof to TGV and shall pay to TGV the corresponding non-refundable and noncreditable one-time milestone payments:

Milestone Event	Milestone Payment	Payment Date
Effective Date	\$170,000 (for reimbursement of patent expenses)	Within thirty (30) days of the Effective Date
Completion of enrollment of subjects for the first Phase I Clinical Trial intended to support a Product in the Ophthalmic Field of Use by Stowe, a Sublicensee, or one of their respective Affiliates	\$400,000	Within fifty (50) days of achievement

4.3 Royalty. Subject to the terms and conditions of this Agreement, on a Product-by-Product and country-by-country basis, Stowe shall pay to TGV, on a quarterly basis, a royalty of three percent (3%) of Net Sales of any Product during the term of this Agreement (the "Royalty"); provided, however, that if the manufacture, use, offer for sale, sale, or import of a particular Product in a particular country would not infringe a Valid Claim (if such Valid Claim were in an issued patent and not licensed to Stowe) or is not subject to a period of regulatory exclusivity, or if the Product is subject to generic competition (i.e., same active ingredient, same dosage form, same strength and same indication) in such particularly country then the applicable Royalty with respect to such Product in such country shall be reduced by one-half (½) to one and one half percent (1½%) of Net Sales.

4.4 Royalty Reports and Payments. Within thirty (30) days after the end of each calendar quarter during the term of this Agreement, or, after the earlier of (i) the first sale of common stock of Stowe to the general public pursuant to a registration statement filed with and declared effective by the Securities and Exchange Commission under the Securities Act of 1933 (as amended) and (ii) Stowe first becoming subject to the reporting obligations under the Securities and Exchange Act of 1934 (as amended), within forty-five (45) days after the end of each calendar quarter during the term of this Agreement, Stowe shall deliver to TGV a report setting forth for such calendar quarter (a) the calculation of the applicable Royalty; (b) the payments due under this Agreement for the sale of each Product; and (c) the applicable exchange rate as determined below. Stowe shall remit the total payments due for the sale of Products during such calendar quarter at the time such report is made. No such reports or payments shall be due for any Product prior to the First Commercial Sale of such Product. With respect to Net Sales received in United States dollars, all amounts shall be expressed in United States dollars. With respect to Net Sales received in a currency other than United States dollars, all amounts shall be expressed both in the currency in which the amount is invoiced (or received as applicable) and in the United States dollar equivalent. The United States dollar equivalent shall be calculated using the average of the exchange rate (local currency per US\$1) published in The Wall Street Journal, Western Edition, under the heading "Currency Trading" on the last business day of each month during the applicable calendar quarter. All amounts paid to TGV shall be in United States dollars.

4.5 Payment Provisions.

4.5.1 Payment Terms. The Royalty shown to have accrued by each report provided for under Section 4.4 shall be due on the date such report is due. Payment of the Royalty in whole or in part may be made in advance of such due date.

4.5.2 Exchange Control. If at any time legal restrictions prevent the prompt remittance of part or all of the Royalty with respect to any country in which a Product is sold, Stowe shall have the right, in its sole discretion, to make such payments by depositing the amount thereof in local currency to TGV's account in a bank or other depository institution in such country. If the payment rate specified in this Agreement should exceed the permissible rate established in any country, the payment rate for sales in such country shall be adjusted to the highest legally permissible or government-approved rate.

4.5.3 Withholding Taxes. Stowe shall be entitled to deduct the amount of any withholding Taxes, value-added Taxes or other Taxes, levies or charges with respect to such amounts, other than United States taxes, payable by Stowe, its Sublicensees or its or their respective Affiliates, or any Taxes required to be withheld by Stowe, its Sublicensees or its or their respective Affiliates, to the extent Stowe, its Sublicensees or its or their respective Affiliates pay to the appropriate governmental authority on behalf of TGV such Taxes, levies or charges. Stowe shall use reasonable efforts to minimize any such Taxes, levies or charges required to be withheld on behalf of TGV by Stowe, its Sublicensees or its or their respective Affiliates. Stowe promptly shall deliver to TGV proof of payment of all such Taxes, levies and other charges, together with copies of all communications from or with such governmental authority with respect thereto.

