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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2019

OR

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

For the transition period from _____ to _____

Commission file number 001-36728

ADMA BIOLOGICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	56-2590442
(State or Other Jurisdiction of Incorporation or Organization) Organization)	(I.R.S. Employer Identification No.)
465 State Route 17, Ramsey, New Jersey	07446
(Address of Principal Executive Offices)	(Zip Code)

(201) 478-5552
(Registrant's Telephone Number, Including Area Code)

_____
(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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

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

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

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

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	ADMA	Nasdaq Capital Market

As of May 7, 2019, there were 46,380,306 shares of the issuer's common stock outstanding.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES

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This Quarterly Report on Form 10-Q includes our trademarks, trade names and service marks, such as "ASCENIV®", "Nabi-HB®" and "BIVIGAM®" which are protected under applicable intellectual property laws and are the property of ADMA Biologics, Inc., or its subsidiaries. Solely for convenience, trademarks, trade names and service marks referred to in this report may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

Special Note Regarding Forward-Looking Statements

Some of the information in this Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the federal securities laws. These statements include, among others, statements about:

- our ability to resume the manufacturing of BIVIGAM on a commercial scale and commercialize this product once the deficiencies identified in a November 2014 warning letter (the "Warning Letter") with respect to the outstanding issues at the plasma fractionation facility in Boca Raton, FL have been resolved by us to the satisfaction of the U.S. Food and Drug Administration (the "FDA"), as well as a positive review of the optimized manufacturing process under a Prior Approval Supplement by the FDA and our ability to adequately address the FDA's questions and information request contained in a Complete Response Letter received by us on December 19, 2018;
- our plans to develop, manufacture, market, launch and expand our own commercial infrastructure and commercialize our current and future products and the success of such efforts;
- the safety, efficacy and expected timing of and our ability to obtain and maintain regulatory approvals for our current products and product candidates, and the labeling or nature of any such approvals;
- the achievement of or expected timing, progress and results of clinical development, clinical trials and potential regulatory approvals;
- our dependence upon our third-party and related-party customers and vendors and their compliance with regulatory bodies;
- our ability to obtain adequate quantities of FDA-approved plasma with proper specifications;
- our plans to increase our supplies of plasma;
- the potential indications for our product candidates;
- potential investigational new product applications;
- the acceptability of any of our products, including Nabi-HB, BIVIGAM and ASCENIV, for any purpose by physicians, patients or payers;
- Federal, state and local regulatory and business review processes and timing by such governmental and regulatory agencies of our business and regulatory submissions;
- concurrence by the FDA with our conclusions and the satisfaction by us of its guidance;
- the comparability of results of our immune globulin products to other comparably run Intravenous Immune Globulin clinical trials;
- the potential of ASCENIV and BIVIGAM to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease or other immune deficiencies;
- our ability to market and promote Nabi-HB in a highly competitive environment with increasing competition from other antiviral therapies and to generate meaningful revenues from this product;
- our intellectual property position and the defense thereof, including our expectations regarding the scope of patent protection with respect to ASCENIV or other future pipeline product candidates;
- our manufacturing capabilities, third-party contractor capabilities and strategy;
- our plans relating to manufacturing, supply and other collaborative agreements;

- our estimates regarding expenses, capital requirements and the need for and availability of additional financing;
- possible or likely reimbursement levels for our currently marketed products and, if any, if and when BIVIGAM is approved for marketing;
- estimates regarding market size, projected growth and sales of our existing products as well as our expectations of market acceptance of ASCENIV;
- future economic conditions or performance; and
- expectations for future capital requirements.

These statements may be found under the “Risk Factors“ and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections of this Quarterly Report on Form 10-Q. Forward-looking statements typically are identified by the use of terms such as “anticipates,” “believes,” “can,” “continue,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “should,” or “will” or the negative thereof or other variations thereof or comparable terminology. You should be aware that our actual results could differ materially from those contained in the forward-looking statements due to the factors referenced above. Any forward-looking statement included or incorporated by reference in this Quarterly Report on Form 10-Q reflects our current views with respect to future events and is subject to these and other risks, uncertainties and assumptions related to our operations, results of operations, industry and future growth. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These forward-looking statements speak only as of the dates such statements are made.

In addition to the foregoing, you should also consider carefully the statements under the section entitled “Risk Factors” and other sections of this Quarterly Report on Form 10-Q, which address additional factors that could cause our actual results to differ from those set forth in the forward-looking statements. Any forward-looking statements that we make in this Quarterly Report on Form 10-Q speak only as of the date of such statements and we undertake no obligation to publicly update any forward-looking statements or to publicly announce revisions to any of the forward-looking statements, whether as a result of new information, future events or otherwise.

PART I
FINANCIAL INFORMATION

Item 1. Financial Statements.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2019	December 31, 2018
ASSETS	(Unaudited)	
Current assets:		
Cash and cash equivalents	$ 16,534,278	$ 22,754,852
Accounts receivable, net	1,310,404	1,392,441
Inventories	18,439,912	18,616,169
Prepaid expenses and other current assets	2,049,552	1,766,163
Total current assets	38,334,146	44,529,625
Property and equipment, net	29,694,764	30,115,730
Intangible assets, net	3,793,177	4,004,412
Goodwill	3,529,509	3,529,509
Assets to be transferred under purchase agreement	—	1,153,508
Restricted cash	—	4,000,000
Deposits and other assets	2,768,374	1,543,737
TOTAL ASSETS	$ 78,119,970	$ 88,876,521
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,479,791	$ 5,900,394
Accrued expenses and other current liabilities	2,505,996	3,551,835
Current portion of deferred revenue	142,834	142,834
Current portion of lease obligations	209,506	29,983
Total current liabilities	8,338,127	9,625,046
Notes payable, net of discount	40,885,103	26,440,830
End of term liability, notes payable	—	2,760,000
Deferred revenue, net of current portion	2,368,657	2,404,365
Note payable - related party, net of discount	14,882,337	14,874,184
Obligation to transfer assets under purchase agreement	—	12,621,844
Lease obligations, net of current portion	1,461,452	119,080
Other non-current liabilities	145,340	260,734
TOTAL LIABILITIES	68,081,016	69,106,083
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Preferred Stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued and outstanding	—	—
Common Stock - voting, $0.0001 par value, 75,000,000 shares authorized, 46,353,068 shares issued and outstanding	4,635	4,635
Additional paid-in capital	239,539,512	236,203,041
Accumulated deficit	(229,505,193)	(216,437,238)
TOTAL STOCKHOLDERS' EQUITY	10,038,954	19,770,438
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 78,119,970	$ 88,876,521

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

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2019	**2018**
REVENUES:		
Product revenue	$ 3,492,881	$ 4,006,298
License revenue	35,708	35,708
Total Revenues	3,528,589	4,042,006
OPERATING EXPENSES:		
Cost of product revenue (exclusive of amortization expense shown below)	9,405,179	12,242,748
Research and development	870,635	965,571
Plasma center operating expenses	654,486	1,833,774
Amortization of intangible assets	211,235	211,235
Selling, general and administrative	5,595,470	5,321,181
Total operating expenses	16,737,005	20,574,509
LOSS FROM OPERATIONS	(13,208,416)	(16,532,503)
OTHER INCOME (EXPENSE):		
Interest and other income	127,399	26,546
Interest expense	(1,540,507)	(1,323,152)
Loss on extinguishment of debt	(9,962,495)	—
Gain on transfer of plasma center assets	11,527,421	—
Other (expense) income	(11,357)	6,967
Other income (expense), net	140,461	(1,289,639)
NET LOSS	$ (13,067,955)	$ (17,822,142)
BASIC AND DILUTED LOSS PER COMMON SHARE	$ (0.28)	$ (0.39)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:		
Basic and Diluted	46,353,068	45,317,042

