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

FORM 10-Q

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

For the quarterly period ended September 30, 2018

[ ] 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

Imprimis Pharmaceuticals, 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.)
12264 El Camino Real, Suite 350 **San Diego, CA** (Address of principal executive offices)	**92130** (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 [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes [X] No [ ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a small reporting company.

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-accelerated filer	[ ] (Do not check if a smaller reporting company)	Smaller reporting company	[X]
		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 [X]

As of November 12, 2018, 23,277,975 shares of the registrant's common stock, $0.001 par value, were outstanding.

IMPRIMIS PHARMACEUTICALS, INC.

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PART I
FINANCIAL INFORMATION

Item 1. Financial Statements

IMPRIMIS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)

	September 30, 2018 (unaudited)	December 31, 2017
ASSETS		
Current assets		
Cash and cash equivalents, including restricted cash of $200	$ 6,315	$ 4,219
Accounts receivable, net	1,731	1,529
Inventories	2,524	2,249
Prepaid expenses and other current assets	1,114	714
Note receivable, current portion	-	95
Total current assets	11,684	8,806
Property, plant and equipment, net	6,061	6,215
Intangible assets, net	2,964	2,860
Investment in Surface Pharmaceuticals	5,090	-
Investment in Eton Pharmaceuticals	263	3,507
Note receivable, less current portion	-	302
Goodwill	2,227	2,227
TOTAL ASSETS	$ 28,289	$ 23,917
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 5,931	$ 3,885
Accrued payroll and related liabilities	1,727	1,209
Deferred revenue and customer deposits	98	29
Current portion of deferred acquisition obligation and accrued interest	-	53
Current portion of note payable, net of unamortized debt discount	1,729	-
Current portion of capital lease obligations, net of unamortized discount	883	598
Total current liabilities	10,368	5,774
Capital lease obligations, net of current portion and unamortized discount	-	720
Accrued expenses, net of current portion	800	800
Note payable, net of current portion and unamortized debt discount	12,668	14,008
TOTAL LIABILITIES	23,836	21,302
STOCKHOLDERS' EQUITY		
Common stock, $0.001 par value, 90,000,000 shares authorized, 22,656,183 and 20,623,129 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	23	21
Additional paid-in capital	96,771	91,430
Accumulated deficit	(92,341)	(88,836)
TOTAL STOCKHOLDERS' EQUITY	4,453	2,615
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 28,289	$ 23,917

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

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

	For the Three Months Ended September 30, 2018	For the Three Months Ended September 30, 2017	For the Nine months Ended September 30, 2018	For the Nine months Ended September 30, 2017
Revenues:				
Product sales, net	$ 10,729	$ 6,473	$ 29,958	$ 19,411
License revenues	10	10	30	26
Total revenues	10,739	6,483	29,988	19,437
Cost of sales	(4,191)	(3,403)	(12,419)	(10,048)
Gross profit	6,548	3,080	17,569	9,389
Operating expenses:				
Selling, general and administrative	6,964	5,781	20,231	19,077
Research and development	233	63	392	324
Total operating expenses	7,197	5,844	20,623	19,401
Loss from operations	(649)	(2,764)	(3,054)	(10,012)
Other income (expense):				
Interest expense, net	(705)	(793)	(2,039)	(2,348)
Investment losses from Surface Pharmaceuticals	(128)	-	(230)	-
Gain on deconsolidation of Surface Pharmaceuticals	-	-	5,320	-
Investment losses from Eton Pharmaceuticals	(1,032)	(1,237)	(3,247)	(1,453)
Gain on deconsolidation of Eton Pharmaceuticals	-	-	-	5,725
Loss on sale of assets	-	(42)	-	(326)
Other expense, net	-	(884)	(255)	(884)
Total other income (expense), net	(1,865)	(2,956)	(451)	714
Loss before income taxes	(2,514)	(5,720)	(3,505)	(9,298)
Income tax benefit, net	-	28	-	84
Net loss	$ (2,514)	$ (5,692)	$ (3,505)	$ (9,214)
Basic and diluted net loss per share of common stock	$ (0.12)	$ (0.28)	$ (0.16)	$ (0.47)
Weighted average number of shares of common stock outstanding, basic and diluted	21,709,392	20,273,347	21,283,078	19,806,759

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

IMPRIMIS PHARMACEUTICALS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	For the Nine months Ended September 30, 2018	For the Nine months Ended September 30, 2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (3,505)	$ (9,214)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization of property, plant and equipment	1,223	1,041
Amortization of intangible assets	176	272
Deferred income taxes	-	(84)
Amortization of debt issuance costs and discount	466	812
Debt extinguishment	-	884
Gain on deconsolidation of Eton Pharmaceuticals	-	(5,725)
Investment loss from Eton Pharmaceuticals	3,247	1,453
Gain on deconsolidation of Surface Pharmaceuticals	(5,320)	-
Investment loss from Surface Pharmaceuticals	230	-
Loss on write down of assets and note receivable	393	111
Loss on sale and disposal of assets	-	215
Stock-based compensation	1,950	2,265
Changes in assets and liabilities:		
Accounts receivable	(202)	296
Inventories	(275)	(946)
Prepaid expenses and other current assets	(400)	45
Accounts payable and accrued expenses	2,153	497
Accrued payroll and related liabilities	518	(348)
Deferred revenue and customer deposits	69	(83)
NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES	723	(8,509)
CASH FLOWS FROM INVESTING ACTIVITIES		
Repayment of note receivable	4	-
Proceeds on sale and disposal of assets	-	110
Investment in patent and trademark assets	(283)	(184)
Purchase of Klarity license	-	(50)
Purchases of property, plant and equipment	(1,068)	(588)
NET CASH USED IN INVESTING ACTIVITIES	(1,347)	(712)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payments on capital lease obligations	(512)	(464)
Net proceeds from public equity offering	-	2,940
Payments on Park deferred acquisition obligation	(53)	(101)
Proceeds from SWK debt, net of costs	-	15,518
Principal payments on LSAF note payable	-	(13,999)
Net proceeds from ATM sales of common stock	642	162
Net proceeds from exercise of warrants and stock options, net of taxes remitted for RSU’s	2,643	179
NET CASH PROVIDED BY FINANCING ACTIVITIES	2,720	4,235
NET CHANGE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	2,096	(4,986)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, beginning of period	4,219	9,053
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, end of period	$ 6,315	$ 4,067
RECONCILIATION OF CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD:		
Cash and cash equivalents	$ 6,115	$ 3,867
Restricted cash	200	200
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF PERIOD	$ 6,315	$ 4,067
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for income taxes	$ 4	$ 9
Cash paid for interest	$ 1,006	$ 1,045
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Issuance of stock options for consulting services included in accounts payable and accrued expenses	$ 108	$ -
Final fee on note payable recorded as debt discount and Included in accrued expenses	$ -	$ 800
Estimated relative fair value of warrants issued in connection with note payable	$ -	$ 982
Note receivable in connection with sale of assets	$ -	$ 410

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

NOTE 1. DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION

Company and Background

Imprimis Pharmaceuticals, Inc. (together with its subsidiaries, unless the context indicates or otherwise requires, the “Company” or “Imprimis”) is a pharmaceutical company specializing in the development, production and sale of innovative medications that offer unique competitive advantages and serve unmet needs in the marketplace. In addition to owning the nation’s leading ophthalmology pharmaceutical compounding business, ImprimisRx, the Company holds large equity positions in Eton Pharmaceuticals, Inc. (“Eton”), Surface Pharmaceuticals, Inc. (“Surface”) and Melt Pharmaceuticals, Inc. (“Melt”), companies originally founded as subsidiaries of Imprimis. The Company also owns royalty rights in certain 505(b)(2) drug candidates being developed by Eton, Surface and Melt.

Basis of Presentation

Imprimis 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, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018 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, 2017.

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

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The following represents an update for the three and nine months ended September 30, 2018 to the significant accounting policies described in the Company’s Annual Report on Form 10-K for the year ended December 31, 2017.

Liquidity

The Company has incurred significant operating losses and negative cash flows from operations since its inception. The Company incurred net losses of $3,505 and $9,214 for the nine months ended September 30, 2018 and 2017, respectively, and had an accumulated deficit of $92,341 and $88,836 as of September 30, 2018 and December 31, 2017, respectively. In addition, while during the nine months ended September 30, 2018 the Company generated cash of $723 from operating activities, there is no guarantee that trend will continue. Historically, the Company has used cash in operating activities and during the nine months ended September 30, 2017 the Company used $8,509 in operating activities.

While there is no assurance, the Company believes its existing cash resources and restricted cash of $6,315 at September 30, 2018, 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 by one or more of the following which may include, but are not limited to: the sale of assets 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 it deems as acceptable, or at all.

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 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 8,387,347 and 9,983,548 at September 30, 2018 and 2017, 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, 2018 and 2017 was 202,603 and 121,344, 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, 2018 and 2017:

	For the Three Months Ended September 30, 2018	For the Three Months Ended September 30, 2017	For the Nine months Ended September 30, 2018	For the Nine months Ended September 30, 2017
Numerator – net loss	$ (2,514)	$ (5,692)	$ (3,505)	$ (9,214)
Denominator – weighted average number of shares outstanding, basic	21,709,392	20,273,347	21,283,078	19,806,759
Net loss per share, basic and diluted	$ (0.12)	$ (0.28)	$ (0.16)	$ (0.47)

Investment in Surface Pharmaceuticals, Inc.

In April 2017, the Company formed Surface as a wholly owned subsidiary. In May and July 2018, Surface entered into and closed on definitive stock purchase agreements with an institutional investor for the purchase of Surface's Series A Preferred Stock (the "Surface Series A Stock") that resulted 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. At September 30, 2018, the Company owned approximately 35% of the issued and outstanding equity interests in Surface. 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 percent in accordance with Accounting Standard Codification ("ASC") 810-10-40-4(c), *Consolidation*.

The Company owns 3,500,000 common shares (which is approximately 30% of the equity interest as of the date of this Report, and calculated after the second closing of the sale Series A Preferred Stock in July 2018) 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 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 shares of common stock and in-substance common stock of Surface held by the Company. Any intra-entity profits and losses are eliminated. During the three and nine months ended September 30, 2018, the Company recorded equity in net loss of Surface of $128 and $230. As of September 30, 2018, the carrying value of the Company's investment in Surface was $5,090.

Reclassification

Certain amounts in the 2017 condensed consolidated financial statements have been reclassified to conform to the classifications used to prepare the 2018 condensed consolidated financial statements. These reclassifications had no material impact on the Company's financial position, results of operations, or cash flow as previously reported.

Recently Adopted Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers* and has subsequently issued several amendments to ASU 2014-09. This updated guidance supersedes the current revenue recognition guidance, including industry-specific guidance. The updated guidance introduces a five-step model to achieve its core principal of the entity recognizing revenue to depict the transfer of goods or services to customers at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard's stated core principle is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this core principle, ASU 2014-09 includes provisions within its five-step model that includes identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations, and recognizing revenue when, or as, an entity satisfies a performance obligation. In addition, the standard requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers.

The new standard became effective for the Company beginning January 1, 2018 and permits two methods of adoption: the full retrospective method, which requires the standard to be applied to each prior period presented, or the modified retrospective method, which requires the cumulative effect of adoption to be recognized as an adjustment to opening retained earnings in the period of adoption. The Company adopted the standard using the modified retrospective method. There was no effect for any adjustments to retained earnings upon adoption of the standard on January 1, 2018. Adoption of the new standard resulted in additional revenue-related disclosures in the footnotes to the Company's condensed consolidated financial statements (see Note 3).

In January 2017, the FASB issued ASU 2017-01, *Business Combinations, Clarifying the Definition of a Business,* which revises the definition of a business and provides new guidance in evaluating when a set of transferred assets and activities is a business. The Company adopted the standard on January 1, 2018. Adoption of the standard did not have an impact on the Company's financial position, results of operations and cash flows.