4.6 Audits. Upon the written request of TGV and not more than once in each calendar year except if a prior audit in such calendar year revealed an Underpayment (as defined below), Stowe shall permit an independent certified public accounting firm of nationally recognized standing selected by TGV and reasonably acceptable to Stowe, at TGV's expense, to have access during normal business hours to such of the financial records of Stowe as may be reasonably necessary to verify the accuracy of the Royalty reports hereunder for the eight (8) calendar quarters immediately prior to the date of such request (other than records for which TGV has already conducted an audit under this Section), which shall include, but not be limited to, review of fair market value calculations of bundled products,. If such accounting firm concludes that additional amounts were owed during the audited period, Stowe shall pay such additional amounts within thirty (30) days after the date TGV delivers to Stowe such accounting firm's written report so concluding. The fees charged by such accounting firm shall be paid by TGV; provided, however, if the audit discloses that the Royalty payable by Stowe for such period is more than one hundred ten percent (110%) of the Royalty actually paid for such period (an "Underpayment"), then Stowe shall pay the reasonable fees and expenses charged by such accounting firm. TGV shall cause its accounting firm to retain all financial information subject to review under this Section 4.6 in strict confidence; provided, however, that Stowe shall have the right to require that such accounting firm, prior to conducting such audit, enter into an appropriate non-disclosure agreement with Stowe regarding such financial information. The accounting firm shall disclose to TGV only whether the reports are correct or not and the amount of any discrepancy. No other information shall be shared. TGV shall treat all such financial information as Stowe's confidential information, and shall not disclose such financial information to any Third Party or use it for any purpose other than as specified in this Section 4.6.

4.7 Non-Royalty Sublicense Income. If Stowe enters into any agreement with a Third Party that includes a worldwide, exclusive (including with respect to Stowe) sublicense ("Worldwide Sublicense") under all or substantially all of the Licensed IP Rights to develop, make, have made, use, offer for sale, sell and import all Products for use in the Field of Use, Stowe shall give prompt written notice to TGV thereof. Within thirty (30) days after receipt of such written notice from Stowe, TGV shall have the right, at its option but only in the event permitted by applicable law or regulation, to exchange the Stowe Shares for an additional sublicense royalty stream as set forth below by giving express written notice to Stowe thereof. If TGV timely exercises its such option as set forth above, then (a) within ten (10) days after the date of such notice, TGV shall duly convey, transfer and assign to Stowe all right, title and interest in and to shares of common stock of Stowe equal to the number of the Stowe Shares (together with any and all new, substituted or additional securities issued in respect of the Stowe Shares upon any stock split, stock dividend, recapitalization, merger, consolidation or similar events), free and clear of all encumbrances, liens and claims, including by duly executing and delivery such assignments and other instruments and agreements as reasonably requested by Stowe, and (b) Stowe shall, within fifty (50) days after the receipt of any Non-Royalty Sublicense Income, provide written notice thereof to TGV and remit to TGV an amount equal to the Applicable Percentage multiplied by such Non-Royalty Sublicense Income. For purposes of this Section 4.7, the term "Worldwide Sublicense" shall mean an exclusive sublicense or series of exclusive sublicenses executed on the same date with the same Third Party where the United States is included within the sublicensed territory. TGV shall have the right to audit the records of Stowe to confirm the accuracy of the amount of the Non-Royalty Sublicense Income pursuant to the terms of Section 4.6.

4.8 Option to the Otic Field.

4.8.1 Option. Within five (5) days after the Effective Date, Stowe shall pay to TGV fifty thousand dollars (\$50,000) (the “Option Fee”). Stowe shall have the exclusive option to expand the Field of Use to include the Otic Field (such option, the “Option”). The Option shall be exercisable by Stowe delivering to TGV, prior to the second (2nd) anniversary of the Effective Date, written notice of Stowe’s election to exercise the Option and a development plan to develop a Product for use in the Otic Field reasonably acceptable to TGV (the “Development Plan”). TGV shall have the right to approve such Development Plan, and such approval shall not be unreasonably withheld, conditioned or delayed. If Stowe fails to timely exercise the Option, then Stowe shall have no further rights to expand the Stowe Field to include the Otic Field hereunder.