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

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)

For the Three Months Ended March 31, 2019

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2018	46,353,068	$ 4,635	$ 236,203,041	$ (216,437,238)	$ 19,770,438
Stock-based compensation	—	—	637,263	—	637,263
Warrants issued in connection with note payable	—	—	2,699,208	—	2,699,208
Net loss	—	—	—	(13,067,955)	(13,067,955)
Balance at March 31, 2019	46,353,068	$ 4,635	$ 239,539,512	$ (229,505,193)	$ 10,038,954

For the Three Months Ended March 31, 2018

	Common Stock				Additional		
	Voting		Non-Voting		Paid-in	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance - December 31, 2017	36,725,499	$ 3,673	8,591,160	$ 859	$ 191,022,018	$ (150,693,793)	$ 40,332,757
Stock-based compensation	—	—	—	—	514,784	—	514,784
Stock options exercised	585	—	—	—	—	—	—
Net loss	—	—	—	—	—	(17,822,142)	(17,822,142)
Balance - March 31, 2018	36,726,084	$ 3,673	8,591,160	$ 859	$ 191,536,802	$ (168,515,935)	$ 23,025,399

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

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Three Months Ended March 31,	
	2019	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (13,067,955)	$ (17,822,142)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	805,330	829,541
Loss on disposal of fixed assets	391	—
Stock-based compensation	637,263	514,784
Gain on transfer of plasma assets	(11,527,420)	—
Amortization of debt discount	244,767	255,847
Loss on extinguishment of debt	9,962,495	—
Amortization of license revenue	(35,708)	(35,708)
Changes in operating assets and liabilities, net of acquisition:		
Accounts receivable	82,037	222,552
Inventories	(25,310)	189,379
Prepaid expenses and other current assets	(289,134)	(652,474)
Deposits and other assets	179,644	(29,515)
Accounts payable	(420,601)	(202,754)
Accrued expenses	(762,541)	88,640
Other current and non-current liabilities	(70,442)	207,736
Net cash used in operating activities	(14,287,184)	(16,434,114)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(110,453)	(549,246)
Net cash used in investing activities	(110,453)	(549,246)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Principal payments on notes payable	(30,000,000)	—
Payment of end of term fee	(2,760,000)	—
Payment of debt refinancing fees	(6,499,867)	—
Proceeds from issuance of note payable	45,000,000	—
Payment of debt issuance costs	(1,555,762)	—
Payments on finance lease obligations	(7,308)	—
Payments of leasehold improvement loan	—	(4,377)
Net cash provided by (used in) financing activities	4,177,063	(4,377)
Net (decrease) increase in cash and cash equivalents	(10,220,574)	(16,987,737)
Cash and cash equivalents, including restricted cash - beginning of period	26,754,852	48,607,574
Cash and cash equivalents, including restricted cash - end of period	$ 16,534,278	$ 31,619,837

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

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. ORGANIZATION AND BUSINESS

ADMA Biologics, Inc. ("ADMA" or the "Company") is a vertically integrated commercial biopharmaceutical and specialty immunoglobulin company that manufactures, markets and develops specialty plasma-derived biologics for the treatment of immune deficiencies and the prevention and treatment of certain infectious diseases. The Company's targeted patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disorder or who may be immune-suppressed for medical reasons. ADMA operates through its wholly-owned subsidiaries ADMA BioManufacturing, LLC ("ADMA BioManufacturing") and ADMA Bio Centers Georgia Inc. ("ADMA Bio Centers"). ADMA BioManufacturing was formed in January 2017 to facilitate the acquisition of the Biotest Therapy Business Unit ("BTBU") from Biotest Pharmaceuticals Corporation ("BPC" and, together with Biotest AG, "Biotest") as more fully described below. BTBU had been the Company's third-party manufacturer for its then-lead pipeline product candidate, previously referred to as "RI-002." ADMA Bio Centers is the Company's source plasma collection business with a plasma collection facility located in Kennesaw, GA which holds an approved license with the U.S. Food and Drug Administration (the "FDA"). Effective January 1, 2019, in connection with the Biotest Transaction defined below, the Company transferred its FDA-approved Norcross, GA and Marietta, GA plasma collection facilities to BPC (see Note 11).

On June 6, 2017, ADMA completed the acquisition of certain assets (the "Biotest Assets") of BTBU, which included two FDA-licensed products, Nabi-HB (Hepatitis B Immune Globulin, Human) and BIVIGAM (Immune Globulin Intravenous, Human), and a plasma fractionation manufacturing facility located in Boca Raton, FL (the "Boca Facility") (the "Biotest Transaction"). In addition to Nabi-HB and BIVIGAM, the Company provides contract manufacturing services for certain clients and expects to generate revenues from the sale of intermediate by-products which result from the immunoglobulin production process. The Boca Facility is FDA-licensed and certified by the German Health Authority. Immediately following the closing of the Biotest Transaction, the Biotest Assets were contributed into ADMA BioManufacturing.

On April 1, 2019, the FDA approved ASCENIV (Immune Globulin Intravenous, Human – slra 10% Liquid), formerly referred to as RI-002. ASCENIV is an Intravenous Immune Globulin ("IVIG") drug product for the treatment of Primary Humoral Immunodeficiency Disease ("PIDD" or "PI") in adults and adolescents (12 to 17 years of age). The Company anticipates having the product available for commercial launch during the second half of 2019.

Prior to the acquisition of BTBU and the FDA approval for ASCENIV, in July 2016 the FDA issued a Complete Response Letter ("CRL") to the Company for the Company's Biologics License Application ("BLA") for RI-002. The RI-002 CRL reaffirmed the issues set forth in the November 2014 warning letter (the "Warning Letter") that had been issued by the FDA to Biotest related to certain compliance issues identified at the Boca Facility, but did not cite any concerns with the clinical safety or efficacy data for RI-002, nor did the FDA request any additional clinical studies be completed prior to FDA approval of RI-002. The FDA identified in the RI-002 CRL, among other things, certain outstanding inspection issues and deficiencies related to chemistry, manufacturing and controls and Good Manufacturing Practices at the Boca Facility and certain of the Company's third-party vendors, and requested documentation of corrections for a number of these issues. The FDA had indicated in the RI-002 CRL that it could not grant final approval of the RI-002 BLA until, among other things, these deficiencies were resolved. Upon the completion of the Biotest Transaction, ADMA gained control over the regulatory, quality, general operations and drug substance manufacturing process at the Boca Facility. In April 2018, the FDA inspected the Boca Facility and in July 2018 the Company's FDA status with respect to the Boca Facility improved from Official Action Indicated to Voluntary Action Indicated, and the Company determined that this inspection of the Boca Facility was successfully closed out.