In August 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows: Classification Restricted Cash*, which requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The Company adopted the standard on January 1, 2018 by using the retrospective transition method. Adoption of the standard effected the presentation of cash equivalents in Company's condensed consolidated statements of cash flows and related disclosures, restricted cash of $200 has been reclassified within that financial statement for the periods presented as a cash equivalent.

In May 2017, the FASB issued ASU 2017-09, *Compensation - Stock Compensation: Scope of Modification Accounting*. The amendments in this update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting under Topic 718. An entity should account for effects of a modification unless all of the following are met: (1) the fair value of the modified award is the same as the fair value of the original award immediately before the original award is modified; (2) the vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified; (3) the classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. The Company adopted this standard on January 1, 2018. Adoption of the standard did not have an effect on the Company's financial position, results of operations and cash flows.

In June 2018, the FASB issued ASU 2018-07, *Compensation – Stock Compensation: Improvements to Nonemployee Share-Based Payment Accounting* which simplifies several aspects of the accounting for nonemployee share-based payment transactions resulting from expanding the scope of Topic 718, *Compensation-Stock Compensation*, to include share-based payment transactions for acquiring goods and services from nonemployees. Some of the areas for simplification apply only to nonpublic entities. The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The amendments also clarify that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606, Revenue from Contracts with Customers. The amendments in this Update are effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted. The Company adopted this standard on July 1, 2018. Adoption of the standard did not have an effect on the Company's financial position, results of operations and cash flows.

Recently Issued 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 will take effect for public companies in fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted and for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, lessees and lessors must apply a modified retrospective transition approach. During the year ended December 31, 2017, the Company evaluated this new accounting standard and engaged professionals in the new lease accounting implementation to assist in determining the effect of the new standard as of January 1, 2018 with respect to the Company's real estate leases. The Company currently has three real estate leases and evaluated each of these leases in accordance with the new lease accounting standard under ASC Topic 842. As of September 30, 2018, the Company estimates that the right of use asset to be recorded on its consolidated balance sheet would be approximately $2,300 and that the related lease liability would be approximately $2,800 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. The Company will continue this effort with respect to equipment leases and any other leases contemplated under Topic 842 in a manner to be appropriately prepared for its implementation on or before January 1, 2019.

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. REVENUE

On January 1, 2018, the Company adopted ASU 2014-09, using the modified retrospective transition method. There was no effect for any adjustments to retained earnings upon adoption of the standard on January 1, 2018. The Company has two primary streams of revenue: (1) revenue recognized from our sale of products within our pharmacy services and (2) revenue recognized from intellectual property license and asset purchase agreements.

Product Revenues from Pharmacy Services

The Company sells prescription drugs directly through our pharmacy and outsourcing facility network. Revenue from our pharmacy services 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 ASU 2014-09, 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 five intellectual property license and related agreements in which the Company has promised to grant a license or sale which provides a customer with 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, each of which revenue 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, 2018 and 2017, consists of the following:

	For the Three months ended September 30,		For the Nine months ended September 30,	
	2018	2017	2018	2017
Product sales, net	$ 10,729	$ 6,473	$ 29,958	$ 19,411
License revenues	10	10	30	26
Total revenues	$ 10,739	$ 6,483	$ 29,988	$ 19,437

Deferred revenue and customer deposits at September 30, 2018 and December 31, 2017, was $98 and $29, retrospectively.

NOTE 4. INVESTMENT IN ETON PHARMACEUTICALS, INC. AND AGREEMENTS - RELATED PARTY TRANSACTIONS

In June 2017, the Company and its subsidiary, Eton, entered into and closed on definitive stock purchase agreements related to the sale of Eton's Series A preferred stock (the "Series A Stock") that resulted in the Company losing voting and ownership control of Eton and it at that time, ceased consolidating Eton's financial statements. The Series A Stock has mandatory conversion requirements into common stock of Eton upon events, including an underwritten IPO of Eton common stock. Under the terms of its Series A Stock, Eton is required to complete an IPO by December 31, 2018, subject to exceptions and extension upon certain conditions.

The Company owns 3,500,000 common shares (approximately 27% issued and outstanding equity interest as of the date of this Report) of Eton 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 Eton. Under this method, the Company recognizes earnings and losses of Eton in its consolidated financial statements and adjusts the carrying amount of its investment in Eton accordingly. The Company's share of earnings and losses are based on the shares of common stock and in-substance common stock of Eton held by the Company. Any intra-entity profits and losses are eliminated. During the three and nine months ended September 30, 2018, the Company recorded equity in net loss of Eton of $1,032 and $3,247, respectively. As of September 30, 2018, the carrying value of the Company's investment in Eton was $263.

The Company's Chief Executive Officer, Mark L. Baum, is a director of Eton, and several employees of the Company (including Mr. Baum and the Company's Chief Financial Officer, Andrew R. Boll) entered into consulting agreements and provided consulting services to Eton, these contracts concluded in April 2018.

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

		For the Nine months ended September 30, 2018
Revenues, net	$	-
Loss from operations		11,162
Net loss	$	(11,162)

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

		At September 30, 2018
Current assets	$	6,803
Non current assets		722
Total assets		7,525
Total liabilities		1,193
Total preferred stock and stockholders’ equity		6,332
Total liabilities and stockholders’ equity	$	7,525

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

In 2017 and amended in April 2018, the Company entered into two asset purchase and license agreements (the “Surface License Agreements”) with its previously wholly owned subsidiary, 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. The certain of the Surface License Agreements were conditioned upon Surface receiving net proceeds of the sale of its equity securities of not less than $10,000, which occurred in May 2018. See also Note 2, under the subheading Investment in Surface Pharmaceuticals, Inc.

In January 2018, the Company and Surface entered into an amended Management Services Agreement (the “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 MSA was terminated effective July 31, 2018.

As of September 30, 2018, the Company was due $50 from Surface for reimbursable expenses and amounts due under the MSA and included in prepaid expenses and other current assets on the accompanying condensed consolidated balance sheets.

As of September 30, 2018, the Company owned 3,500,000 shares of Surface common stock (approximately 30% issued and outstanding equity interests). The Company’s 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.

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

		For the Nine months September 30, 2018
Revenues, net	$	-
Loss from operations		891
Net loss	$	(891)

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

	At September 30, 2018
Current assets	$ 20,090
Non current assets	46
Total assets	20,136
Total liabilities	225
Total stockholders' equity	19,911
Total liabilities and stockholders' equity	$ 20,136

NOTE 6. RESTRICTED CASH

The restricted cash at September 30, 2018 and December 31, 2017 consisted of funds held in a money market account. At September 30, 2018 and December 31, 2017, the restricted cash was recorded at amortized cost, which approximates fair value.

At September 30, 2018 and December 31, 2017, the funds held in a money market account of $200 were classified as a current asset. The money market account funds are required as collateral as additional security for the Company's New Jersey facility lease.

NOTE 7. INVENTORIES

Inventories are comprised of finished compounded formulations, over-the-counter and prescription retail pharmacy products, commercial pharmaceutical products, related laboratory supplies and active pharmaceutical ingredients. The composition of inventories as of September 30, 2018 and December 31, 2017 was as follows:

	September 30, 2018	**December 31, 2017**
Raw materials	$ 1,248	$ 956
Work in progress	11	-
Finished goods	1,265	1,293
Total inventories	$ 2,524	$ 2,249

NOTE 8. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following:

	September 30, 2018	**December 31, 2017**
Prepaid insurance	$ 328	$ 164
Other prepaid expenses	611	426
Amounts due from Surface Pharmaceuticals	50	-
Deposits and other current assets	125	124
Total prepaid expenses and other current assets	$ 1,114	$ 714

NOTE 9. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following:

	September 30, 2018	December 31, 2017
Property, plant and equipment, net:		
Computer software and hardware	$ 1,588	$ 1,239
Furniture and equipment	382	377
Lab and pharmacy equipment	2,794	2,545
Leasehold improvements	5,275	4,810
	10,039	8,971
Accumulated depreciation and amortization	(3,978)	(2,756)
	$ 6,061	$ 6,215

For the three and nine months ended September 30, 2018, depreciation related to the property, plant and equipment was $423 and $1,223, respectively.

NOTE 10. NOTE RECEIVABLE

The Company recorded a loss of $393, which was recorded in other expense, net, during the three and nine months ended September 30, 2018, related to the impairment and write-off of all amounts owed to it under its note receivable. The write-off is due to the Company's estimate of collectability of the asset.

NOTE 11. INTANGIBLE ASSETS AND GOODWILL

The Company's intangible assets at September 30, 2018 consisted of the following:

	Amortization periods (in years)	Cost	Accumulated amortization	Impairment	Net Carrying value
Patents	17-19 years	$ 617	$ (40)	$ -	$ 577
Licenses	20 years	50	-	-	50
Trademarks	Indefinite	301	-	-	301
Customer relationships	3-15 years	2,998	(963)	(15)	2,020
Trade name	5 years	16	(12)	(1)	3
Non-competition clause	3-4 years	294	(274)	(20)	-
State pharmacy licenses	25 years	45	(4)	(28)	13
		$ 4,321	$ (1,293)	$ (64)	$ 2,964

Amortization expense for intangible assets for the three and nine months ended September 30, 2018 was as follows:

	For the Three Months Ended September 30, 2018	For the Three Months Ended September 30, 2017	For the Nine months Ended September 30, 2018	For the Nine months Ended September 30, 2017
Patents	$ 6	$ 3	$ 19	$ 10
Licenses	-	-	-	-
Customer relationships	50	65	150	194
Trade name	-	-	3	2
Non-competition clause	-	21	1	65
State pharmacy licenses	-	-	-	1
	$ 56	$ 89	$ 173	$ 272

Estimated future amortization expense for the Company's intangible assets at September 30, 2018 is as follows:

Remainder of 2018	$	61
2019		237
2020		235
2021		235
2022		235
Thereafter		1,961
	$	2,964

There have been no changes in the carrying value of the Company's goodwill during the three and nine months ended September 30, 2018.

NOTE 12. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

		September 30, 2018		December 31, 2017
Accounts payable	$	5,313	$	3,241
Deferred rent		358		388
Accrued interest		260		256
Accrued exit fee for note payable		800		800
Total accounts payable and accrued expenses		6,731		4,685
Less: Current portion		(5,931)		(3,885)
Non-current total accrued expenses	$	800	$	800

NOTE 13. DEBT

At September 30, 2018, future minimum payments under the Company's note payable were as follows:

		Amount
Remainder of 2018	$	751
2019		4,762
2020		4,402
2021		4,033
2022		7,410
Total minimum payments		21,358
Less: amount representing interest		(5,358)
Notes payable, gross		16,000
Less: unamortized discount		(1,603)
Less: current portion, net of unamortized discount		(1,729)
Note payable, net of current portion and unamortized debt discount	$	12,668

For the three and nine months ended September 30, 2018, debt discount amortization related to note payable was $131 and $389, respectively.

NOTE 14. CAPITAL LEASE OBLIGATION

At September 30, 2018, future payments under the Company's capital leases were as follows:

	Amount
Remainder of 2018	$ 194
2019	751
Total minimum lease payments	945
Less: amount representing interest payments	(29)
Present value of future minimum lease payment	916
Less: unamortized discount	(33)
	883
Less: current portion, net of unamortized discount	(883)
Capital lease obligation net of current portion and unamortized discount	$ -

For the three and nine months ended September 30, 2018, debt discount amortization related to the capital lease obligation was $21 and $77, respectively.

NOTE 15. STOCKHOLDERS' EQUITY AND STOCK-BASED COMPENSATION

Common Stock

In January 2018, the Company issued 25,273 shares of its restricted common stock, with a fair value of $44, in lieu of a cash payment for accrued royalty expenses.