4.8.2 Exclusivity. Prior to the expiration of the Option, TGV (a) shall not (and shall cause its Affiliates not to) exploit the Technology or the Licensed IP Rights in the Otic Field, (b) shall not enter into any agreement or grant any license or other right to any Third Party to exploit the Technology or the Licensed IP Rights in the Otic Field, and (c) shall not solicit, initiate or encourage submission of proposals or offers from any Third Party for a license or other grant of rights to exploit the Technology or the Licensed IP Rights in the Otic Field.

5. Indemnification.

5.1 Indemnification by TGV. Subject to the provisions of this Section 5, TGV shall indemnify, defend and hold harmless Stowe, its Affiliates, and its and their respective officers, directors, agents, stockholders and representatives, from and against any and all losses, liabilities, damages and expenses (including without limitation reasonable attorneys’ fees and costs) (collectively, “Losses”) resulting from any claim, demand, action or proceeding by any Third Party (each a “Claim”) the extent resulting from or arising out of:

5.1.1 the actual or alleged breach of any representations, warranties or covenants of TGV in this Agreement; or

5.1.2 the actual or alleged negligence, gross negligence or willful misconduct of TGV, its Affiliates or their respective agents or representatives.

5.2 Indemnification by Stowe. Subject to the provisions of this Section 5, Stowe shall indemnify and hold harmless TGV, its Affiliates, and its and their respective officers, directors, agents, stockholders and representatives, from and against any and all Losses resulting from any Claim to the extent resulting from or arising out of:

5.2.1 the actual or alleged breach of any representations, warranties or covenants of Stowe in this Agreement;

5.2.2 the actual or alleged negligence, gross negligence or willful misconduct of Stowe, its Affiliates or their respective agents or representatives; or

5.2.3 the development or exploitation of Product by or on behalf of Stowe, its Sublicensees or their respective Affiliates, customers or end-users.

5.3 Procedure. A party seeking indemnification (the “Indemnitee”) shall promptly notify the other party (the “Indemnifying Party”) in writing of a claim or suit; provided that an Indemnitee’s failure to give such notice or delay in giving such notice shall not affect such Indemnitee’s right to indemnification under this Section 5 except to the extent that the Indemnifying Party has been prejudiced by such failure or delay. The Indemnifying Party shall have the right to control the defense of all indemnification claims hereunder. The Indemnitee shall have the right to participate at its own expense in the claim or suit with counsel of its own choosing. The Indemnifying Party shall consult with the Indemnitee in good faith with respect to all non-privileged aspects of the defense strategy. The Indemnitee shall cooperate with the Indemnifying Party as reasonably requested, at the Indemnifying Party’s sole cost and expense. The Indemnifying Party shall not settle any claim or suit without the Indemnitee’s prior written consent, which consent shall not be unreasonably withheld.

6. Confidentiality.

6.1 Confidential Information. During the term of this Agreement, and for a period of five (5) years following the expiration or earlier termination hereof, each party shall maintain in confidence all information of the other party that is disclosed by the other party and identified as, or acknowledged to be, confidential at the time of disclosure (the “Confidential Information”), and shall not use, disclose or grant the use of the Confidential Information except on a need-to-know basis to those directors, officers, affiliates, employees, permitted actual or prospective licensees, permitted actual or prospective assignees and agents, consultants, clinical investigators or contractors, to the extent such disclosure is reasonably necessary in connection with performing its obligations or exercising its rights under this Agreement. For purposes of this Section, all Technology shall constitute the Confidential Information of both parties. To the extent that disclosure is authorized by this Agreement, prior to disclosure, the disclosing party shall obtain agreement of any such Person to hold in confidence and not make use of the Confidential Information for any purpose other than those permitted by this Agreement. Each party shall notify the other promptly upon discovery of any unauthorized use or disclosure of the other party’s Confidential Information.