Nabi-HB is a hyperimmune globulin that is rich in antibodies to the Hepatitis B virus. Nabi-HB is indicated for the treatment of acute exposure to blood containing hepatitis B surface antigen ("HBsAg"), prenatal exposure to infants born to HBsAg-positive mothers, sexual exposure to HBsAg-positive persons and household exposure to persons with acute Hepatitis B virus infection. FDA approval for Nabi-HB was received on March 24, 1999. Under ADMA's ownership, production of Nabi-HB resumed during the third quarter of 2017, resulting in ongoing commercial revenues.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

BIVIGAM is an intravenous immune globulin indicated for the treatment of primary humoral immunodeficiency. BIVIGAM is currently under FDA review for the Prior Approval Supplement (the "PAS") that the Company submitted to the FDA in June 2018 to amend BIVIGAM's FDA-approved BLA which, once approved, would enable the Company to relaunch and commercialize this product in the U.S. In December 2018, the Company received a CRL from the FDA in response to the PAS (the "BIVIGAM CRL"), and the Company has since received several information requests from the FDA, each containing a limited number of questions. The Company believes that all requests contained in the various information requests were addressable, and has responded to all of them. The Company to date has not received a formal BIVIGAM CRL resubmission acknowledgement and has not received clarity on the FDA's intended classification or review timing. Although the Company believes that the FDA is actively reviewing the PAS submission and subsequent information request responses, the Company cannot provide any assurance or predict with certainty the schedule for when the Company will, if at all, receive authorization from the FDA with respect to the PAS. In addition, the anticipated relaunch of BIVIGAM is dependent upon the timing of certain FDA decisions, production slots available with the Company's contract fill/finish provider, approvals that may need to be obtained for product labeling as well as other commercial requirements and regulatory factors. Biotest had originally received FDA approval for BIVIGAM on December 19, 2012, prior to the acquisition of BTBU, and product sales commenced in the first quarter of 2013. In December 2016, Biotest temporarily suspended the commercial production of BIVIGAM in order to focus on the completion of planned improvements to the manufacturing process. ADMA resumed production of BIVIGAM during the fourth quarter of 2017.

As of March 31, 2019, the Company had working capital of $30.0 million, including $16.5 million of cash and cash equivalents. Based upon the Company's current projected revenue and expenditures, including capital expenditures and continued implementation of the Company's commercialization and expansion activities, as well as certain other assumptions, the Company's management currently believes that its cash, cash equivalents, projected revenue and accounts receivable, along with the additional $40.0 million it is able to access under its senior credit facility, $12.5 million of which is contingent upon FDA approval of the PAS, will be sufficient to fund ADMA's operations, as currently conducted, into the fourth quarter of 2019. In order to have sufficient cash to fund its operations thereafter and to continue as a going concern, the Company will need to raise capital by the fourth quarter of 2019. These estimates may change based upon how quickly the Company is able to obtain FDA approval for BIVIGAM, commercial manufacturing ramp-up activities and the various financing options being explored. The Company currently has no firm commitments for additional financing, and there can be no assurances that the Company will be able to secure additional financing on terms that are acceptable to the Company, or at all. Furthermore, if the Company's assumptions underlying its estimated expenses and revenues are incorrect, it may have to raise additional capital sooner than currently anticipated.

Due to numerous risks and uncertainties associated with FDA approval of the Company's products, ongoing remediation and capacity expansion efforts at the Company's Boca Facility and potential future commercialization of the Company's products and product candidates, the Company is unable to estimate with certainty the amounts of increased capital outlays and operating expenditures required to fund its development activities. The Company's current estimates may be subject to change as circumstances regarding its business requirements evolve. The Company may decide to raise capital through public or private equity offerings or debt financings, or obtain a bank credit facility or corporate collaboration and licensing arrangements. The sale of additional equity or debt securities, if convertible, could result in dilution to the Company's stockholders and, in such event, the value and potential future market price of its common stock may decline. The incurrence of additional indebtedness would result in increased fixed obligations and could also result in covenants that would restrict the Company's operations or other financing alternatives. Failure to secure any necessary financing in a timely manner and on commercially reasonable terms could have a material adverse effect on the Company's business plan and financial performance and it could be forced to delay or discontinue its product development, clinical trial or commercialization activities, delay or discontinue the approval efforts for any of the Company's potential products or potentially cease operations. The Company has reported cumulative losses since inception in June 2004 through March 31, 2019 of $229.5 million. Management believes that the Company will continue to incur net losses and negative net cash flows from operating activities to fund its operations and meet its obligations on a timely basis through the foreseeable future. As such, these factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments related to the recoverability and classification of asset carrying amounts and the classification of liabilities that might be necessary from the outcome of this uncertainty.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

In February 2019, the Company refinanced its senior debt (see Note 6) whereby the Company received net proceeds of approximately $4.2 million, and an additional $4.0 million, which was reflected as restricted cash in the accompanying consolidated balance sheet at December 31, 2018, was released by the Company's then-senior creditor to the Company. On May 3, 2019, the Company received the additional $27.5 million that was available to the Company under its senior credit facility and amended the facility to increase the total amount available under the facility by an additional $12.5 million (see Note 14).

There can be no assurance that the Company's research and development will be successfully completed or that any product will be approved or commercially viable. The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, dependence on collaborative arrangements, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, and compliance with FDA and other governmental regulations and approval requirements.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information. Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board (the "FASB").

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the annual audited consolidated financial statements and notes thereto as of and for the year ended December 31, 2018 included in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC") on March 13, 2019. The accompanying consolidated balance sheet as of December 31, 2018 was derived from the audited financial statements for the year ended December 31, 2018. These condensed consolidated interim financial statements have been prepared in accordance with the instructions to Form 10-Q and Article 8 of Regulation S-X, and therefore omit or condense certain footnotes and other information normally included in consolidated interim financial statements prepared in accordance with U.S. GAAP. All intercompany balances and transactions have been eliminated in consolidation. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's financial position as of March 31, 2019 and its results of operations for the three months ended March 31, 2019 and 2018 and cash flows for the three months ended March 31, 2019 and 2018.

During the three months ended March 31, 2019 and 2018, comprehensive loss was equal to the net loss amounts presented for the respective periods in the accompanying condensed consolidated statements of operations. In addition, certain prior year balances have been reclassified to conform to the current presentation. Specifically, for the three months ended March 31, 2018, approximately $0.3 million was reclassified from research and development expenses to selling, general and administrative expenses in the accompanying consolidated statements of operations. Operating results for interim periods are not necessarily indicative of the results that may be expected for the full fiscal year.

Use of estimates

The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include the fair value of assets acquired and liabilities assumed in a business combination, realizable value of accounts receivable, valuation of inventory, assumptions used in the fair value of awards granted under the Company's equity incentive plans and warrants issued in connection with the issuance of notes payable and the valuation allowance for the Company's deferred tax assets.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Fair value of financial instruments

The carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents and accounts payable, are shown at cost which approximates fair value due to the short-term nature of these instruments. The debt outstanding under the Company's senior secured term loan (see Note 6) approximates fair value due to the variable interest rate on this debt. With respect to the related party note payable in the amount of $15.0 million as of March 31, 2019 and December 31, 2018, which is held by a principal stockholder of the Company and was issued concurrent with an acquisition transaction with an affiliate of such stockholder (see Note 6), the Company has concluded that an estimation of fair value for this note is not practicable.

Accounts receivable

Accounts receivable are reported at realizable value, net of allowances for contractual credits and doubtful accounts, which are recognized in the period the related revenue is recorded. At March 31, 2019, four customers accounted for an aggregate of 96% of the Company's total accounts receivable, and at December 31, 2018, three customers accounted for approximately 95% of the Company's total accounts receivable.

Inventories

Inventories, including plasma intended for resale and plasma intended for internal use in the Company's research and development and future anticipated commercialization activities, are carried at the lower of cost or net realizable value determined by the first-in, first-out method. Although the Company expects that BIVIGAM and ASCENIV inventory manufactured prior to March 31, 2019 will ultimately be available for commercial sale, due to uncertainties surrounding the Warning Letter, the PAS and, as of March 31, 2019, the RI-002 BLA, resolution of which are dependent upon action by the FDA prior to this inventory being available for commercial sale, all costs related to the production of BIVIGAM and ASCENIV during the three months ended March 31, 2019 and 2018 in the amount of $0.6 million and $3.7 million, respectively, have been charged to cost of product revenue in the accompanying consolidated statements of operations.

Goodwill

Goodwill represents the excess of purchase price over the fair value of net assets acquired by the Company. Goodwill at March 31, 2019 and December 31, 2018 was $3.5 million. All of the Company's goodwill is attributable to its ADMA BioManufacturing business segment.