RSUs granted in February 2015 to Andrew R. Boll, the Company's Chief Financial Officer, vested, and in February 2018, 30,000 shares the Company's common stock were issued to Mr. Boll.

RSUs granted in February 2015 to John P. Saharek, the Company's Chief Commercial Officer, vested, and in February 2018, 30,000 shares the Company's common stock were issued to Mr. Saharek.

In March 2018, the Company issued 35,427 shares of its restricted common stock, with a fair value of $64, in lieu of a cash payment for accrued royalty expenses.

In November 2015, the Company entered into a Controlled Equity Offering[SM] sales agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as agent ("Cantor Fitzgerald"), pursuant to which the Company may offer and sell, from time to time through Cantor Fitzgerald, shares of our common stock having an aggregate offering price as set forth in the Sales Agreement and a related prospectus supplement filed with the Securities and Exchange Commission. The Company agreed to pay Cantor Fitzgerald a cash commission of 3.0% of the aggregate gross proceeds from each sale of shares under the Sales Agreement. The Company sold 305,619 shares of common stock and received net proceeds of $642, after deducting $20 for sales commission and offering expenses, under the Sales Agreement during the nine months ended September 30, 2018, leaving an aggregate of $7,378 available for future sales of shares thereunder as of September 30, 2018. In November 2018, the Company terminated the Sales Agreement.

During the nine months ended September 30, 2018, the Company issued 1,476,613 shares of its common stock related to the exercise of common stock warrants with an exercise price of $1.79, and received net proceeds of $2,643.

During the nine months ended September 30, 2018, the Company issued 130,122 shares of its common stock related to the cashless exercise of 321,945 common stock warrants with an exercise price of $1.79.

During the nine months ended September 30, 2018, 65,536 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, 2018, 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.

Stock Options

A summary of stock option activity under the Plans for the nine months ended September 30, 2018 is as follows:

	Number of shares	Weighted Avg. Exercise Price	Weighted Avg. Remaining Contractual Life	Aggregate Intrinsic Value
Options outstanding - January 1, 2018	2,259,979	$ 5.51		
Options granted	295,000	$ 1.79		
Options exercised	-	$ -		
Options cancelled/forfeit	(29,974)	$ 3.36		
Options outstanding - September 30, 2018	2,525,005	$ 5.10	5.79	$ 631
Options exercisable	1,277,557	$ 5.12	6.22	$ 258
Options vested and expected to vest	2,396,105	$ 5.10	5.80	$ 585

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, 2018, based on the closing price of the Company's common stock of $2.78 on that date.

During the nine months ended September 30, 2018, the Company granted stock options to certain employees and consultants. 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, 2018 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; and 100% of the shares subject to the option vest on a quarterly basis in equal installments over three years. 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:

		2018
Weighted-average fair value of options granted	$	1.42
Expected terms (in years)		5.8 - 6.1
Expected volatility		76% - 126%
Risk-free interest rate		2.05 - 3.00%
Dividend yield		-

The following table summarizes information about stock options outstanding and exercisable at September 30, 2018:

	Options Outstanding				Options Exercisable		
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life in Years		Weighted Average Exercise Price	Number Exercisable		Weighted Average Exercise Price
$1.47 - $2.60	851,000	8.01	$	2.04	367,921	$	2.18
$3.04 - $4.50	547,031	7.23	$	3.96	392,138	$	3.98
$5.49 - $6.36	101,536	4.82	$	5.98	99,658	$	5.98
$6.64 - $8.99	1,020,408	3.29	$	7.98	412,810	$	8.15
$42.80	5,030	1.87	$	42.80	5,030	$	42.80
$1.47 - $42.80	2,525,005	5.79	$	5.10	1,277,557	$	5.12

As of September 30, 2018, there was approximately $2,139 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 2.2 years. The stock-based compensation expense for all stock options was $291 and $1,063 during the three and nine months ended September 30, 2018, 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 three and nine months ended September 30, 2018, the Company's board of directors were granted 136,360 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, 2018 is as follows:

	Number of RSUs	Weighted Average Grant Date Fair Value	
RSUs unvested - January 1, 2018	1,298,946	$	2.42
RSUs granted	136,360		2.20
RSUs vested	(125,536)		3.94
RSUs cancelled/forfeit	-		
RSUs unvested at September 30, 2018	1,309,770	$	2.16

As of September 30, 2018, the total unrecognized compensation expense related to unvested RSUs was approximately $756, which is expected to be recognized over a weighted-average period of 0.5 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, 2018 was $293 and $870.

Warrants

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

A summary of warrant activity for the nine months ended September 30, 2018 is as follows:

	Number of Shares Subject to Warrants Outstanding	Weighted Avg. Exercise Price	
Warrants outstanding - January 1, 2018	6,264,215	$	1.91
Granted	-		
Exercised	(1,798,558)		1.79
Expired	(115,688)		6.94
Warrants outstanding and exercisable - September 30, 2018	4,349,969	$	1.90
Weighted average remaining contractual life of the outstanding warrants in years - September 30, 2018	2.06		

A list of the warrants outstanding as of September 30, 2018 is included in the following table:

	Warrants Outstanding				Warrants Exercisable	
Warrant Series	Issue Date	Warrants Outstanding	Exercise Price		Warrants Exercisable	Expiration Date
Lender warrants	5/11/2015	125,000	$	1.79	125,000	5/11/2025
Settlement warrants	8/16/2016	40,000	$	3.75	40,000	8/16/2021
Placement Agent Warrants	12/27/2016	210,313	$	1.79	210,313	12/27/2019
PIPE Investor Warrants	12/27/2016	3,359,270	$	1.79	3,359,270	12/27/2019
Lender warrants	7/19/2017	615,386	$	2.08	615,386	7/19/2024
		4,349,969	$	1.90	4,349,969	

Subsidiary Stock-Based Transactions

During the nine months ended September 30, 2018 the Company recognized $17 in stock-based compensation related to equity instruments granted by Surface and Melt to consultants, Imprimis employees and directors, including Mark Baum, CEO of the Company, Andrew Boll, CFO of the Company, and Richard Lindstrom, a director of the Company.

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, 2018		For the Three Months Ended September 30, 2017		For the Nine months Ended September 30, 2018		For the Nine months Ended September 30, 2017	
Employees - selling, general and administrative	$	527	$	598	$	1,790	$	2,050
Directors - selling, general and administrative		75		50		160		155
Consultants - selling, general and administrative		-		-		108		60
Total	$	602	$	648	$	2,058	$	2,265

NOTE 16. COMMITMENTS AND CONTINGENCIES

Legal

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 our alleged transmittal of advertisements to our clients via facsimile. In June 2018, Sobol filed a motion for class certification and in July 2018 the Company filed a response in opposition to the motion for class certification. A hearing on class certification was heard on October 24, 2018, however, as of the date of this Report no decision has been made. The Company believes the claims are frivolous and has previously and will continue to dispute all claims asserted against it and intends to vigorously defend these allegations. Nonetheless, the Company cannot predict the eventual outcome of this this litigation, it could result in substantial costs and a diversion of management’s resources and attention, which could harm the Company’s business and the value of its common stock.

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 other state laws. The case is currently in discovery, with a trial date set for April 2019. The Company believes the claims are frivolous and has previously and will continue to dispute all asserted claims against it and intends to vigorously defend these allegations. Nonetheless, the Company cannot predict the eventual outcome of this this litigation, it could result in substantial costs and a diversion of management’s resources and attention, which could harm the Company’s business and the value of its common stock.

Spectrum

In February 2018, the Company filed a complaint against Spectrum Laboratory Products, Inc., Spectrum Chemical Manufacturing Corp. and Spectrum Pharmacy Products, Inc. (collectively "Spectrum") in the Los Angeles County Superior Court asserting claims for breach of contract, breach of implied covenant of good faith and fair dealing, violation of California Commercial Code Section 2101 and fraud. The claims stem from prior business dealings between the Company and Spectrum and allege false representation by Spectrum regarding their products, fraudulent labeling and misrepresentations of approved product usages. The complaint has been filed with the Court and in May 2018, Spectrum filed an answer with the Court. The matter is currently in the beginning stages of discovery.

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 2018, NDS filed a first amended complaint which added a claim for fraudulent inducement. In July 2018, the Company filed a motion to dismiss certain causes of action found in the complaint, and its motion to dismiss was denied. In October 2018, the Company filed counterclaims alleging breach of contract and breach of covenant of good faith and fair dealing and named certain individual defendants. The Company believes the claims against it are frivolous and has previously and will continue to dispute all claims asserted against it and intend to vigorously defend these allegations. Nonetheless, the Company cannot predict the eventual outcome of this this litigation, it could result in substantial costs 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 our wholly owned subsidiary, Park Compounding, Inc. ("Park") related to a compounded formulation the Company believes was legally dispensed and was, without the Company's knowledge, inappropriately administered to a patient unknown to the Company, by the prescribing healthcare professional. The Company has filed its response to the accusation and has requested a formal hearing. The Company disputes all claims against it and intends to vigorously defend against the allegations. Nonetheless, the Company cannot predict the outcome of this matter, it could result in substantial costs, suspension or revocation of Park's pharmacy license 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. The Company utilizes traditional third-party insurance policies with regard to its 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 the Company 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 Company believes the claims are frivolous and has previously and will continue to dispute all asserted claims against it and intends to vigorously defend these allegations. Nonetheless, the Company cannot predict the eventual outcome of this this litigation, it could result in substantial costs 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 the Company may, from time to time, make claims or take legal actions to assert the Company's rights, including intellectual property disputes, contractual disputes and other commercial disputes. Any of these claims could subject the Company to litigation. Management believes the outcomes of currently pending claims are not likely to have a material effect on the Company's consolidated financial position and results of operations.

Indemnities

In addition to the indemnification provisions contained in the Company's charter 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

In April 2017 and as amended in April 2018, the Company entered into a license agreement (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 $110 were made during the three and nine months ended September 30, 2018, and $12 was due to Dr. Lindstrom at September 30, 2018.

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 Imprimis 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 to 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. No stock-based payments were made and $507 and $1,065 were incurred under these agreements for commission expenses during the three and nine months ended September 30, 2018, respectively.

NOTE 17. SEGMENT INFORMATION AND CONCENTRATIONS

The Company operates its business on the basis of a single reportable segment, which is the business of developing proprietary drug therapies and providing such therapies through sterile and non-sterile pharmaceutical compounding services. The Company's chief operating decision-maker is the Chief Executive Officer, who evaluates the Company as a single operating segment.

The Company categorizes revenues by geographic area based on selling location. All operations are currently located in the U.S.; therefore, total revenues for 2018 and 2017 are attributed to the U.S. All long-lived assets at September 30, 2018 and December 31, 2017 are located in the U.S.

The Company sells its compounded formulations to a large number of customers. Less than 10% of the Company's total pharmacy sales were derived from a single customer for the three and nine months ended September 30, 2018 and 2017.

The Company receives its active pharmaceutical ingredients from three main suppliers. These suppliers collectively accounted for 58% and 51% of active pharmaceutical ingredient purchases during the three and nine months ended September 30, 2018, respectively, and 72% and 70% during the three and nine months ended September 30, 2017, respectively.

NOTE 18. SUBSEQUENT EVENTS

The Company has performed an evaluation of events occurring subsequent to September 30, 2018 through the filing date of this Quarterly Report. Based on its evaluation, nothing other than the events described below need to be disclosed.

In October and November 2018, the Company issued 553,619 shares of its common stock related to the exercise of common stock warrants with an exercise price of $1.79, and received net proceeds of $991.

In October and November 2018, the Company issued 68,173 shares of its common stock related to the cashless exercise of 131,592 common stock warrants with an exercise price of $1.79.