6.2 Terms of this Agreement. Except as otherwise provided in this Section 6, neither party shall disclose any terms or conditions of this Agreement to any Third Party without the prior consent of the other party; provided, however, that a party may disclose the terms or conditions of this Agreement, (a) on a need-to-know basis to its legal and financial advisors to the extent such disclosure is reasonably necessary, and (b) to a Third Party in connection with (i) an equity investment in such party, (ii) a merger, consolidation or similar transaction by such party, (iii) a permitted (sub)license under this Agreement, or (iv) the sale of all or substantially all of the assets of such party. Notwithstanding the foregoing, prior to execution of this Agreement, the parties have agreed upon the substance of information that can be used to describe the terms of this transaction, and each party may disclose such information, as modified by mutual agreement from time to time, without the other party’s consent.

6.3 Permitted Disclosures. The confidentiality obligations contained in this Section 6 shall not apply to the extent that (a) a party is required (i) in the reasonable opinion of such party's legal counsel, to disclose information by applicable law, regulation, rule (including rule of a stock exchange or automated quotation system), order of a governmental agency or a court of competent jurisdiction or legal process, including tax authorities, or (ii) to disclose information to any governmental agency for purposes of obtaining approval to test or market a product, provided in either case that, to the extent practicable, such party shall provide written notice thereof to the other party and sufficient opportunity to object to any such disclosure or to request confidential treatment thereof; or (b) a party can demonstrate that (i) the information was or became public knowledge, other than as a result of actions of such party in violation hereof; or (ii) the information was disclosed to the recipient on an unrestricted basis from a source unrelated to any party to this Agreement and not under a duty of confidentiality to the other party. Notwithstanding anything to the contrary herein, Stowe may disclose the terms and conditions of this Agreement to any Person with whom Stowe has, or is proposing to enter into, a business relationship, as long as such Person has entered into a confidentiality agreement with Stowe.

6.4 Injunctive Relief. Each party acknowledges that it will be impossible to measure in money the damage to the other party if such party fails to comply with the obligations imposed by this Section 6, and that, in the event of any such failure, the other party may not have an adequate remedy at law or in damages. Accordingly, each party agrees that injunctive relief or other equitable remedy, in addition to remedies at law or damages, is an appropriate remedy for any such failure and shall not oppose the granting of such relief on the basis that the disclosing party has an adequate remedy at law. Each party agrees that it shall not seek, and agrees to waive any requirement for, the securing or posting of a bond in connection with the other party seeking or obtaining such equitable relief.

7. Patents.

7.1 Patent Prosecution and Maintenance.

7.1.1 Prosecution by TGV. As between the parties, TGV shall control, at its own expense, the preparation, filing, prosecution and maintenance of the Licensed Patent Rights consistent with prudent business practices and shall consider in good faith the interests of Stowe and its Affiliates and Sublicensees. With respect to each patent application and patent within the Field-Specific Patent Rights, TGV shall (a) provide Stowe with each patent application to be filed by TGV reasonably in advance of filing and incorporate reasonable comments by Stowe thereon; (b) provide Stowe with a copy of any patent application filed by TGV promptly after such filing; (c) coordinate with Stowe regarding patent strategy, provide Stowe with copies of all correspondence and communications received regarding such patent applications and patents and implement reasonable comments by Stowe in connection therewith; (d) provide Stowe with copies of all correspondence and communications sent regarding such patents and patent applications; and (e) notify Stowe of any interference, opposition, reexamination request, nullity proceeding, appeal or other similar action regarding such patents and patent applications, review it with Stowe as reasonably requested, and implement reasonable comments by Stowe thereon. TGV shall determine in what countries the Field-Specific Patent Rights will be filed and shall notify Stowe of such countries. In the event that Stowe wishes for TGV to file in additional countries, TGV shall have thirty (30) days to decide on whether to add such countries as its responsibility (and at its cost) and if it declines to do so, it shall notify Stowe and TGV shall file such applications, but (i) Stowe shall reimburse TGV for the costs associated with the additional country filings, (ii) TGV shall assign to Stowe all right, title and interest in and to such patent or patent application, (iii) such patent or patent application shall no longer be within the Licensed Patent Rights and (iv) TGV shall assist Stowe, upon request and to the extent commercially reasonable, in connection with the continued prosecution and maintenance thereof, at the sole expense of Stowe. With respect to each patent application and patent within the Licensed Patent Rights that are not Field-Specific Patent Rights but can be exploited in the Field of Use, TGV shall deliver to Stowe reasonably complete drafts of all material submissions, correspondence, filings and responses to patent authorities related to such Licensed Patent Rights, including without limitation patent applications and amendments, give Stowe a reasonable opportunity to comment thereon prior to their submission, and consider in good faith such comments.