Goodwill is not amortized, but is assessed for impairment on an annual basis or more frequently if impairment indicators exist. The Company has the option to perform a qualitative assessment of goodwill to determine whether it is more likely than not that the fair value of its reporting unit is less than its carrying amount, including goodwill and other intangible assets. If the Company concludes that this is the case, then it must perform a goodwill impairment test by comparing the fair value of the reporting unit to its carrying value. An impairment charge is recorded to the extent the reporting unit's carrying value exceeds its fair value, not to exceed the total amount of goodwill allocated to that reporting unit. The Company performs its annual goodwill impairment test as of October 1 of each year, and the Company did not record any impairment charges related to goodwill for the three months ended March 31, 2019 and 2018.

Impairment of long-lived assets

The Company assesses the recoverability of its long-lived assets, which include property and equipment and definite-lived intangible assets, whenever significant events or changes in circumstances indicate impairment may have occurred. If indicators of impairment exist, projected future undiscounted cash flows associated with the asset are compared to its carrying amount to determine whether the asset's carrying value is recoverable. Any resulting impairment is recorded as a reduction in the carrying value of the related asset in excess of fair value and a charge to operating results. For the three months ended March 31, 2019 and 2018, the Company determined that there was no impairment of its long-lived assets.

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Revenue recognition

Revenues for the three months ended March 31, 2019 and 2018 are comprised of (i) revenues from the sale of Nabi-HB, (ii) product revenues from the sale of human plasma collected from the Company's Plasma Collection Centers business segment; and (iii) license and other revenues primarily attributable to the out-licensing of ASCENIV to Biotest to market and sell this product in Europe and selected countries in North Africa and the Middle East. Biotest has provided the Company with certain services and financial payments in accordance with the related Biotest license agreement and is obligated to pay the Company certain amounts in the future if certain milestones are achieved. Deferred revenue is recognized over the term of the Biotest license. Deferred revenue is amortized into income for a period of approximately 22 years, the term of the Biotest license agreement.

Product revenue is recognized when the customer is deemed to have control over the product. Control is determined based on when the product is shipped or delivered and title passes to the customer. Revenue is recorded in an amount that reflects the consideration the Company expects to receive in exchange. Revenue from the sale of Nabi-HB is recognized when the product reaches the customer's destination, and is recorded net of estimated rebates, price protection arrangements and customer incentives, including prompt pay discounts, wholesaler chargebacks and other wholesaler fees. These estimates are based on historical experience, and the Company believes that such estimates are reasonable. For revenues associated with contract manufacturing, control transfers to the customer and the performance obligation is satisfied when the customer takes possession of the product from the Boca Facility.

Product revenues from the sale of human plasma collected at the Company's plasma collection centers are recognized at the time control of the product has been transferred to the customer, which generally occurs at the time of shipment. Product revenues are recognized at the time of delivery if the Company retains control of the product during shipment.

For the three months ended March 31, 2019, two customers represented an aggregate of 81% of the Company's consolidated revenues. For the three months ended March 31, 2018, sales to BPC represented 58% of the Company's consolidated revenues, and two other customers represented 32% of the Company's consolidated revenues.

Cost of product revenue

Cost of product revenue includes expenses related to process development as well as scientific and technical operations when these operations are attributable to marketed products. When the activities of these operations are attributable to new products in development, the expenses are classified as research and development expenses.

Expenses associated with remediating the issues identified in the Warning Letter for the three months ended March 31, 2019 and 2018 were approximately $0.1 million and $0.7 million, respectively, and are reflected in cost of product revenue in the accompanying consolidated statements of operations. In addition, for the three months ended March 31, 2019, all operating expenses associated with the Boca Facility, other than the Nabi-HB production and contract manufacturing production that was capitalized into inventory, have been expensed as incurred.

Loss per common share

Basic loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Diluted loss per common share is calculated by dividing net loss attributable to common stockholders, as adjusted for the effect of dilutive securities, if any, by the weighted average number of shares of common stock and dilutive common stock outstanding during the period. Potentially dilutive common stock includes the shares of common stock issuable upon the exercise of outstanding stock options and warrants, using the treasury stock method. Potentially dilutive common stock is excluded from the diluted loss per common share computation to the extent that it would be anti-dilutive. As a result, no potentially dilutive securities are included in the computation of any of the accompanying diluted loss per share amounts as the Company reported a net loss for all periods presented. For the three months ended March 31, 2019 and 2018, the following securities were excluded from the calculation of diluted loss per common share because of their anti-dilutive effects:

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	For the Three Months Ended March 31,	
	2019	**2018**
Stock options	5,599,435	4,127,950
Warrants	1,888,160	528,160
	7,487,595	4,656,110

Stock-based compensation

The Company follows recognized accounting guidance which requires all equity-based payments, including grants of stock options, to be recognized in the statements of operations as compensation expense based on their fair values at the date of grant. The Company uses the Black-Scholes option pricing model to determine the fair value of options granted. Compensation expense related to awards to employees and directors with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated vesting period of the award, which is generally four years (see Note 7). Stock options granted under the Company's equity incentive plans generally have a term of 10 years.

Income Taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or its tax returns. Under this method, deferred tax assets and liabilities are recognized for the temporary differences between the tax bases of assets and liabilities and their respective financial reporting amounts at enacted tax rates in effect for the years in which the temporary differences are expected to reverse. The Company records a valuation allowance on its deferred tax assets if it is more likely than not that the Company will not generate sufficient taxable income to utilize its deferred tax assets. The Company is subject to income tax examinations by major taxing authorities for all tax years since 2015 and for previous periods as it relates to the Company's net operating loss carryforwards.

In accordance with U.S. GAAP, the Company is required to determine whether a tax position of the Company is more likely than not to be sustained upon examination by the applicable taxing authority, including resolution of any related appeals or litigation processes, based on the technical merits of the position. The tax benefit to be recognized is measured as the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. Derecognition of a tax benefit previously recognized could result in the Company recording a tax liability that would reduce net assets. Based on its analysis, the Company has determined that it has not incurred any liability for unrecognized tax benefits as of March 31, 2019 and December 31, 2018, and during the three months ended March 31, 2019 and 2018, the Company recognized no adjustments for uncertain tax positions.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which requires lessees to recognize assets and liabilities for the rights and obligations created by most leases on their balance sheet. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. ASU 2016-02 requires modified retrospective adoption for all leases existing at, or entered into after, the date of initial application, with an option to use certain transition relief. The Company adopted ASU 2016-02 on January 1, 2019 using the option to recognize the cumulative-effect adjustment, if any, as of the date of application, which was also January 1, 2019. As a result, there will be no restatement of comparative periods. The Company recognized right-to-use assets and corresponding lease liabilities of approximately $1.4 million at the date of adoption (see Note 12). The Company also elected the "package of practical expedients", which permits the Company to not reassess under the new standard its prior conclusions about lease identification, lease classification and initial direct costs. In addition, the Company elected the short-term lease recognition exemption for all leases that qualify, including the agreement under which the Company occupies certain office space as discussed in Note 8.

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In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815)*" ("ASU 2017-11"). ASU 2017-11 changed the classification analysis of certain equity-linked financial instruments (or embedded features within such instruments) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) would no longer be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share ("EPS") in accordance with ASC 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. In addition, convertible instruments with embedded conversion options that have down round features are now subject to the specialized guidance for contingent beneficial conversion features in ASC 470-20, "Debt—Debt with Conversion and Other Options." ASU 2017-11 became effective for the Company on January 1, 2019, and this update did not have a significant impact on the Company's consolidated financial statements.