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, 2017 and subsequent reports on Form 8-K, which discuss our business in greater detail. As used in this discussion and analysis, unless the context indicates otherwise, the terms the "Company", "Imprimis" "we", "us" and "our" refer to Imprimis Pharmaceuticals, Inc. and its consolidated subsidiaries, consisting of Park Compounding, Inc., Imprimis Rx NJ, LLC dba ImprimisRx, Imprimis NJOF, LLC, and Melt Pharmaceuticals, Inc. In this discussion and analysis, we refer to our consolidated subsidiaries collectively as our "ImprimisRx compounding pharmacies."

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; 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

We are a pharmaceutical company specializing in the development, production and sale of innovative medications that offer unique competitive advantages and serve unmet needs in the marketplace. In addition to owning the nation's leading ophthalmology pharmaceutical compounding business, ImprimisRx, the Company holds large equity positions in Eton Pharmaceuticals, Inc. ("Eton"), Surface Pharmaceuticals, Inc. ("Surface") and Melt Pharmaceuticals, Inc. ("Melt") companies originally founded as subsidiaries of Imprimis. The Company also owns royalty rights in certain 505(b)(2) drug candidates being developed by Eton, Surface and Melt.

During the nine months ended September 30, 2018, we produced cash from operating activities of $723,000, and we expect this trend to continue. However, for years prior to 2018 and historically we have incurred recurring operating losses and have had negative operating cash flows since July 24, 1998 (inception). In addition, we have an accumulated deficit of approximately $92,341,000 at September 30, 2018. Beginning on April 1, 2014, when we acquired our first compounding pharmacy, we began generating revenue from sales of certain of our proprietary drug formulations and other non-proprietary formulations; however, we may incur further losses as we develop our pharmacy operations, evaluate other programs, pursue certain regualatory and market approvals for our drug candidates and continue the development of our formulations and drug assets.

Pharmaceutical Compounding Businesses

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 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.

Our Compounding Facilities

We operate three compounding facilities. Our New Jersey operations comprises two separate entities and facilities, with one facility registered with the FDA as an outsourcing facility ("NJOF") under Section 503B of the Federal Food Drug and Cosmetic Act (the "FDCA"). The other New Jersey facility ("RxNJ"), and Park Compounding, Inc. ("Park") our California based pharmacy, are both licensed pharmacies operating under Section 503A of the FDCA. All products that we sell, produce and dispense are made in the United States of America.

We believe that our current compounding facilities provide us with the infrastructure to scale our business appropriately under the current regulatory landscape and meet the growth in demand we are targeting. We plan to maintain and invest our facilities to further their capacity and efficiencies. Also, we may seek to access greater redundancy and markets through acquisitions, partnerships or other strategic transactions.

ImprimisRx

ImprimisRx is our ophthalmology focused pharmaceutical compounding business. We offer our over 3,000 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), in our FDA-registered NJOF outsourcing facility.

Park Compounding

Park, our wholly owned subsidiary pharmacy based in Irvine, California, is focused on general customizable pharmaceutical compounding. Park dispenses sterile and non-sterile compounded medications prescribed by licensed practitioners when commercially available choices do not meet a patient's needs. Park also produces and dispenses certain of our ophthalmic formulations.

Pharmaceutical Development Businesses

We are large shareholders of Eton, Surface, and Melt, and hold royalty interests in certain of their drug candidates. These companies are pursuing market approval for their drug candidates under the 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, we formed and created subsidiaries named Radley Pharmaceuticals, Inc. and Mayfield Pharmaceuticals, Inc., 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 for certain proprietary drug formulations.

Eton Pharmaceuticals, Inc.

Eton is a biopharmaceutical company focused on developing and commercializing innovative products utilizing the FDA's 505(b)(2) regulatory pathway. Its pipeline includes seven products 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, we entered into two asset purchase and license agreements (the "Eton License Agreements") with our previously wholly owned subsidiary, Eton. Pursuant to the terms of the Eton License Agreements, we assigned and licensed to Eton certain intellectual property and related rights to develop, formulate, make, sell, and sub-license our proprietary formulations of synthetic corticotropin (Eton drug candidate CT-100) and a patented injectable pentoxifylline (collectively, the "Imprimis Products"). Eton, by itself or through a development partner, intends to seek FDA approval for the commercialization of CT-100 through the Section 505(b)(2) regulatory pathway. If approved by the FDA, Eton is required to make royalty payments to us on CT-100. In addition to CT-100, Eton has acquired several additional drug candidates and ones that qualify under the Drug Efficacy Study Implementation (DESI) program which it plans to develop and commercialize. Imprimis is only eligible to receive royalties on CT-100 (corticotropin) and will not receive royalties on any other drug candidates currently being developed by Eton.

In June 2018, Eton informed Imprimis that it did not intend to pursue development of its injectable pentoxifylline drug candidate. As a result, we exercised our rights under the related asset purchase agreement and re-acquired the intellectual property and related rights for the injectable pentoxifylline formulation and mutually terminated the pentoxifylline asset purchase agreement between us and Eton in August 2018 in exchange for $50,000.

In June 2017, Eton closed an offering of its Series A Preferred Stock at $3.00 a share for gross proceeds of approximately $20 million (the "Series A Round"). At the time of closing we lost our controlling interest, and deconsolidated Eton from our consolidated financial statements. In November 2018, Eton announced an initial public offering of 3,600,000 shares of its common stock at $6.00 a share for gross proceeds of approximately $21.6 million (the "Eton IPO"), and the underwriters are allowed to purchase an additional 540,000 shares of Eton common stock to cover any over-allotments related to the Eton IPO. Following the close of the Eton IPO, all shares of the Eton Series A Preferred Stock converted to Eton common stock. We are currently the largest shareholder of Eton and own 3.5 million shares of Eton common stock, which we estimate is approximately 19.99% of the equity and voting interests issued and outstanding of Eton following the close of the Eton IPO, and assuming the underwriter fully exercises its over-allotments option. Eton's common stock currently trades on the NASDAQ Global Market exchange under the ticker symbol "ETON".

Surface Pharmaceuticals, Inc.

Surface is a biopharmaceutical 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, Imprimis 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 Imprimis 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 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 2018, Surface closed on its first tranche of an offering of its Series A Preferred Stock at $3.30 a share for proceeds of approximately $15 million (the "Surface Series A Round"), and in July Surface closed a second tranche of the Surface Series A Round for proceeds of approximately $6 million ($21 million in aggregate). At the time of the first closing we lost our controlling interest, and deconsolidated Surface from our consolidated financial statements. We own 3.5 million shares of Surface common stock, which is approximately 30% of the equity and voting interests issued and outstanding of Surface. Pursuant to the terms of the Surface License Agreements, Imprimis is eligible to receive royalties on sales of contributed drug candidates.

Melt Pharmaceuticals, Inc.

Melt is a pharmaceutical company focused on the development and commercialization of proprietary non-intravenous, or non-IV, 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 these proprietary technologies, where possible. The core intellectual property, or IP, Melt owns is a patented series of combination non-opioid sedation drug formulations that we estimate to have multitudinous applications. In addition to assembling an excellent clinical advisory team, we have contracted with the nation's leading 505(b)(2) drug development company to help steward our lead drug through an approval process. As we did with Eton and Surface, we intend to build out the Melt management team and work towards a deconsolidating transaction over the next 12 months.

Melt's lead 505(b)(2) drug candidate is similar to Imprimis's MKO Melt compounded formulation that has been dispensed nearly 100,000 times. Based on our experience, we believe there is a strong patient preference for sedation medications delivered sublingually as opposed to the traditional route, which is IV. Recently, a prospective controlled IRB-approved multi-arm clinical study of the MKO Melt was completed. We believe parts of this study is similar to what FDA may require for approval of Melt's lead drug candidate. In this study, more than 600 cataract surgery patients were randomly assigned to receive either (i) diazepam, (ii) diazepam/tramadol/ondansetron, or (iii) the MKO Melt. An analysis of the study groups showed the MKO Melt had a safe and effective conscious sedation profile, and provided the lowest incidence/need for additional IV medications out of the three arms. When reviewing the statistical significance between study arms, MKO Melt group compared to the diazepam group generated a positive p-value of 0.01 for patients needing additional IV medications. We believe data and information generated from this study will help better inform us as we build and plan Melt's clinical development program.

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 and Pricing Optimization

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 formal labeling approval. Further, the Health Reform Law may have a considerable impact on the existing U.S. system for the delivery and financing of health care and could conceivable have a material effect on our business. As a result, reimbursement from Medicare, Medicaid and other third-party payors may never be available for any of our products or, if available, may not be sufficient to allow us to sell the products on a competitive basis and at desirable price points. 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 ophthalmic formulations. An economic study conducted in 2015 by researchers at Andrew Chang & Co, LLC and co-sponsored by us demonstrated that, assuming the cost of Dropless Therapy is $100 per dose, our formulations may provide collective savings to Medicare, Medicaid and patients of up to $13 billion, with a most likely savings estimate of $8.7 billion, over a 10-year period. Based on this research, we believe optimized pricing for certain of our compounded formulations could be greater than $100 per dose. Any efforts to attain optimized pricing for these 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.

Recent Developments

The following describes certain developments in 2018 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.

Surface Pharmaceuticals License Agreements and Series A Round

As described more fully above under the sub-heading "Surface Pharmaceuticals, Inc.", in 2017 and amended in April 2018, we entered the Surface License Agreements with our previously wholly owned subsidiary, Surface. The Surface License Agreements were made effective in May 2018, following the close of the Surface Series A Round. Pursuant to the terms of the Surface License Agreements, we assigned and licensed to Surface certain intellectual property and related rights to develop, formulate, make, sell, and sub-license the its current drug candidate pipeline.

Results of Operations

The following period-to-period comparisons of our financial results are not necessarily indicative of results for the current period or any future period.

Comparison of the three and nine months ended September 30, 2018 and 2017

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, 2018 and 2017:

	For the Three months ended September 30, 2018	For the Three months ended September 30, 2017	$ Variance	For the Nine months ended September 30, 2018	For the Nine months ended September 30, 2017	$ Variance
Product sales, net	$ 10,729,000	$ 6,473,000	$ 4,256,000	$ 29,958,000	$ 19,411,000	$ 10,547,000
License revenues	10,000	10,000	-	30,000	26,000	4,000
Total revenues	$ 10,739,000	$ 6,483,000	$ 4,256,000	$ 29,988,000	$ 19,437,000	$ 10,551,000

The increase in revenue between periods was largely attributable to increased sales of our proprietary formulations and furtherance of our ophthalmology related compounded formulations. Our gross ophthalmology related sales were approximately $8,860,000 and $24,102,000 for the three and nine months ended September 30, 2018, compared to $4,897,000 and $13,315,000 during the same period last year. Net revenues generated from NJOF (which include certain ophthalmology related sales) totaled $6,378,000 and $16,876,000 during the three and nine months ended September 30, 2018.

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, 2018 and 2017:

	For the Three months ended September 30, 2018	For the Three months ended September 30, 2017	$ Variance	For the Nine months ended September 30, 2018	For the Nine months ended September 30, 2017	$ Variance
Cost of sales	$ 4,191,000	$ 3,403,000	$ 788,000	$ 12,419,000	$ 10,048,000	$ 2,371,000

The increase in our cost of sales between periods was largely attributable to an increase in the volume of units sold of our formulations and products and our associated costs of such sales.

Gross Profit and Margin

	For the Three months ended September 30,		$	For the Nine months ended September 30,		$
	2018	2017	Variance	2018	2017	Variance
Gross Profit	$ 6,548,000	$ 3,080,000	$ 3,468,000	$ 17,569,000	$ 9,389,000	$ 8,180,000
Gross Margin	61%	48%	14%	59%	48%	10%

The increase in gross profit and gross margin between periods is largely attributable to increased efficiencies in our production process and utilization of capacities as a result of increased output.