7.1.2 Abandonment. TGV shall not abandon any patent or patent application within the Field-Specific Patent Rights without providing to Stowe written notice thereof reasonably in advance of any such abandonment. If TGV decides to abandon any such patent or patent application, then TGV shall provide reasonable prior written notice to Stowe thereof. Stowe shall have the right to assume control of such patent or patent application at its sole expense by providing TGV written notice thereof within thirty (30) days after receipt of the notice to abandon, whereupon (a) TGV shall assign to Stowe all right, title and interest in and to such patent or patent application, (b) such patent or patent application shall no longer be within the Licensed Patent Rights and (c) TGV shall assist Stowe, upon request and to the extent commercially reasonable, in connection with the continued prosecution and maintenance thereof, at the sole expense of Stowe.

7.1.3 Transfer of Improvement Patents. Stowe shall not enter into any agreement with a Third Party that is not a Sublicensee or permitted assignee described in Section 9.3 (such Third Party, an "Unaffiliated Third Party") to sell, convey, transfer or assign the Improvement Patent Rights without first giving to TGV the first right to negotiate with Stowe for the purchase of such Improvement Patent Rights on the terms of this Section 7.1.3. If Stowe desires to sell, convey, transfer or assign such Improvement Patent Rights to an Unaffiliated Third Party, then Stowe shall provide prompt written notice thereof to TGV. If, within thirty (30) days after receipt of such notice, TGV provides written notice to Stowe of its exercise of such right of first negotiation, then the parties shall negotiate in good faith, for a period not to exceed sixty (60) days, regarding terms and conditions of a mutually acceptable agreement therefor. If TGV fails to provide Stowe timely written notice of its exercise of such right of first negotiation, or if the parties fail to reach mutual agreement and enter into a written agreement to sell, convey, transfer and assign such Improvement Patent Rights to TGV prior to the expiration of such sixty (60)-day period, then thereafter Stowe shall have the right to enter into any agreement with any Unaffiliated Third Party, and TGV shall have no rights, regarding the sale, conveyance, transfer and/or assignment of such Improvement Patent Rights.

7.2 Notification of Infringement. Each shall promptly notify the other party of any substantial and continuing infringement known to such party of any Licensed Patent Rights in the Field of Use and shall provide the other party with the available evidence, if any, of such infringement.

7.3 Enforcement and Defense of Patent Rights in the Field of Use.

7.3.1 Field-Specific Patent Rights. As between the parties, Stowe shall have the sole right, at its expense and in its sole discretion, to control the enforcement and defense of the Field-Specific Patent Rights. TGV shall reasonably assist Stowe, upon request and at Stowe's sole expense, in connection therewith.

7.3.2 Other Licensed Patent Rights. Except as set forth otherwise in this Agreement, as between the parties, TGV shall have the sole right, at its expense and in its sole discretion, to control the enforcement and defense of the Licensed Patent Rights other than the Field-Specific Patent Rights ("Other Licensed Patent Rights"). Stowe shall reasonably assist TGV, upon request and at TGV's sole expense, in connection therewith. In the event of any substantial and continuing infringement of such Licensed Patent Rights in a country by a Third Party in the Field of Use, if TGV fails to abate such infringement or to file an action to abate such infringement within ninety (90) days after a written request from Stowe to do so, or if TGV discontinues the prosecution of any such action after filing without abating such infringement, then until such time as such infringement is abated, the royalty rate in such country shall be reduced to zero.