3. INVENTORIES

The following table provides the components of inventories:

	March 31, 2019	December 31, 2018
Raw materials	$ 13,799,170	$ 14,019,668
Work-in-progress	870,264	—
Finished goods	3,770,478	4,596,501
Total inventories	$ 18,439,912	$ 18,616,169

Inventories are stated at the lower of cost or net realizable value with cost being determined on the first-in, first-out method. Raw materials includes plasma and other materials expected to be used in the production of ASCENIV and BIVIGAM, as there are alternative uses for these materials which provide a probable future benefit or will be consumed in the production of goods expected to be available for sale. All other activities and materials associated with the production of inventories used in research and development activities are expensed as incurred.

Finished goods inventory at March 31, 2019 is comprised of $2.1 million of Nabi-HB, $1.5 million of product manufactured under a contract manufacturing agreement and $0.2 million of plasma collected at the Company's plasma collection center. Finished goods inventory at December 31, 2018 is comprised of $2.3 million of Nabi-HB, $1.2 million of product manufactured under a contract manufacturing agreement and $1.1 million of plasma collected at the Company's plasma collection centers.

4. INTANGIBLE ASSETS

Intangible assets at March 31, 2019 and December 31, 2018 consist of the following:

	March 31, 2019			December 31, 2018		
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Trademark and other intangible rights related to Nabi-HB	$ 4,100,046	$ 1,073,821	$ 3,026,225	$ 4,100,046	$ 927,391	$ 3,172,655
Rights to intermediates	907,421	237,659	669,762	907,421	205,250	702,171
Customer contract	1,076,557	979,367	97,190	1,076,557	946,971	129,586
	$ 6,084,024	$ 2,290,847	$ 3,793,177	$ 6,084,024	$ 2,079,612	$ 4,004,412

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All of the Company's intangible assets were acquired in the Biotest Transaction. Amortization expense related to these intangible assets for the three months ended March 31, 2019 and 2018 was $0.2 million. Estimated aggregate future aggregate amortization expense for the next five years is expected to be as follows:

Remainder of 2019	$ 633,704
2020	715,352
2021	715,352
2022	715,352
2023	715,352

5. PROPERTY AND EQUIPMENT

Property and equipment and related accumulated depreciation are summarized as follows:

	March 31, 2019	December 31, 2018
Manufacturing and laboratory equipment	$ 8,366,402	$ 8,233,203
Office equipment and computer software	1,571,178	1,608,994
Furniture and fixtures	1,212,045	1,163,552
Construction in process	911,744	845,538
Leasehold improvements	1,673,084	1,660,709
Land	4,339,441	4,339,441
Buildings and building improvements	15,700,092	15,685,325
	33,773,986	33,536,762
Less: Accumulated depreciation	(4,079,222)	(3,421,032)
Total property and equipment, net	$ 29,694,764	$ 30,115,730

Fixed assets are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the asset's estimated useful life. Land is not depreciated. The buildings were assigned a useful life of 30 years. Property and equipment other than land and buildings have useful lives ranging from 3 to 10 years. Leasehold improvements are amortized over the lesser of the lease term or their estimated useful lives.

The Company recorded depreciation expense on property and equipment for the three months ended March 31, 2019 and 2018 of $0.6 million. Depreciation expense for the three months ended March 31, 2018 includes $0.1 million on the plasma assets that were transferred to Biotest on January 1, 2019 (see Notes 1 and 11).

6. DEBT

Senior Notes Payable

A summary of outstanding senior notes payable is as follows:

	March 31, 2019	December 31, 2018
Notes payable:	$ 45,000,000	$ 30,000,000
Less:		
Debt discount	(4,114,897)	(3,559,170)
Senior notes payable	$ 40,885,103	$ 26,440,830

On February 11, 2019, (the "Perceptive Closing Date"), the Company and all of its subsidiaries entered into a Credit Agreement and Guaranty (the "Perceptive Credit Agreement") with Perceptive Credit Holdings II, LP, as the lender and administrative agent ("Perceptive"). The Perceptive Credit Agreement provides for a senior secured term loan facility in a principal amount of up to $72.5 million (the "Perceptive Credit Facility"), comprised of (i) a term loan made on the Perceptive Closing Date in the principal amount of $45.0 million, as evidenced by the Company's issuance of a promissory note (the "Perceptive Tranche I Note") in favor of Perceptive on the Perceptive Closing Date (the "Perceptive Tranche I Loan"), and (ii) an additional term loan in the principal amount of up to $27.5 million, but no less than $10.0 million (the "Perceptive Tranche II Loan" and, together with the Perceptive Tranche I Loan, the "Initial Perceptive Loans"), which Perceptive Tranche II Loan was made in full on May 3, 2019 (see Note 14). The Perceptive Credit Facility has a maturity date of March 1, 2022 (the "Maturity Date"), subject to acceleration pursuant to the Perceptive Credit Agreement, including upon an Event of Default (as defined in the Perceptive Credit Agreement).

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On the Perceptive Closing Date, the Company used $30.0 million of the Perceptive Tranche I Loan to terminate and pay in full all of the outstanding obligations under its previously existing credit agreement with Marathon Healthcare Finance Fund, L.P. ("Marathon") (the "Marathon Credit Facility"). The Company also (i) used $2.8 million of the Perceptive Tranche I Loan to pay a deferred facility fee to Marathon, (ii) used $6.5 million of the Perceptive Tranche I Loan to pay a prepayment penalty to Marathon, (iii) used $0.7 million of the Perceptive Tranche I Loan to pay outstanding accrued interest to Marathon, and (iv) used proceeds of the Perceptive Tranche I Loan to pay certain fees and expenses incurred in connection with the Perceptive Credit Facility of approximately $1.5 million. In addition, Marathon released $4.0 million of cash that was held in a debt service reserve account per the terms of the Marathon Credit Facility, which was reflected as restricted cash in the accompanying consolidated balance sheet as of December 31, 2018, to the Company.

As a result of the Company's entering into the Perceptive Credit Agreement and terminating the Marathon Credit Facility, the Company recognized a loss on the extinguishment of debt in the amount of approximately $10.0 million, comprised of the $6.5 million prepayment penalty and the write-off of unamortized debt discount related to the Marathon Credit Facility in the amount of $3.5 million.

Borrowings under the Perceptive Credit Agreement bear interest at a rate per annum equal to 7.5% plus the greater of (i) one-month LIBOR and (ii) 3.5%; provided, however, that upon, and during the continuance of, an Event of Default, the interest rate will automatically increase by an additional 400 basis points. On the last day of each month during the term of the Perceptive Credit Facility, the Company will pay accrued interest to Perceptive. The rate of interest in effect as of the Perceptive Closing Date and at March 31, 2019 was 11.0%.

On the Maturity Date, the Company will pay Perceptive the entire outstanding principal amount underlying the Perceptive Loans and any accrued and unpaid interest thereon. Prior to the Maturity Date, there will be no scheduled principal payments on the Perceptive Loans. The Company may prepay outstanding principal on the Perceptive Loans at any time and from time to time upon three business days' prior written notice, subject to the payment to Perceptive of, (A) any accrued but unpaid interest on the prepaid principal amount plus (B) a redemption premium amount equal to (i) 5.0% of the prepaid principal amount, if prepaid on or prior to the first anniversary of the Perceptive Closing Date, (ii) 4.0% of the prepaid principal amount, if prepaid after the first anniversary of the Perceptive Closing Date and on or prior to the second anniversary of the Perceptive Closing Date, or (iii) 3.0% of the prepaid principal amount, if prepaid after the second anniversary of the Perceptive Closing Date and on or prior to the third anniversary of the Perceptive Closing Date.