Selling, General and Administrative Expenses

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

The following presents our selling, general and administrative expenses for the three and nine months ended September 30, 2018 and 2017:

	For the Three months ended September 30,		$	For the Nine months ended September 30,		$
	2018	2017	Variance	2018	2017	Variance
Selling, general and administrative	$ 6,964,000	$ 5,781,000	$ 1,183,000	$ 20,231,000	$ 19,077,000	$ 1,154,000

The increase in selling, general and administrative expenses between for the three and nine months ended September 30, 2018 was largely attributable to increased sales commission amounts, legal expenses incurred associated with ongoing litigation and costs related to the operations of Melt.

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, 2018 and 2017:

	For the Three months ended September 30,		$	For the Nine months ended September 30,		$
	2018	2017	Variance	2018	2017	Variance
Research and development	$ 233,000	$ 63,000	$ 170,000	$ 392,000	$ 324,000	$ 68,000

The increase in research and development expenses between periods was primarily attributable to the increase in formulation development studies and the clinical development program for our subsidiary Melt that occurred during the three and nine months ended September 30, 2018.

Interest Income

Interest income was $1,000 and $2,000, respectively, for three and nine months ended September 30, 2018, compared to $2,000 and $7,000 during the same periods, respectively, in the prior year.

Interest Expense

Interest expense was $706,000 and $2,040,000 for three and nine months ended September 30, 2018, respectively, compared to $795,000 and $2,355,000 during the same period last year, respectively. The decrease was primarily due to interest expense recognition related to the deferred acquisition obligations of our acquisition of Park being fulfilled and amortization of our capital lease obligations.

Equity Loss from 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. 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, their losses were consolidated within our statements of operations.

Gain on Deconsolidation of Surface

During the nine months ended September 30, 2018, we recorded a gain of $5,320,000 on the deconsolidation of Surface, see Note 2 and Note 5 in the notes to the condensed consolidated financial statements for a more detailed explanation of this transaction.

Equity Loss from Eton

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 using equity method accounting for our investment in Eton beginning on June 16, 2017, the date we no longer had a controlling interest, prior to that date, their losses were consolidated within our statement of operations.

Gain on Deconsolidation of Eton

During the nine months ended September 30, 2017, we recorded a gain of $5,725,000 on the deconsolidation of Eton, see Note 4 in the notes to the condensed consolidated financial statements for a more detailed explanation of this transaction.

Loss on Sale of Assets

During the three and nine months ended September 30, 2017, we recorded a loss of $42,000 and $326,000, respectively, related to assets associated with the sale of Imprimis TX and our sinus business.

Other Expense, net

During the 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, 2018 and 2017:

	For the Three Months Ended September 30, 2018	For the Three Months Ended September 30, 2017	For the Nine months Ended September 30, 2018	For the Nine months Ended September 30, 2017
Net loss	$ (2,514,000)	$ (5,692,000)	$ (3,505,000)	$ (9,214,000)
Basic and diluted net loss per share of common stock	$ (0.12)	$ (0.28)	$ (0.16)	$ (0.47)

Liquidity and Capital Resources

Liquidity

Our cash on hand (including restricted cash) at September 30, 2018 was $6,315,000 compared to $4,219,000 at December 31, 2017. Since inception through September 30, 2018 we have incurred aggregate losses to common stockholders of $(92,341,000). 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 $6,115,000 and restricted cash of $200,000 totaling $6,315,000 at September 30, 2018, will be sufficient to sustain our planned level of operations and capital expenditures for at least the next 12 months. 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 product 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, 2018 and 2017:

	For the Nine months Ended September 30, 2018	**For the Nine months Ended September 30, 2017**
Net cash provided by (used in) operating activities	$ 723,000	$ (8,509,000)
Net cash used in investing activities	(1,347,000)	(712,000)
Net cash provided by financing activities	2,720,000	4,235,000
Net change in cash and cash equivalents	2,096,000	(4,986,000)
Cash and cash equivalents at beginning of the period	4,219,000	9,053,000
Cash and cash equivalents at end of the year	$ 6,315,000	$ 4,067,000

Operating Activities

Net cash provided by (used in) operating activities was $723,000 in 2018, as compared to $(8,509,000) used in operating activities during the same period in the prior year. The decrease in net cash used in and increase in cash provided by operating activities during the periods was mainly attributed to increased unit volumes and sales, production efficiencies and management of operating expenses.

Investing Activities

Net cash used in investing activities in 2018 and 2017 was $(1,347,000) and $(712,000), respectively. Cash used in investing activities in 2018 and 2017, were primarily associated with equipment purchases and upgrades and investments in our intellectual property portfolio.

Financing Activities

Net cash provided by financing activities in 2018 and 2017 was $2,720,000 and $4,235,000, respectively. Cash provided by financing activities during 2018 was primarily attributable to proceeds from the exercise of stock purchase warrants with an exercise price of $1.79. In 2017, cash provided by financing activities was primarily attributable to proceeds from the registered direct offering and sale of shares of common stock in March 2017.

Sources of Capital

Our principal sources of cash consist 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 or our other subsidiaries. We just recently began producing cash from our operations in the second quarter of 2018, however historically, we haven’t received 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 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 SWK Loan. 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 Securities and Exchange Commission (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, 2018. 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, 2018, 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 our quarter ended September 30, 2018, 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. In June 2018, Sobol filed a motion for class certification and in July 2018 we filed a response in opposition to the motion for class certification. A hearing on class certification was heard on October 24, 2018, however, as of the date of this Report no decision has been made. We believe the claims are frivolous and have previously and will continue to dispute all claims asserted against us and intend to vigorously defend these allegations. Nonetheless, we 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 our business and the value of our common stock.

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 us, primarily claiming violations under the federal Lanham Act and other state laws. The case is currently in discovery, with a trial date set for April 2019. We believe the claims are frivolous and have previously and will continue to dispute all claims asserted against us and intend to vigorously defend these allegations. Nonetheless, we 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 our business and the value of our common stock.

Spectrum

In February 2018, we filed a complaint against Spectrum Laboratory Products, Inc., Spectrum Chemical Manufacturing Corp. and Spectrum Pharmacy Products, Inc. (collectively "Spectrum") in the Los Angeles County Superior Court asserting claims for breach of contract, breach of implied covenant of good faith and fair dealing, violation of California Commercial Code Section 2101 and fraud. The claims stem from prior business dealings between us and Spectrum and allege false representation by Spectrum regarding their products, fraudulent labeling and misrepresentations of approved product usages. The complaint has been filed with the Court and in May 2018, Spectrum filed an answer with the Court. The matter is currently in the beginning stages of discovery.

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 2018, NDS filed a first amended complaint which added a claim for fraudulent inducement. In July 2018, we filed a motion to dismiss certain causes of action found in the complaint, and our motion to dismiss was denied. In October 2018, we filed counterclaims alleging breach of contract and breach of covenant of good faith and fair dealing and named certain individual defendants. We believe the claims are frivolous and have previously and will continue to dispute all claims asserted against us and intend to vigorously defend these allegations. Nonetheless, we 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.

California Board of Pharmacy

In March 2018, the California Board of Pharmacy filed an accusation against our wholly owned subsidiary, Park Compounding, Inc. ("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 professional. We filed our response to the accusation and have requested a formal hearing. We dispute all claims against us and intend to vigorously defend against the allegations. Nonetheless, we cannot predict the outcome of this matter, it could result in substantial costs, losses, suspension or revocation of Park's pharmacy license and a diversion of management's resources and attention, which could harm our business and the value of our 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 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. We believe the claims are frivolous and have previously and will continue to dispute all claims asserted against us and intend to vigorously defend these allegations. Nonetheless, we 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, 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. Management believes the outcomes of currently pending claims are not likely to have a material effect on our financial position and results of operations.

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

We have incurred losses in every year of our operations, and we may never become profitable.

We have incurred losses in every year of our operations, including net losses of $(11,985,000) and $(19,087,000) for the years ended December 31, 2017 and 2016, respectively, and net losses of $(2,514,000) and $(3,505,000) for the three and nine months ended September 30, 2018 and $(5,692,000) and $(9,214,000) for the three and nine months ended September 30, 2017, respectively. As of September 30, 2018, our accumulated deficit was $(92,341,000). We expect to decrease our operating losses during 2018 and 2019, however, our projections may not be correct and our plans could change, and we could incur increasing operating losses in the foreseeable future for our commercialization activities, research and development and our pharmacy operations. Although we have been generating some revenue from our pharmacy operations, our ability to generate significant revenues and 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 three 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 and California 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 taking steps to address the items outlined in the letter and will continue to work with the FDA to assure that all allegations in the warning letter have been addressed. We believe we have addressed all of the material items of concern in the FDA's warning letter and those related to the MedWatch notification (and any other requirements observed by FDA and noted to us), and do not believe there will be any further action taken by FDA in this regard. Nonetheless, these two 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 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, as 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 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 our 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 Compounding, Inc. 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 us and intend to vigorously defend against the accusations, if Park Compounding is found to be in non-compliance pursuant to this accusation, it may be required to permanently or temporarily cease or limit its operations including its sterile compounding operations. If Park Compounding is required to permanently or temporarily cease or limit its sterile compounding operations, we would be unable to realize the expected benefits of this pharmacy's operations, including its sales of our proprietary formulations. Although we distribute our proprietary formulations through other compounding pharmacies, and not solely through Park Compounding, the loss of Park Compounding's ability to compound sterile formulations would have an immediate 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 a 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.

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 Reform Law may have a considerable impact on the existing U.S. system for the delivery and financing of health care and could conceivable have a material effect on our business. As a result, reimbursement from Medicare, Medicaid and other third-party payors may never be available for any of our products or, if available, may not be sufficient to allow us to sell the products on a competitive basis and at desirable price points. 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 development opportunities in 2014 and 2015, 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.

On July 19, 2017, we incurred $16,000,000 of indebtedness under a loan agreement with SWK Funding, LLC and its partners (SWK) and concurrent with the funding, we utilized a portion of the SWK Loan funds as full payment to an affiliate of Life Sciences Alternative Funding, LLC (LSAF) to terminate all amounts due to LSAF in connection with the existing term loan and security agreements, as amended, originally entered into between the Company and LSAF on May 11, 2015 (the "LSAF Loan"), which loan had a principal balance of $12,120,000 at the time of final payment.

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 Surface and Eton, 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 or, collectively, 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 as a result of the balance of power in Congress and the President's veto power. However, the recent Presidential and Congressional elections, which resulted in the election of the Republican presidential nominee and Republican majorities in both houses of Congress, may result in additional efforts to repeal, modify or delay implementation of the Health Reform Law. 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, modification or delay in the implementation of the Health Care Reform Law on us at this time. Due to the substantial regulatory changes that will need to be implemented by Centers for Medicare & Medicaid Services ("CMS") and others, and the numerous processes required to implement these reforms, we cannot predict which healthcare initiatives will be implemented at the federal or state level, the timing of any such reforms, or the effect such reforms or any other future legislation or regulation will have on our business.

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 3 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 Unites 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 July 26, 2018, we own and/or license 34 U.S. patents or patent applications and we own 11 international patent applications filed under the Patent Cooperation Treaty and 38 foreign patent or 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 counties.

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 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 Chief Commercial Officer, 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 for 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

Because of their significant stock ownership, some of our existing stockholders are able to exert control over us and our significant corporate decisions.

Our executive officers and directors collectively own, or have the right to acquire within 60 days after August 3, 2018, approximately 14% of our common stock that would be outstanding following such issuances. These persons, acting together, have the ability to exercise significant influence over or control the outcome of all matters submitted to our stockholders for approval, including the election and removal of directors and any significant transaction involving us, and to control our management and affairs. Additionally, since our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws permit our stockholders to act by written consent, a limited number of stockholders may approve stockholder actions without holding a meeting of stockholders. This concentration of ownership may harm the market price of our common stock by, among other things: delaying, deferring, or preventing a change in control of our Company or changes to our board of directors; impeding a merger, consolidation, takeover or other business combination involving our Company; causing us to enter into transactions or agreements that are not in the best interests of all stockholders; or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our Company.