7.3.3 Combined Patent Rights. Subject to this Section 7.3.3, in the event of litigation that will involve both Field-Specific Patent Rights and Other Licensed Patent Rights, the parties shall work together to develop the strategy for the litigation. In the event of a litigation that results from a generic filing (either ANDA or 505(b)(2) filing) seeking approval of a generic product for the same indication as the Stowe commercially marketed Product ("Hatch- Waxman Litigation"), regardless of the Licensed Patent Rights involved in such litigation, Stowe shall have the sole right, at its expense and in its sole discretion, to control the litigation (including without limitation the enforcement and defense of any of the Licensed Patent Rights), but shall not stipulate to the invalidity or unenforceability of the Other Licensed Patent Rights without obtaining TGV's prior written consent. If the litigation involves both Field-Specific Patent Rights and Other Licensed Patent Rights but is not Hatch-Waxman Litigation, as between the parties Stowe shall be responsible for and shall have the sole right to control the litigation.

7.4 Recoveries. With respect to any action to enforce the Licensed Patent Rights to abate any infringement of the Licensed Patent Rights in the Field of Use or in any Hatch-Waxman Litigation, all monies recovered upon the final judgment or settlement of any such action shall be applied as follows: (a) first, to reimburse the costs and expenses (including reasonable attorneys' fees and costs) of Stowe and TGV; (b) second (to the extent that damages are awarded for lost sales or lost profits from the sale of Products), to Stowe and TGV in shares that reflect the damages incurred by each party; and (c) the remainder to the account of Stowe.

8. Term and Termination.

8.1 Term. The term of this Agreement shall continue until expiration of all payment obligations hereunder.

8.2 Termination by Stowe. Stowe may terminate this Agreement, in its sole discretion, upon thirty (30) days prior written notice of termination to TGV.

8.3 Termination for Cause or Financial Hardship.

8.3.1 Cause. TGV may terminate this Agreement upon or after the material breach of this Agreement by Stowe if Stowe has not cured such breach within ninety (90) days after receipt of express written notice thereof by TGV; provided, however, if any default is not capable of being cured within such ninety (90) day period and Stowe is diligently undertaking to cure such default as soon as commercially feasible thereafter under the circumstances, TGV shall have no right to terminate this Agreement under this provision. Stowe may terminate this Agreement upon or after the material breach of this Agreement by TGV if TGV has not cured such breach within ninety (90) days after receipt of express written notice thereof by Stowe; provided, however, if any default is not capable of being cured within such ninety (90) day period and TGV is diligently undertaking to cure such default as soon as commercially feasible thereafter under the circumstances, Stowe shall have no right to terminate this Agreement under this provision.

8.3.2 Financial Hardship. If either party applies for or consents to the appointment of a receiver, trustee or liquidator for all or a substantial part of its assets; admits in writing its inability to pay its debts generally as they mature; makes a general assignment for the benefit of creditors; is adjudicated as bankrupt; submits a petition or an answer seeking an arrangement with creditors; takes advantage of any insolvency law except as a creditor; submits an answer admitting the material allegations of a petition in bankruptcy or insolvency proceeding; has an order, judgment or decree entered by any court of competent jurisdiction approving a petition seeking reorganization of such party or appointing a receiver, trustee or liquidator for such party, or for all or a substantial part of any of its assets and such order, judgment or decree shall continue unstayed and in effect for a period of ninety (90) consecutive days; files a voluntary petition of bankruptcy or fails to remove an involuntary petition in bankruptcy filed against it within ninety (90) days of the filing thereof, the other party may terminate this Agreement immediately upon providing written notice to the first party.

8.4 Termination if an IND is not Filed within 48 Months. TGV may terminate this agreement in the event that an IND for a Product has not been filed within forty-eight (48) months after the Effective Date.

8.5 Termination for Lack of Minimum Annual Royalty. In the event that, commencing with the date that is two years after the First Commercial Sale of the first Product in the United States and ending with the date when there is a generic version of the Product available in the United States, the annual royalties paid by Stowe is less than fifty thousand dollars (\$50,000), TGV shall have the right to terminate this Agreement by providing sixty (60) days' prior written notice of termination to Stowe unless Stowe pays TGV within such sixty (60)-day period the difference between fifty thousand dollars (\$50,000) and the amount of royalties actually paid for such year.