All of the Company's obligations under the Perceptive Credit Agreement are secured by a first-priority lien and security interest in substantially all of the Company's tangible and intangible assets, including intellectual property and all of the equity interests in the Company's subsidiaries. The Perceptive Credit Agreement contains certain representations and warranties, affirmative covenants, negative covenants and conditions that are customarily required for similar financings. The negative covenants restrict or limit the ability of the Company and its subsidiaries to, among other things and subject to certain exceptions contained in the Perceptive Credit Agreement, incur new indebtedness; create liens on assets; engage in certain fundamental corporate changes, such as mergers or acquisitions, or changes to the Company's or subsidiaries' business activities; make certain Investments or Restricted Payments (each as defined in the Perceptive Credit Agreement); change its fiscal year; pay dividends; repay other certain indebtedness; engage in certain affiliate transactions; or enter into, amend or terminate any other agreements that have the impact of restricting the Company's ability to make loan repayments under the Perceptive Credit Agreement. In addition, the Company must (i) at all times prior to the Maturity Date maintain a minimum cash balance of $3.0 million; and (ii) as of the last day of each fiscal quarter commencing with the fiscal quarter ending June 30, 2019, receive revenue for the trailing 12-month period in amounts set forth in the Perceptive Credit Agreement, which range from $7.0 million for the fiscal quarter ending June 30, 2019 to $55.0 million for the fiscal quarter ending December 31, 2021.

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As consideration for the Perceptive Credit Agreement, the Company issued to Perceptive, on the Perceptive Closing Date, a warrant to purchase 1,360,000 shares of the Company's common stock (the "Perceptive Warrant"). The Perceptive Warrant has an exercise price equal to $3.28 per share, which is equal to the trailing 10-day VWAP of the Company's common stock on the business day immediately prior to the Perceptive Closing Date multiplied by 1.15. The Perceptive Warrant was valued by the Company at $2.7 million as of the Perceptive Closing Date and has an expiration date of February 11, 2029. Perceptive represented to the Company, among other things, that it was an "accredited investor" (as such term is defined in Rule 501(a) of Regulation D under the Securities Act) and the Company issued the Perceptive Warrant in reliance upon an exemption from registration contained in Section 4(2) under the Securities Act. The Perceptive Warrant and the shares of common stock issuable thereunder may not be offered, sold, pledged or otherwise transferred in the U.S. absent registration or an applicable exemption from the registration requirements under the Securities Act.

As a result of the fees paid to Perceptive and the value of the Perceptive Warrant, the Company recognized a discount on the Perceptive Initial Note in the amount of $4.3 million. The Company records debt discount as a reduction to the face amount of the debt, and the debt discount is amortized as interest expense over the life of the debt using the interest method. Based on the fair value of the Perceptive Warrant and the aggregate amount of fees and expenses associated with obtaining the Perceptive Credit Facility, the effective interest rate on the Perceptive Initial Note as of the Perceptive Closing Date was approximately 14.7%.

Related Party Note Payable

A summary of the outstanding related party note payable is as follows:

	March 31, 2019	December 31, 2018
Related party note payable to Biotest	$ 15,000,000	$ 15,000,000
Less:		
Debt discount	(117,663)	(125,816)
Note payable - related party	$ 14,882,337	$ 14,874,184

In connection with the acquisition of the Biotest Assets (see Note 1), ADMA BioManufacturing issued a subordinated note payable to BPC and in connection therewith received cash proceeds of $15.0 million. This note has since been assigned from BPC to Biotest AG. The note bears interest at a rate of 6.0% per annum and matures on June 6, 2022. The Company is obligated to make semi-annual interest payments, with all principal and unpaid interest due at maturity. The note is subordinate to all amounts outstanding under the Perceptive Credit Agreement. In the event of default, all principal and unpaid interest is due on demand. The subordinated note also contains several non-financial covenants with which the Company was in compliance as of March 31, 2019.

7. STOCKHOLDERS' EQUITY

Preferred Stock

The Company is currently authorized to issue up to 10 million shares of preferred stock, $0.0001, par value per share. There were no shares of preferred stock outstanding at March 31, 2019 and December 31, 2018.

Common Stock

As of March 31, 2019 and December 31, 2018, the Company was authorized to issue 75,000,000 shares of its common stock, $0.0001 par value per share, and 46,353,068 shares of common stock were outstanding. After giving effect to shares reserved for the issuance of warrants and stock options, as of March 31, 2019, 21,159,337 shares of common stock were available for issuance.

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Warrants

On the Perceptive Closing Date, the Company issued the Perceptive Warrant, whereby Perceptive may purchase an aggregate of 1,360,000 shares of common stock at an exercise price of $3.28 per share. The Perceptive Warrant became exercisable on the Perceptive Closing Date, and were valued at $2.7 million. The Perceptive Warrant was valued using the Black-Scholes option-pricing model assuming an expected term of 10 years, a volatility of 61.2%, a dividend yield of 0% and a risk-free interest rate of 2.65%. At March 31, 2019, the Company had outstanding warrants to purchase an aggregate of 1,888,160 shares of common stock, with a weighted average exercise price of $3.69 per share and expiration dates ranging between June 2022 and February 2029.

Equity Incentive Plans

The fair value of stock options granted under the Company's 2007 Employee Stock Option Plan (the "2007 Plan") and the ADMA Biologics, Inc. 2014 Omnibus Incentive Compensation Plan, as amended and restated (the "2014 Plan"), was determined on the date of grant using the Black-Scholes option valuation model. The Black-Scholes model was developed for use in estimating the fair value of publicly traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of certain subjective assumptions including the expected stock price volatility. The stock options granted to employees and directors have characteristics significantly different from those of traded options, and changes in the subjective input assumptions can materially affect the fair value estimate. The following assumptions were used to determine the fair value of options granted during the three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,	
	2019	**2018**
Expected term	5.8 - 6.3 years	6.3 years
Volatility	61%	57%
Dividend yield	0.0	0.0
Risk-free interest rate	2.25-2.63%	2.59%

During the three months ended March 31, 2019 and 2018, the Company granted options to purchase an aggregate of 1,330,850 and 848,700 shares of common stock, respectively, to its directors and employees. Also during the three months ended March 31, 2019 and 2018, the Company granted options to purchase 5,000 and 20,000 shares of common stock, respectively, to third party service providers.

The weighted average remaining contractual life of stock options outstanding and expected to vest at March 31, 2019 is 7.8 years. The weighted average remaining contractual life of stock options exercisable at March 31, 2019 is 6.3 years.

A summary of the Company's option activity under the 2007 Plan and 2014 Plan and related information is as follows:

	Shares	**Weighted Average Exercise Price**
Balance at December 31, 2018	4,342,231	$ 5.16
Forfeited	(74,906)	$ 4.61
Expired	(3,740)	$ 4.75
Granted	1,335,850	$ 3.42
Exercised	—	$ —
Balance at March 31, 2019	5,599,435	$ 4.75
Options exercisable	2,588,091	$ 5.93

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Stock-based compensation expense for the three ended March 31, 2019 and 2018 is as follows:

	2019	2018
Research and development	$ 86,523	$ 78,305
Plasma centers	11,540	7,086
Selling, general and administrative	498,471	394,858
Cost of product revenue	40,729	34,535
Total stock-based compensation expense	$ 637,263	$ 514,784

As of March 31, 2019, the Company had $6.2 million of unrecognized compensation expense related to options granted under the Company's equity incentive plans, which is expected to be recognized over a weighted-average period of 2.8 years.

8. RELATED PARTY TRANSACTIONS

The Company leases an office building and equipment from Areth, LLC ("Areth") pursuant to an agreement for services effective as of January 1, 2016, as amended from time to time. Effective October 1, 2017, monthly rent on this facility was reduced to $10,000. On September 27, 2018, the agreement was amended to extend the term of the agreement through September 30, 2019. Rent expense amounted to $30,000 for the three months ended March 31, 2019 and 2018, and includes fees for the use of such office space and for other information technology, general warehousing and administrative services. Areth is a company controlled by Dr. Jerrold B. Grossman, the Company's Vice Chairman, and Adam S. Grossman, the Company's President and Chief Executive Officer. The Company also reimburses Areth for office and building related (common area) expenses, equipment and certain other operational expenses, which were not material to the consolidated financial statements for the three months ended March 31, 2019 and 2018.