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 financial statements could be misstated, our reputation may be harmed and the trading price of our common stock could decline. As we discussed in Item 9A of our 2017 Annual Report, our management concluded that our internal controls over financial reporting were effective as of December 31, 2017. 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 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, as 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 and convertible note, 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

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

On November 9, 2018, we amended our asset purchase agreement with Buderer Drug Company, Inc. related to our pentoxifylline and tranexamic acid plus an antibiotic drug formulations to clarify certain milestone payment terms that allow for three separate $25,000 milestone payments to Buderer Drug Company, Inc. ($75,000, in aggregate) upon two patent issuances and an investigational new drug applications being filed.

Item 6. Exhibits

Exhibit Number	Description
10.1*	Consulting Agreement dated May 1, 2018 between Melt Pharmaceuticals, Inc. and Mark L. Baum
10.2*	Consulting Agreement dated May 1, 2018 between Melt Pharmaceuticals, Inc. and Andrew R. Boll
10.3*	Consulting Agreement dated May 1, 2018 between Melt Pharmaceuticals, Inc. and John P. Saharek
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.

Imprimis Pharmaceuticals, Inc.

Dated: November 13, 2018

By: */s/ Mark L. Baum*
Mark L. Baum
Chief Executive Officer and Director
(Principal Executive Officer)

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

EXHIBIT 10.1

CONSULTING AGREEMENT

THIS CONSULTING AGREEMENT (the "Agreement") is effective as the last date provided for on the signature page and is entered into by and between Mark L. Baum, an individual ("Consultant") and Melt Pharmaceuticals, Inc., a Nevada corporation with its principal address located at 12264 El Camino Real, Suite 350, San Diego, CA 92130 (the "Company").

WHEREAS, the Company wishes to retain Consultant as an advisor to the Company; and

WHEREAS, Consultant wishes to provide advisory services to the Company as set forth below.

NOW THEREFORE, in consideration of the mutual promises contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Consultant and the Company agree, intending to be legally bound, as follows:

1. Consulting Services.

1.1. Consultant will provide consulting services to the Company during the Term (as further defined below) of this Agreement. The consulting services ("Services") are set forth in the Statement of Work ("SOW") that is attached hereto as ***Appendix A*** and made a part hereof, as it may be amended from time to time by the parties hereto. Consultant shall perform all Services in compliance with all applicable laws.

2. Effective Date; Term and Termination.

2.1. This Agreement shall be effective on the later of the dates that it is executed by the Company and Consultant (the "Effective Date") and shall terminate as of the date Services are completed (the "Term" as further defined and outlined in ***Appendix A***) unless: (i) this Agreement is sooner terminated as provided in Section 2.2 below; or (ii) the parties agree in writing to extend the Term for a mutually agreed upon period.

2.2. The Agreement and the Services provided by Consultant may be terminated by either Consultant or the Company, at any time and for any reason, upon five (5) days prior written notice of termination.

3. Consulting Fees.

3.1. In consideration of the Services provided hereunder, the Company shall provide Consultant the compensation as set forth in the applicable SOW ("Consulting Fee").

3.2. Consultant shall be responsible for all expenses incurred in association with performance of the Services, unless pre-approved by the Company in writing in advance.

4. Confidentiality. Consultant acknowledges that Consultant will receive confidential and proprietary information from, on behalf of, or at the direction of, the Company in connection with, and during the course of providing, the Services, including but not limited to technical, clinical, marketing, commercial and/or legal information, data, reports, drawings, models, designs, prototypes, biological material, specimens, chemical compounds, formulas, manufacturing or other processes, software, specifications, patent applications, marketing strategies, customer information and customer lists ("Confidential Information"). All Confidential Information is and shall at all times remain the exclusive property of the Company. Consultant agrees:

4.1. to hold the Confidential Information in strict confidence and not to disclose or make available any Confidential Information to any third party whatsoever, without the prior written consent of the Company;

4.2. to use the Confidential Information only for the benefit of the Company and only for the purpose of providing the Services;

4.3. to take at least the same degree of care to prevent disclosure of Confidential Information as Consultant takes to preserve and safeguard Consultant's own confidential and proprietary information, but in any event, no less than a reasonable degree of care;

4.4. not to make copies of the Confidential Information except to the extent that the copies are reasonably necessary for providing the Services;

4.5. to return or destroy (as the Company may direct) any Confidential Information held by Consultant immediately upon termination of the Term of this Agreement pursuant to Section 2 above and provide the Company with a letter certifying that all such Confidential Information has been returned or destroyed as directed;

4.6. that Confidential Information excludes information that:

(a) as evidenced by Consultant's written records, was lawfully known to Consultant prior to its communication by, on behalf of, or at the direction of the Company and was not communicated to Consultant subject to any restrictions on disclosure or use; or

(b) as evidenced by Consultant's written records, is independently developed by Consultant without use or knowledge of the Confidential Information; or

(c) is or becomes a part of the public domain other than by a breach of this Agreement by Consultant;

(d) becomes known to Consultant by the action of a third party not in breach of any obligation of confidence; or

(e) is required to be disclosed or made available by Consultant to a third party pursuant to any applicable law, governmental regulation, or decision of any court or tribunal of competent jurisdiction, so long as Consultant takes reasonable steps, in light of the circumstances, to give the Company sufficient prior notice in order to contest such law, governmental regulation, or decision;

4.7. that no representation or warranty, express or implied, is made by the Company as to the accuracy, completeness or reasonableness of any Confidential Information and that neither the Company will have any liability to Consultant as a result of Consultant's possession or use of the Confidential information; and

4.8. that money damages may not be sufficient remedy for any breach of this Section and that the Company will be entitled to seek specific performance and injunctive or equitable relief as a remedy for any such breach.

4.9. Nothing in this Section is intended to limit any remedy of the Company under the California Uniform Trade Secrets Act (California Civil Code Section 3426), or otherwise available under law.

4.10. Notwithstanding the other provisions of this Agreement, pursuant to 18 U.S.C. Section 1833(b), Consultant shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law; or is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

5. Independent Contractor. The relationship of Consultant to the Company shall be that of an independent contractor rendering professional services. Consultant is not an employee of the Company. Nothing contained in this Agreement shall be deemed to create a relationship of employer and employee or principal and agent between the Company and Consultant. In no circumstance shall Consultant look to the Company as Consultant's employer, partner, agent or principal. Consultant is not entitled to and will be excluded from participating in any of Company's fringe benefit plans or programs as a result of the performance of the Services under this Agreement, including, but not limited to, health, sickness, accident or dental coverage, life insurance, disability benefits, accidental death and dismemberment coverage, unemployment insurance coverage, workers' compensation coverage, and pension or 401(k) benefit(s) provided by Company to its employees (and Consultant waives the right to receive any such benefits). Consultant agrees, as an independent contractor, that Consultant is not entitled to unemployment benefits in the event this Agreement terminates, or workers' compensation benefits in the event that Consultant is injured in any manner or becomes ill while performing the work under this Agreement. Consultant is solely responsible for all tax returns, payments, or reports required to be filed with or made to any federal, state or local tax authority with respect to Consultant's performance of Services and receipt of consideration (including Consulting Fees) under this Agreement. Consultant is not authorized to make any representation, contract or commitment on behalf of the Company unless specifically requested or authorized in writing to do so by an executive officer or Board member of the Company.

6. Waiver. No waiver of this Agreement or any of its provisions shall be binding upon a party unless in writing and signed by each party. The waiver by either party of a breach or violation of any provision of this Agreement shall not constitute or be construed as a waiver of any subsequent breach or violation of that provision or as a waiver of any breach or violation of any other provision.

7. Severability. If any provision of this Agreement is held by a court of competent jurisdiction to be invalid, illegal or unenforceable, the remaining provisions of this Agreement shall be unimpaired, and the invalid, illegal or unenforceable provision shall be replaced by a mutually acceptable provision, which, being valid, legal and enforceable, comes closest to the intention of the parties underlying the invalid, illegal or unenforceable provision.

8. Survival. The provisions of Sections 2.2, 3, 4, 6-11 and any other obligation under this Agreement which is to survive or be performed after termination of this Agreement, regardless of the cause therefor, shall survive any termination or expiration of this Agreement.

9. Notices. Any notice or other communication required or permitted to be made or given under this Agreement to either party shall be in writing and shall be sufficiently given if (i) hand delivered, (ii) sent by overnight guaranteed delivery service, such as Federal Express or UPS; or (iii) sent by facsimile transmission or electronic mail during addressee's normal business hours, with a duplicate copy sent by overnight delivery or certified or registered mail, addressed as either party may from time to time designate to the other by written notice. Any such notice or other communication shall be deemed to be given as of the date it is received by the addressee.

10. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of California, excluding the choice of law rules, and the parties hereby agree to submit to the jurisdiction and venue of the State and Federal courts of the State of California, and agree that the State and Federal courts of the State of California shall be the exclusive forum for the resolution of all disputes related to or arising out of this Agreement.

11. Entire Agreement; Amendments. This Agreement, including any applicable SOW, represents the entire agreement between the parties in relation to the subject matter contained herein and supersedes all previous other agreements and representations, whether oral or written. This Agreement may be modified only if such modification is in writing and signed by a duly authorized representative of each party.

SIGNATURE PAGE FOLLOWS

SIGNATURE PAGE

IN WITNESS WHEREOF, the parties hereto have executed this Consulting Agreement as of the date first above written.

COMPANY:

MELT PHARMACEUTICALS, INC.

/s/ Andrew R. Boll

By: Andrew R. Boll
Its: Executive Director

Date: 5/1/2018

CONSULTANT:

MARK L. BAUM

/s/ Mark L. Baum

By: Mark L. Baum
An individual

Date: 5/1/2018

<u>Reviewed and approved by</u>:

IMPRIMIS PHARMACEUTICALS, INC.

/s/ Robert J. Kammer

By: Robert J. Kammer
Chairman of the Board of
Imprimis Pharmaceutical, Inc.,
Parent Corporation to
Melt Pharmaceuticals, Inc.

Appendix A
Statement of Work
under Consulting Agreement
by and between
Mark L. Baum and Melt Pharmaceuticals, Inc.

Services:

Consultant shall provide management advisory services to the Company relating to its establishment, formulation development and optimization, invention support and other related services as may be requested from time to time by the Company.

Compensation:

Upon or shortly following commencement of Consultant's Services to the Company, the Company shall grant to Consultant either (a) 725,000 shares (the "Shares") of the Company's restricted common stock, par value $0.001 ("Common Stock") under the terms of the Company's 2018 Equity Incentive Plan (the "Plan") and a Restricted Stock Award Grant Notice and Agreement thereunder to be provided to Consultant by the Company (collectively with the Plan, the "Restricted Stock Documents") or (b) an option to purchase up to 725,000 shares of Common Stock (the "Options") under the terms of the Plan and a Stock Option Grant Notice and Agreement thereunder to be provided to Consultant by the Company (collectively with the Plan, the "Stock Option Documents"). The issuance of equity by the Company to Consultant in the form of Shares or Options shall be determined and agreed upon in writing at a later time by the Company and Consultant.

The Shares and/or Options shall vest upon the earliest of:

(1) a Change in Control (as defined in the Plan);
(2) the date of any underwriting agreement between the Company and the underwriter(s) managing an initial public offering of the Company's common stock, pursuant to which the common stock is priced for initial public offering (the "IPO");
(3) the date of closing of any bona-fide equity financing with third party investors resulting in cash gross proceeds to the Company of at least $10,000,000 ("Subsequent Financing"); or
(4) immediately prior to the one year anniversary of the date of grant of the Shares (as indicated in the Restricted Stock Documents) (the "Date of Grant").

and in any case of (1), (2), (3) and (4), subject to Consultant's Continuous Service through such vesting date; *provided, however*, in the event Consultant's Continuous Service is terminated by the Company (other than for Cause) or by death of Consultant prior to the completion of the Term (as defined in this Consulting Agreement), the Shares and/or Options shall vest immediately upon such termination.