8.6 Effect of Expiration or Termination. Expiration or termination of this Agreement shall not relieve the parties of any obligation accruing prior to such expiration or termination, and the provisions of Sections 3.4, 4.2 (to the extent that a milestone has been achieved prior to termination), 5, 6, this 8.6 and 9 survive the expiration or termination of this Agreement. Upon any termination of this Agreement, TGV shall grant a direct license to any Sublicensee of Stowe hereunder having the same scope as such sublicense and on terms and conditions no less favorable to such Sublicensee than the terms and conditions of this Agreement, provided that such Sublicensee is not in default of any applicable obligations under this Agreement and agrees in writing to be bound by the terms and conditions of such direct license and provided that such Sublicensee is not a direct competitor of TGV.

8.7 Effect of Termination Except for Breach by TGV. In the event that this Agreement is terminated by Stowe pursuant to Section 8.2 or by TGV pursuant to Section 8.3 or 8.4, Stowe shall assign to TGV all of its rights in and to (a) all compositions, samples, data and information specific to the Technology derived by Stowe hereunder, (b) all results of experimentation and testing and other know-how specific to the Technology derived by Stowe hereunder, (c) all Improvement Patent Rights owned by Stowe that are specific to the Technology, and (d) all regulatory filings, regulatory applications and regulatory approval for Mul-1867 owned by Stowe. Such assignment is subject to TGV agreeing to pay Stowe an amount equal to one and one-half percent (1½%) of net sales (determined using a definition equivalent to “Net Sales” hereunder) of products comprising Mul-1867, until such payments total the full amount of Stowe’s Development Costs. Payment from TGV to Stowe shall occur within thirty (30) days after the end of each calendar quarter for which TGV achieves such net sales, and TGV shall deliver to Stowe together with such payment a report equivalent to the royalty report under Section 4.4. Stowe shall have a right to audit TGV equivalent to TGV’s right to audit Stowe under Section 4.6. In addition, in the event that termination occurs while a Phase I Clinical Trial, Phase II Clinical Trial or Phase III Clinical Trial is ongoing, TGV shall have the right, but not the obligation to accept assignment of the associated clinical study agreement. If TGV declines to accept assignment of the clinical study agreement, as between the parties, Stowe shall be responsible for any provisions in the clinical study agreement relating to termination of the study, including payment of all amounts required for termination.

8.8 Effect of Termination for Breach by TGV. In the event that this Agreement is terminated by Stowe pursuant to Section 8.3, the provisions of Section 3.1 through 3.3 shall additionally survive such termination, except that the rights and licenses granted to Stowe hereunder shall become fully paid-up and royalty free.

9. Miscellaneous.

9.1 Public Announcements. Neither party shall make any public announcements concerning matters concerning this Agreement or the negotiation thereof without the prior written consent of the other party unless such disclosure is required by law, in which case the announcing party shall provide the other party with reasonable notice of such disclosure.

9.2 No Consequential Damages. NOTWITHSTANDING ANYTHING TO THE CONTRARY HEREIN, EXCEPT WITH RESPECT TO A BREACH OF SECTION 6 OR WITH RESPECT TO A PARTY’S OBLIGATIONS TO INDEMNIFY, DEFEND AND HOLD HARMLESS PURSUANT TO SECTION 5, NEITHER PARTY SHALL BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER FORESEEABLE OR NOT, ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES.

9.3 Assignment. Neither party shall assign its rights or obligations under this Agreement without the prior written consent of the other party; provided, however, that a party may, without such consent, assign this Agreement and its rights and obligations hereunder (a) to any Affiliate, or (b) in connection with the transfer or sale of all or substantially all of its business to which this Agreement relates, or in the event of its merger, consolidation, change in control or similar transaction. Any permitted assignee shall assume all obligations of its assignor under this Agreement. Any purported assignment in violation of this Section 9.3 shall be void.