As part of the Biotest Transaction, the Company issued a $15.0 million subordinated note payable to Biotest (see Note 6), and recognized interest expense on this note for the three months ended March 31, 2019 and 2018 in the amount of $0.2.

For the three months ended March 31, 2019 and 2018, the Company recognized revenues under its out-licensing agreements with Biotest of approximately $36,000. Deferred revenue of $2.5 million as of March 31, 2019 and December 31, 2018 is related to these agreements.

Biotest was historically the Company's largest customer for the sale of normal source plasma. Plasma sales to Biotest for the three months ended March 31, 2018 were $2.3 million. The agreement under which the Company supplied normal source plasma to Biotest expired by its terms on December 31, 2018 and was not renewed. Accounts receivable includes $0 and $1.0 million due from Biotest as of March 31, 2019 and December 31, 2018, respectively. Additionally, Biotest is a supplier of plasma to ADMA. For the three months ended March 31, 2019 and 2018, the Company purchased $0.2 million of plasma from Biotest. Included in accounts payable is $0.3 million and $2.0 million due to Biotest as of March 31, 2019 and December 31, 2018, respectively. The following table summarizes the related party balances with Biotest:

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	Three Months Ended March 31,	
	2019	**2018**
Sale and purchase of plasma		
Product revenue	$ —	$ 2,328,291
Purchases	160,489	195,018
License revenue	35,708	35,708
Interest expense	225,000	225,000

	March 31, 2019	**December 31, 2018**
Accounts receivable	$ —	$ 961,145
Accounts payable	296,362	2,010,774
Accrued expenses	24,049	10,659
Note payable, net of discount	14,882,337	14,874,184
Accrued interest	290,000	65,000
Deferred revenue	2,511,491	2,547,199

In connection with the acquisition of the Biotest Assets, the Company entered into a Transition Services Agreement with BPC pursuant to which each of the Company and BPC agreed to provide transition services to the other party, including services related to finance, human resources, information technologies, leasing of equipment and clinical and regulatory services for a period of up to 24 months after the June 6, 2017 closing date, as well as agreements to lease certain laboratory space within the Boca Facility to BPC for a period of up to 24 months after the closing date of the acquisition transaction. As of March 31, 2019 and December 31, 2018, approximately $24,000 and $11,000, respectively, was payable by the Company to BPC for services rendered and expenses incurred on behalf of the Company related to these agreements. This amount is reflected in accrued expenses in the accompanying consolidated balance sheets.

Under the terms of the acquisition of the Biotest Assets, the Company transferred ownership of two plasma collection centers to BPC on January 1, 2019 (see Note 11). The Company and BPC entered into an additional transition services agreement effective as of January 1, 2019 under which the Company agreed to provide certain transition services to BPC related to the plasma collection centers that were transferred. Amounts billed to BPC by the Company under this agreement for the three months ended March 31, 2019 were not material to the consolidated financial statements.

See Notes 6 and 14 for a discussion of the Company's credit facility and related transactions with Perceptive, a holder of greater than 10% of the Company's common stock.

9. COMMITMENTS AND CONTINGENCIES

General Legal Matters

From time to time the Company is or may become subject to certain legal proceedings and claims arising in connection with the normal course of its business. Management does not expect that the outcome of any such claims or actions will have a material effect on the Company's liquidity, results of operations or financial condition.

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NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Contract manufacturing agreement

In connection with the acquisition of the Biotest Assets, the Company acquired all of the rights and assumed all of the obligations under an existing agreement with a third party related to the fractionation of plasma provided by the third party. This contract, as amended from time to time, maintains minimum production requirements as well as a payment due to the counterparty to the contract of $1.5 million per year if the minimum volume is not manufactured in that year and no other breach or default under the contract has occurred.

Post-marketing commitments

In connection with the approval of the BLA for BIVIGAM, on December 19, 2012 Biotest committed to perform two additional post-marketing studies, a pediatric study to evaluate the efficacy and safety of BIVIGAM in children and adolescents, and a post-authorization safety study to further assess the potential risk of hypotension and hepatic and renal impairment in BIVIGAM-treated patients with primary humoral immunodeficiency. These studies are still pending completion, ADMA has assumed the remaining obligations, and the costs of the studies will be expensed as incurred as research and development expenses. The Company currently expects both studies to be completed by the end of 2021. However, the timing of the completion of these studies is dependent upon the availability of BIVIGAM and the completion of the planned manufacturing process improvements.

Other commitments

In the normal course of business, the Company enters into contracts that contain a variety of indemnifications with its employees, licensors, suppliers and service providers. Further, the Company indemnifies its directors and officers who are, or were, serving at the Company's request in such capacities. The Company's maximum exposure under these arrangements is unknown as of March 31, 2019. The Company does not anticipate recognizing any significant losses relating to these arrangements.

10. SEGMENTS

The Company is engaged in the manufacture, marketing and development of specialty plasma-derived biologics. The Company's ADMA BioManufacturing segment reflects the Company's immune globulin manufacturing and development operations in Boca Raton, FL, acquired on June 6, 2017 (see Note 1). The Plasma Collection Centers segment consists of one and three FDA-licensed source plasma collection facility located in Georgia for the three months ended March 31, 2019 and 2018, respectively. The Corporate segment includes general and administrative overhead expenses. The Company defines its segments as those business units whose operating results are regularly reviewed by the chief operating decision maker ("CODM") to analyze performance and allocate resources. The Company's CODM is its President and Chief Executive Officer. Summarized financial information concerning reportable segments is shown in the following tables:

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Three Months Ended March 31, 2019

	ADMA BioManufacturing	Plasma Collection Centers	Corporate	Consolidated
Revenues	$ 1,343,983	$ 2,148,898	$ 35,708	$ 3,528,589
Cost of product revenue	7,940,346	1,464,833	—	9,405,179
(Loss) income from operations	(10,620,807)	29,579	(2,617,188)	(13,208,416)
Interest and other (expense) income, net	(169,613)	13,620	(1,268,472)	(1,424,465)
Gain on transfer of plasma center assets	—	11,527,421	—	11,527,421
Loss on extinguishment of debt	—	—	(9,962,495)	(9,962,495)
Net (loss) income	(10,790,420)	11,570,620	(13,848,155)	(13,067,955)
Capital expenditures	110,453	—	—	110,453
Depreciation and amortization expense	687,393	114,241	3,696	805,330
Total assets	57,529,070	4,038,367	16,552,533	78,119,970

Three Months Ended March 31, 2018

	ADMA BioManufacturing	Plasma Collection Centers	Corporate	Consolidated
Revenues	$ 1,666,243	$ 2,340,055	$ 35,708	$ 4,042,006
Cost of product revenue	10,697,642	1,545,106	—	12,242,748
Loss from operations	(12,724,718)	(1,038,824)	(2,768,961)	(16,532,503)
Interest and other expense, net	(240,054)	(435)	(1,049,150)	(1,289,639)
Net loss	(12,964,772)	(1,039,259)	(3,818,111)	(17,822,142)
Total assets	47,481,781	27,532,613	16,123,231	91,137,625
Depreciation and amortization expense	631,832	188,914	8,795	829,541
Capital expenditures	105,199	444,047	—	549,246