Consultant understands that that the receipt of the Shares and/or Options hereunder may trigger tax consequences to Consultant for which Consultant will be solely responsible and that the Shares and/or Options have not been registered under the Securities Act of 1933, as amended, or any applicable state securities law. Consultant must execute the Restricted Stock Documents and/or Stock Option Documents as a condition to receipt of the Shares and/or Options hereunder.

Term:

Consultant commenced providing Services to the Company on or about May 1, 2018 and shall provide the Services through the earlier of (i) one year from the Date of Grant, (ii) a Change in Control, (iii) the IPO, (iv) a Subsequent Financing or (v) such earlier date as the Services are terminated by the Company or Consultant in accordance with this Agreement (the "Term").

EXHIBIT 10.2

CONSULTING AGREEMENT

THIS CONSULTING AGREEMENT (the "Agreement") is effective as the last date provided for on the signature page and is entered into by and between Andrew R. Boll, an individual ("Consultant") and Melt Pharmaceuticals, Inc., a Nevada corporation with its principal address located at 12264 El Camino Real, Suite 350, San Diego, CA 92130 (the "Company").

WHEREAS, the Company wishes to retain Consultant as an advisor to the Company; and

WHEREAS, Consultant wishes to provide advisory services to the Company as set forth below.

NOW THEREFORE, in consideration of the mutual promises contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Consultant and the Company agree, intending to be legally bound, as follows:

1. Consulting Services.

1.1. Consultant will provide consulting services to the Company during the Term (as further defined below) of this Agreement. The consulting services ("Services") are set forth in the Statement of Work ("SOW") that is attached hereto as ***Appendix A*** and made a part hereof, as it may be amended from time to time by the parties hereto. Consultant shall perform all Services in compliance with all applicable laws.

2. Effective Date; Term and Termination.

2.1. This Agreement shall be effective on the later of the dates that it is executed by the Company and Consultant (the "Effective Date") and shall terminate as of the date Services are completed (the "Term" as further defined and outlined in ***Appendix A***) unless: (i) this Agreement is sooner terminated as provided in Section 2.2 below; or (ii) the parties agree in writing to extend the Term for a mutually agreed upon period.

2.2. The Agreement and the Services provided by Consultant may be terminated by either Consultant or the Company, at any time and for any reason, upon five (5) days prior written notice of termination.

3. Consulting Fees.

3.1. In consideration of the Services provided hereunder, the Company shall provide Consultant the compensation as set forth in the applicable SOW ("Consulting Fee").

3.2. Consultant shall be responsible for all expenses incurred in association with performance of the Services, unless pre-approved by the Company in writing in advance.

4. Confidentiality. Consultant acknowledges that Consultant will receive confidential and proprietary information from, on behalf of, or at the direction of, the Company in connection with, and during the course of providing, the Services, including but not limited to technical, clinical, marketing, commercial and/or legal information, data, reports, drawings, models, designs, prototypes, biological material, specimens, chemical compounds, formulas, manufacturing or other processes, software, specifications, patent applications, marketing strategies, customer information and customer lists ("Confidential Information"). All Confidential Information is and shall at all times remain the exclusive property of the Company. Consultant agrees:

4.1. to hold the Confidential Information in strict confidence and not to disclose or make available any Confidential Information to any third party whatsoever, without the prior written consent of the Company;

4.2. to use the Confidential Information only for the benefit of the Company and only for the purpose of providing the Services;

4.3. to take at least the same degree of care to prevent disclosure of Confidential Information as Consultant takes to preserve and safeguard Consultant's own confidential and proprietary information, but in any event, no less than a reasonable degree of care;

4.4. not to make copies of the Confidential Information except to the extent that the copies are reasonably necessary for providing the Services;

4.5. to return or destroy (as the Company may direct) any Confidential Information held by Consultant immediately upon termination of the Term of this Agreement pursuant to Section 2 above and provide the Company with a letter certifying that all such Confidential Information has been returned or destroyed as directed;

4.6. that Confidential Information excludes information that:

(a) as evidenced by Consultant's written records, was lawfully known to Consultant prior to its communication by, on behalf of, or at the direction of the Company and was not communicated to Consultant subject to any restrictions on disclosure or use; or

(b) as evidenced by Consultant's written records, is independently developed by Consultant without use or knowledge of the Confidential Information; or

(c) is or becomes a part of the public domain other than by a breach of this Agreement by Consultant;

(d) becomes known to Consultant by the action of a third party not in breach of any obligation of confidence; or

(e) is required to be disclosed or made available by Consultant to a third party pursuant to any applicable law, governmental regulation, or decision of any court or tribunal of competent jurisdiction, so long as Consultant takes reasonable steps, in light of the circumstances, to give the Company sufficient prior notice in order to contest such law, governmental regulation, or decision;

4.7. that no representation or warranty, express or implied, is made by the Company as to the accuracy, completeness or reasonableness of any Confidential Information and that neither the Company will have any liability to Consultant as a result of Consultant's possession or use of the Confidential information; and

4.8. that money damages may not be sufficient remedy for any breach of this Section and that the Company will be entitled to seek specific performance and injunctive or equitable relief as a remedy for any such breach.

4.9. Nothing in this Section is intended to limit any remedy of the Company under the California Uniform Trade Secrets Act (California Civil Code Section 3426), or otherwise available under law.

4.10. Notwithstanding the other provisions of this Agreement, pursuant to 18 U.S.C. Section 1833(b), Consultant shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law; or is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

5. Independent Contractor. The relationship of Consultant to the Company shall be that of an independent contractor rendering professional services. Consultant is not an employee of the Company. Nothing contained in this Agreement shall be deemed to create a relationship of employer and employee or principal and agent between the Company and Consultant. In no circumstance shall Consultant look to the Company as Consultant's employer, partner, agent or principal. Consultant is not entitled to and will be excluded from participating in any of Company's fringe benefit plans or programs as a result of the performance of the Services under this Agreement, including, but not limited to, health, sickness, accident or dental coverage, life insurance, disability benefits, accidental death and dismemberment coverage, unemployment insurance coverage, workers' compensation coverage, and pension or 401(k) benefit(s) provided by Company to its employees (and Consultant waives the right to receive any such benefits). Consultant agrees, as an independent contractor, that Consultant is not entitled to unemployment benefits in the event this Agreement terminates, or workers' compensation benefits in the event that Consultant is injured in any manner or becomes ill while performing the work under this Agreement. Consultant is solely responsible for all tax returns, payments, or reports required to be filed with or made to any federal, state or local tax authority with respect to Consultant's performance of Services and receipt of consideration (including Consulting Fees) under this Agreement. Consultant is not authorized to make any representation, contract or commitment on behalf of the Company unless specifically requested or authorized in writing to do so by an executive officer or Board member of the Company.

6. Waiver. No waiver of this Agreement or any of its provisions shall be binding upon a party unless in writing and signed by each party. The waiver by either party of a breach or violation of any provision of this Agreement shall not constitute or be construed as a waiver of any subsequent breach or violation of that provision or as a waiver of any breach or violation of any other provision.

7. Severability. If any provision of this Agreement is held by a court of competent jurisdiction to be invalid, illegal or unenforceable, the remaining provisions of this Agreement shall be unimpaired, and the invalid, illegal or unenforceable provision shall be replaced by a mutually acceptable provision, which, being valid, legal and enforceable, comes closest to the intention of the parties underlying the invalid, illegal or unenforceable provision.

8. Survival. The provisions of Sections 2.2, 3, 4, 6-11 and any other obligation under this Agreement which is to survive or be performed after termination of this Agreement, regardless of the cause therefor, shall survive any termination or expiration of this Agreement.

9. Notices. Any notice or other communication required or permitted to be made or given under this Agreement to either party shall be in writing and shall be sufficiently given if (i) hand delivered, (ii) sent by overnight guaranteed delivery service, such as Federal Express or UPS; or (iii) sent by facsimile transmission or electronic mail during addressee's normal business hours, with a duplicate copy sent by overnight delivery or certified or registered mail, addressed as either party may from time to time designate to the other by written notice. Any such notice or other communication shall be deemed to be given as of the date it is received by the addressee.

10. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of California, excluding the choice of law rules, and the parties hereby agree to submit to the jurisdiction and venue of the State and Federal courts of the State of California, and agree that the State and Federal courts of the State of California shall be the exclusive forum for the resolution of all disputes related to or arising out of this Agreement.

11. Entire Agreement; Amendments. This Agreement, including any applicable SOW, represents the entire agreement between the parties in relation to the subject matter contained herein and supersedes all previous other agreements and representations, whether oral or written. This Agreement may be modified only if such modification is in writing and signed by a duly authorized representative of each party.

SIGNATURE PAGE FOLLOWS

SIGNATURE PAGE

IN WITNESS WHEREOF, the parties hereto have executed this Consulting Agreement as of the date first above written.

COMPANY:

MELT PHARMACEUTICALS, INC.

/s/ Mark L. Baum

By: Mark L. Baum
Its: Executive Director

Date: 5/1/2018

CONSULTANT:

ANDREW R. BOLL

/s/ Andrew R. Boll

By: Andrew R. Boll
An individual

Date: 5/1/2018

Reviewed and approved by:

IMPRIMIS PHARMACEUTICALS, INC.

/s/ Robert J. Kammer

By: Robert J. Kammer
Chairman of the Board of
Imprimis Pharmaceutical, Inc.,
Parent Corporation to
Melt Pharmaceuticals, Inc.

Appendix A
Statement of Work
under Consulting Agreement
by and between
Andrew R. Boll and Melt Pharmaceuticals, Inc.

Services:

Consultant shall provide advisory services to the Company relating to its establishment, financing activities and other related services as may be requested from time to time by the Company.

Compensation:

Upon or shortly following commencement of Consultant's Services to the Company, the Company shall grant to Consultant either (a) 362,500 shares (the "Shares") of the Company's restricted common stock, par value $0.001 ("Common Stock") under the terms of the Company's 2018 Equity Incentive Plan (the "Plan") and a Restricted Stock Award Grant Notice and Agreement thereunder to be provided to Consultant by the Company (collectively with the Plan, the "Restricted Stock Documents") or (b) an option to purchase up to 362,500 shares of Common Stock (the "Options") under the terms of the Plan and a Stock Option Grant Notice and Agreement thereunder to be provided to Consultant by the Company (collectively with the Plan, the "Stock Option Documents"). The issuance of equity by the Company to Consultant in the form of Shares or Options shall be determined and agreed upon in writing at a later time by the Company and Consultant.

The Shares and/or Options shall vest upon the earliest of:

(1) a Change in Control (as defined in the Plan);
(2) the date of any underwriting agreement between the Company and the underwriter(s) managing an initial public offering of the Company's common stock, pursuant to which the common stock is priced for initial public offering (the "IPO");
(3) the date of closing of any bona-fide equity financing with third party investors resulting in cash gross proceeds to the Company of at least $10,000,000 ("Subsequent Financing"); or
(4) immediately prior to the one year anniversary of the date of grant of the Shares (as indicated in the Restricted Stock Documents) (the "Date of Grant").

and in any case of (1), (2), (3) and (4), subject to Consultant's Continuous Service through such vesting date; *provided, however*, in the event Consultant's Continuous Service is terminated by the Company (other than for Cause) or by death of Consultant prior to the completion of the Term (as defined in this Consulting Agreement), the Shares and/or Options shall vest immediately upon such termination.

Consultant understands that that the receipt of the Shares and/or Options hereunder may trigger tax consequences to Consultant for which Consultant will be solely responsible and that the Shares and/or Options have not been registered under the Securities Act of 1933, as amended, or any applicable state securities law. Consultant must execute the Restricted Stock Documents and/or Stock Option Documents as a condition to receipt of the Shares and/or Options hereunder.