9.4 Severability. Any provision of this Agreement which is illegal, invalid or unenforceable shall be ineffective to the extent of such illegality, invalidity or unenforceability, without affecting in any way the remaining provisions hereof.

9.5 Relationship of the Parties. For all purposes of this Agreement, TGV and Stowe shall be deemed to be independent entities and anything in this Agreement to the contrary notwithstanding, nothing herein shall be deemed to constitute TGV and Stowe as partners, joint ventures, co-owners, an association or any entity separate and apart from each party itself, nor shall this Agreement constitute any party hereto an employee or agent, legal or otherwise, of the other party for any purposes whatsoever. Neither party is authorized to make any statements nor representations on behalf of the other party or in any way obligate the other party, except as expressly authorized in writing by the other party. Anything in this Agreement to the contrary notwithstanding, no party hereto shall assume nor shall be liable for any liabilities or obligations of the other party, whether past, present or future.

9.6 Headings. The headings set forth at the beginning of the various Articles of this Agreement are for reference and convenience and shall not affect the meanings of the provisions of this Agreement.

9.7 Governing Law; Exclusive Jurisdiction. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without regard to the conflicts of law principles thereof. Each of the parties hereto irrevocably consents to the exclusive jurisdiction and venue of any federal court located in the District of the State of Delaware or state court in Wilmington, Delaware having jurisdiction, in connection with any matter based upon or arising out of this Agreement or the matters contemplated herein, agrees that process may be served upon them in any manner authorized by laws of the State of Delaware for such persons and waives and covenants not to assert or plead any objection which they might otherwise have to such jurisdiction, venue and such process.

9.8 Entire Agreement; Amendment. This Agreement, together with the Exhibits hereto, and each additional document, instrument or other agreement to be executed and delivered pursuant hereto, including the Stock Issuance Agreement and the Consulting Agreement constitute all of the agreements of the parties with respect to, and supersede all prior agreements and understandings relating to the subject matter of, this Agreement or the transactions contemplated by this Agreement. This Agreement may not be modified or amended except by a written instrument specifically referring to this Agreement signed by the parties hereto.

9.9 Waiver. No waiver by one party of the other party's obligations, or of any breach or default hereunder by any other party, shall be valid or effective, unless such waiver is set forth in writing and is signed by the party giving such waiver; and no such waiver shall be deemed a waiver of any subsequent breach or default of the same or similar nature or any other breach or default by such other party.

9.10 Notices. Any consent, notice or report required or permitted to be given or made under this Agreement by a party to the other party shall be in writing, delivered by any lawful means to such other party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor and (except as otherwise provided in this Agreement) shall be effective upon receipt by the addressee.

If to TGV: TGV-Health, LLC
101 Avenue of the Americas
New York, New York 10013
Attention: President/Chief Executive Officer

and

TGV-Ophthalmix, LLC101
Avenue of the Americas
New York, New York 10013
Attention: President/Chief Executive Officer

With a copy to: Polsinelli
100 S. Fourth Street, Suite 1000
St. Louis, MO 63102
Attention: Kathryn J. Doty, Esq.

If to Stowe: Stowe Pharmaceuticals, Inc.
12264 El Camino Real, Suite 350
San Diego, California 92130
Attention: Chief Executive Officer

9.11 Counterparts. This Agreement may be executed in separate counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[SIGNATURE PAGE FOLLOWS.]

IN WITNESS WHEREOF, each party has caused a duly authorized representative to execute and deliver this License Agreement as of the Effective Date.

TGV-Health, LLC

By: /s/ George Tets
Name: George Tets
Title: Chief Executive Officer

TGV-Ophthalmix, LLC

By: /s/ George Tets
Name: George Tets
Title: Chief Executive Officer

Stowe Pharmaceuticals, Inc.

By: /s/ Mark Baum
Name: Mark Baum
Title: Executive Director

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: November 13, 2019

/s/ Mark L. Baum

Mark L. Baum
Chief Executive Officer
Principal Executive Officer

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: November 13, 2019

/s/ Andrew R. Boll

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

**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 September 30, 2019 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: November 13, 2019

/s/ Mark L. Baum

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

Date: November 13, 2019

/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.