Term:

Consultant commenced providing Services to the Company on or about May 1, 2018 and shall provide the Services through the earlier of (i) one year from the Date of Grant, (ii) a Change in Control, (iii) the IPO, (iv) a Subsequent Financing or (v) such earlier date as the Services are terminated by the Company or Consultant in accordance with this Agreement (the "Term").

EXHIBIT 10.3

CONSULTING AGREEMENT

THIS CONSULTING AGREEMENT (the "Agreement") is effective as the last date provided for on the signature page and is entered into by and between John Saharek, an individual ("Consultant") and Melt Pharmaceuticals, Inc., a Nevada corporation with its principal address located at 12264 El Camino Real, Suite 350, San Diego, CA 92130 (the "Company").

WHEREAS, the Company wishes to retain Consultant as an advisor to the Company; and

WHEREAS, Consultant wishes to provide advisory services to the Company as set forth below.

NOW THEREFORE, in consideration of the mutual promises contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Consultant and the Company agree, intending to be legally bound, as follows:

1. Consulting Services.

1.1. Consultant will provide consulting services to the Company during the Term (as further defined below) of this Agreement. The consulting services ("Services") are set forth in the Statement of Work ("SOW") that is attached hereto as ***Appendix A*** and made a part hereof, as it may be amended from time to time by the parties hereto. Consultant shall perform all Services in compliance with all applicable laws.

2. Effective Date; Term and Termination.

2.1. This Agreement shall be effective on the later of the dates that it is executed by the Company and Consultant (the "Effective Date") and shall terminate as of the date Services are completed (the "Term" as further defined and outlined in ***Appendix A***) unless: (i) this Agreement is sooner terminated as provided in Section 2.2 below; or (ii) the parties agree in writing to extend the Term for a mutually agreed upon period.

2.2. The Agreement and the Services provided by Consultant may be terminated by either Consultant or the Company, at any time and for any reason, upon five (5) days prior written notice of termination.

3. Consulting Fees.

3.1. In consideration of the Services provided hereunder, the Company shall provide Consultant the compensation as set forth in the applicable SOW ("Consulting Fee").

3.2. Consultant shall be responsible for all expenses incurred in association with performance of the Services, unless pre-approved by the Company in writing in advance.

4. Confidentiality. Consultant acknowledges that Consultant will receive confidential and proprietary information from, on behalf of, or at the direction of, the Company in connection with, and during the course of providing, the Services, including but not limited to technical, clinical, marketing, commercial and/or legal information, data, reports, drawings, models, designs, prototypes, biological material, specimens, chemical compounds, formulas, manufacturing or other processes, software, specifications, patent applications, marketing strategies, customer information and customer lists ("Confidential Information"). All Confidential Information is and shall at all times remain the exclusive property of the Company. Consultant agrees:

4.1. to hold the Confidential Information in strict confidence and not to disclose or make available any Confidential Information to any third party whatsoever, without the prior written consent of the Company;

4.2. to use the Confidential Information only for the benefit of the Company and only for the purpose of providing the Services;

4.3. to take at least the same degree of care to prevent disclosure of Confidential Information as Consultant takes to preserve and safeguard Consultant's own confidential and proprietary information, but in any event, no less than a reasonable degree of care;

4.4. not to make copies of the Confidential Information except to the extent that the copies are reasonably necessary for providing the Services;

4.5. to return or destroy (as the Company may direct) any Confidential Information held by Consultant immediately upon termination of the Term of this Agreement pursuant to Section 2 above and provide the Company with a letter certifying that all such Confidential Information has been returned or destroyed as directed;

4.6. that Confidential Information excludes information that:

(a) as evidenced by Consultant's written records, was lawfully known to Consultant prior to its communication by, on behalf of, or at the direction of the Company and was not communicated to Consultant subject to any restrictions on disclosure or use; or

(b) as evidenced by Consultant's written records, is independently developed by Consultant without use or knowledge of the Confidential Information; or

(c) is or becomes a part of the public domain other than by a breach of this Agreement by Consultant;

(d) becomes known to Consultant by the action of a third party not in breach of any obligation of confidence; or

(e) is required to be disclosed or made available by Consultant to a third party pursuant to any applicable law, governmental regulation, or decision of any court or tribunal of competent jurisdiction, so long as Consultant takes reasonable steps, in light of the circumstances, to give the Company sufficient prior notice in order to contest such law, governmental regulation, or decision;

4.7. that no representation or warranty, express or implied, is made by the Company as to the accuracy, completeness or reasonableness of any Confidential Information and that neither the Company will have any liability to Consultant as a result of Consultant's possession or use of the Confidential information; and

4.8. that money damages may not be sufficient remedy for any breach of this Section and that the Company will be entitled to seek specific performance and injunctive or equitable relief as a remedy for any such breach.

4.9. Nothing in this Section is intended to limit any remedy of the Company under the California Uniform Trade Secrets Act (California Civil Code Section 3426), or otherwise available under law.

4.10. Notwithstanding the other provisions of this Agreement, pursuant to 18 U.S.C. Section 1833(b), Consultant shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law; or is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

5. Independent Contractor. The relationship of Consultant to the Company shall be that of an independent contractor rendering professional services. Consultant is not an employee of the Company. Nothing contained in this Agreement shall be deemed to create a relationship of employer and employee or principal and agent between the Company and Consultant. In no circumstance shall Consultant look to the Company as Consultant's employer, partner, agent or principal. Consultant is not entitled to and will be excluded from participating in any of Company's fringe benefit plans or programs as a result of the performance of the Services under this Agreement, including, but not limited to, health, sickness, accident or dental coverage, life insurance, disability benefits, accidental death and dismemberment coverage, unemployment insurance coverage, workers' compensation coverage, and pension or 401(k) benefit(s) provided by Company to its employees (and Consultant waives the right to receive any such benefits). Consultant agrees, as an independent contractor, that Consultant is not entitled to unemployment benefits in the event this Agreement terminates, or workers' compensation benefits in the event that Consultant is injured in any manner or becomes ill while performing the work under this Agreement. Consultant is solely responsible for all tax returns, payments, or reports required to be filed with or made to any federal, state or local tax authority with respect to Consultant's performance of Services and receipt of consideration (including Consulting Fees) under this Agreement. Consultant is not authorized to make any representation, contract or commitment on behalf of the Company unless specifically requested or authorized in writing to do so by an executive officer or Board member of the Company.

6. Waiver. No waiver of this Agreement or any of its provisions shall be binding upon a party unless in writing and signed by each party. The waiver by either party of a breach or violation of any provision of this Agreement shall not constitute or be construed as a waiver of any subsequent breach or violation of that provision or as a waiver of any breach or violation of any other provision.

7. Severability. If any provision of this Agreement is held by a court of competent jurisdiction to be invalid, illegal or unenforceable, the remaining provisions of this Agreement shall be unimpaired, and the invalid, illegal or unenforceable provision shall be replaced by a mutually acceptable provision, which, being valid, legal and enforceable, comes closest to the intention of the parties underlying the invalid, illegal or unenforceable provision.

8. Survival. The provisions of Sections 2.2, 3, 4, 6-11 and any other obligation under this Agreement which is to survive or be performed after termination of this Agreement, regardless of the cause therefor, shall survive any termination or expiration of this Agreement.

9. Notices. Any notice or other communication required or permitted to be made or given under this Agreement to either party shall be in writing and shall be sufficiently given if (i) hand delivered, (ii) sent by overnight guaranteed delivery service, such as Federal Express or UPS; or (iii) sent by facsimile transmission or electronic mail during addressee's normal business hours, with a duplicate copy sent by overnight delivery or certified or registered mail, addressed as either party may from time to time designate to the other by written notice. Any such notice or other communication shall be deemed to be given as of the date it is received by the addressee.

10. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of California, excluding the choice of law rules, and the parties hereby agree to submit to the jurisdiction and venue of the State and Federal courts of the State of California, and agree that the State and Federal courts of the State of California shall be the exclusive forum for the resolution of all disputes related to or arising out of this Agreement.

11. Entire Agreement; Amendments. This Agreement, including any applicable SOW, represents the entire agreement between the parties in relation to the subject matter contained herein and supersedes all previous other agreements and representations, whether oral or written. This Agreement may be modified only if such modification is in writing and signed by a duly authorized representative of each party.

******SIGNATURE PAGE FOLLOWS******

SIGNATURE PAGE

IN WITNESS WHEREOF, the parties hereto have executed this Consulting Agreement as of the date first above written.

COMPANY:

MELT PHARMACEUTICALS, INC.

/s/ Mark L. Baum

By: Mark L. Baum
Its: Executive Director

Date: 5/1/2018

CONSULTANT:

JOHN SAHAREK

/s/ John Saharek

By: John Saharek
An individual

Date: 5/1/2018

Reviewed and approved by:

IMPRIMIS PHARMACEUTICALS, INC.

/s/ Robert J. Kammer

By: Robert J. Kammer
Chairman of the Board of
Imprimis Pharmaceutical, Inc.,
Parent Corporation to
Melt Pharmaceuticals, Inc.

Appendix A

Statement of Work
under Consulting Agreement
by and between
John Saharek and Melt Pharmaceuticals, Inc.

Services:

Consultant shall provide advisory services to the Company relating to its sales and marketing activities and other related services as may be requested from time to time by the Company.

Compensation:

Upon or shortly following commencement of Consultant's Services to the Company, the Company shall grant to Consultant an option to purchase up to 20,000 shares of the Company's restricted common stock, par value $0.001 ("Common Stock") under the terms of the Company's 2018 Equity Incentive Plan (the "Plan") and a Stock Option Grant Notice and Agreement thereunder to be provided to Consultant by the Company (collectively with the Plan, the "Stock Option Documents").

The shares subject to the option shall vest upon the earliest of:

(1) a Change in Control (as defined in the Plan);
(2) the date of any underwriting agreement between the Company and the underwriter(s) managing an initial public offering of the Company's common stock, pursuant to which the common stock is priced for initial public offering (the "IPO");
(3) immediately prior to the one year anniversary of the date of grant of the option (as indicated in the Stock Option Documents).

and in any case of (1), (2) and (3), subject to Consultant's Continuous Service through such vesting date; *provided, however*, in the event Consultant's Continuous Service is terminated by the Company (other than for Cause) or by death of Consultant prior to the completion of the Term (as defined in this Consulting Agreement), the shares subject to the option shall vest immediately upon such termination.

Consultant understands that that the receipt of the option and/or shares subject to the option hereunder will trigger tax consequences to Consultant for which Consultant will be solely responsible and that the option and/or shares subject to the option have not been registered under the Securities Act of 1933, as amended, or any applicable state securities law. Consultant must execute the Restricted Stock Documents as a condition to receipt of the option and/or shares subject to the option hereunder.

Term:

Consultant commenced providing Services to the Company on or about May 1, 2018 and shall provide the Services through the earliest of (i) one year from the date of grant of the option, (ii) a Change in Control, (iii) the IPO, or (iv) such earlier date as the Services are terminated by the Company or Consultant in accordance with this Agreement (the "Term").

EXHIBIT 31.1

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

I, Mark L. Baum, certify that:

(1) I have reviewed this quarterly report on Form 10-Q of Imprimis Pharmaceuticals, 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, 2018

/s/ *Mark L. Baum*

Mark L. Baum
Chief Executive Officer
Principal Executive Officer

EXHIBIT 31.2

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

I, Andrew R. Boll, certify that:

(1) I have reviewed this quarterly report on Form 10-Q of Imprimis Pharmaceuticals, 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, 2018

/s/ *Andrew R. Boll*

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

Exhibit 32.1

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

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned hereby certifies in his capacity as the specified officer of Imprimis Pharmaceuticals, 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, 2018 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, 2018

/s/ Mark L. Baum

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

Date: November 13, 2018

/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.