11. TRANSFER OF PLASMA CENTER ASSETS

As part of the purchase price for the Biotest Transaction (see Note 1), the Company transferred its Marietta, GA and Norcross, GA plasma collection centers to BPC effective January 1, 2019. The Company had estimated the combined fair value of the two facilities to be $12.6 million, and the Company recorded an obligation for this amount as of the date of the Biotest Transaction, which is reflected in non-current liabilities in the accompanying consolidated balance sheet as of December 31, 2018. On January 1, 2019, upon the transfer of the two plasma collection facilities to BPC, the Company recorded a gain in the amount of $11.5 million, which reflects the derecognition of the obligation to transfer ownership of the two facilities net of the carrying value of the assets associated with these facilities, primarily property and equipment and inventory, in the amount of $1.1 million.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

12. LEASE OBLIGATIONS

The Company leases certain properties and equipment for its ADMA Bio Centers subsidiary and certain equipment for its ADMA BioManufacturing subsidiary, which leases provide the right to use the underlying assets and require lease payments through the respective lease terms which expire at various dates through 2026. The Company's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

The Company determines if an arrangement is an operating lease at inception. Leases with an initial term of 12 months or less are not recorded on the balance sheet. All other leases are recorded on the balance sheet with assets representing the right to use the underlying asset for the lease term and lease liabilities representing the obligation to make lease payments arising from the lease. Right-to-use assets and lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term and include options to extend or terminate the lease when they are reasonably certain to be exercised. The present value of the lease payments is determined using the Company's incremental borrowing rate as of the date of application of ASU 2016-02, or the lease commencement date. For the lease liabilities recognized upon the application of ASU 2016-02, the Company used a discount rate of 13% to determine the present value of its lease obligations. The Company's operating lease expense is recognized on a straight-line basis over the lease term and is reflected in Plasma center operating expenses and Selling, general and administrative expenses. Aggregate rent expense and cash paid for the Company's operating leases was $0.1 million for the three months ended March 31, 2019.

In connection with the adoption of ASU 2016-02 on January 1, 2019 (see Note 2), the Company recognized right to use assets and lease liabilities of approximately $1.4 million. The right-to-use assets are reflected in Deposits and other assets in the accompanying consolidated balance sheet as of March 31, 2019. Including a finance lease the Company entered into in June 2018, the Company has aggregate lease liabilities of $1.7 million as of March 31, 2019, which are comprised primarily of the lease for the Company's plasma collection center in Kennesaw, GA and an administrative office lease in Roswell, GA related to the Company's ADMA Bio Centers subsidiary. The Company's operating leases have a weighted average remaining term of 6.6 years. Scheduled payments under the Company's lease obligations are as follows:

Remainder of 2019	$	303,686
Year ended December 31, 2020		400,837
2021		378,932
2022		379,969
2023		360,197
Thereafter		606,913
Total payments		2,430,534
Less: imputed interest		(759,576)
Balance at March 31, 2019	$	1,670,958

13. SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

Supplemental cash flow information for the three months ended March 31, 2019 and 2018 is as follows:

	2019	2018
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	$ 1,369,939	$ 825,513
Noncash Financing and Investing Activities:		
Equipment acquired reflected in accounts payable and accrued liabilities	$ 35,823	$ 116,766
Warrants issued in connection with notes payable	$ 2,699,208	$ —

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

14. SUBSEQUENT EVENTS

BLA Approval

On April 1, 2019, the FDA approved ASCENIV, Immune Globulin Intravenous, Human – slra 10% Liquid, formerly referred to as RI-002. ASCENIV is an IVIG drug product for the treatment of PI in adults and adolescents (12 to 17 years of age). The Company anticipates having the product available for commercial launch during the second half of 2019.

Credit Facility

On May 3, 2019, in connection with the FDA's approval of ASCENIV, the Company accessed the additional $27.5 million available under the Perceptive Credit Facility through the issuance of a promissory note evidencing the Perceptive Tranche II Loan (see Note 6). The Company intends to use the proceeds from the Perceptive Tranche II Loan (i) to support the commercial launch of ASCENIV anticipated during the second half of 2019, (ii) to expand the Company's plasma collection facility network; and (iii) for working capital and general corporate purposes, including the procurement of raw material inventory.

Also on May 3, 2019, the Company and Perceptive entered into an amendment to the Perceptive Credit Agreement (the "Perceptive Amendment") whereby Perceptive agreed to an additional commitment under the Perceptive Credit Facility in the principal amount of up to $12.5 million (the "Perceptive Tranche III Loan") to be drawn-down at the Company's sole option. The Perceptive Tranche III Loan is subject to the satisfaction of certain conditions, including, but not limited to, FDA approval of the BIVIGAM PAS and no Material Adverse Changes (as defined in the Perceptive Credit Agreement) having occurred since December 31, 2018; provided that the Perceptive Tranche III Loan would not be made later than March 31, 2020. The Perceptive Tranche III Loan will have terms that are substantially identical to those of the Initial Perceptive Loans. The Perceptive Amendment required the Company to pay certain proceeds of the Perceptive Tranche II Loan to Perceptive on May 3, 2019 as a facility fee. In addition, the Company issued a warrant (the "Perceptive Tranche III Warrant") to purchase 250,000 shares of the Company's common stock to Perceptive with an exercise price equal to $4.64 per share, which represents the trailing 10-day volume weighted average price of the Company's common stock as of May 2, 2019. The warrant has an expiration date of May 3, 2029.

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

The following discussion of our financial condition and results of operations, which refers to our historical results, should be read in conjunction with the other sections of this Quarterly Report on Form 10-Q, including "Risk Factors" and our unaudited consolidated financial statements and the notes thereto appearing elsewhere herein, and in conjunction with the Management's Discussion and Analysis of Financial Condition and Results of Operations set forth in our Annual Report on Form 10-K for the year ended December 31, 2018, filed on March 13, 2019 (the "2018 10-K"). The various sections of this discussion contain a number of forward-looking statements, all of which are based on our current expectations and could be affected by the uncertainties and risk factors described throughout or referenced within this Quarterly Report on Form 10-Q. See "Special Note Regarding Forward-Looking Statements." Our actual results may differ materially.

OVERVIEW

Our Business

ADMA Biologics, Inc. (the "Company", "ADMA", "we", "us" or "our") is a vertically integrated commercial biopharmaceutical and specialty immunoglobulin company that manufactures, markets and develops specialty plasma-derived biologics for the treatment of immune deficiencies and the prevention and treatment of certain infectious diseases. Our targeted patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disorder or who may be immune-suppressed for medical reasons.

We currently have three products with United States Food and Drug Administration (the "FDA") Biologics License Application ("BLA") approvals: Nabi-HB (Hepatitis B Immune Globulin, Human), which is currently marketed and commercially available and is indicated for the treatment of acute exposure to blood containing Hepatitis B surface antigen ("HBsAg"), and other listed exposures to Hepatitis B; ASCENIV (Immune Globulin Intravenous, Human – slra 10% Liquid), previously referred to as RI-002, an Intravenous Immune Globulin ("IVIG") product for the treatment of Primary Humoral Immunodeficiency Disease ("PIDD" or "PI"), for which we received FDA approval on April 1, 2019; and BIVIGAM (Immune Globulin Intravenous, Human), for which commercial distribution has been temporarily suspended since December 2016 and for which we have submitted a Prior Approval Supplement (the "PAS") to the FDA to amend the approved BLA to allow for the commercial re-launch of the product, which is indicated for the treatment of primary humoral immunodeficiency. We cannot provide any assurances or predict with any certainty the schedule for which we will, if at all, receive approval from the FDA with respect to the PAS. We seek to develop a pipeline of plasma-derived therapeutics, including a product based on our most recently approved patent application under U.S. Patent No. 10,259,865 related to methods of treatment and prevention of *S. pneumonia* infection for an immunoglobulin manufactured to contain standardized antibodies to numerous serotypes of *S. pneumonia*. Our products and product candidates are intended to be used by physician specialists focused on caring for immune-compromised patients with or at risk for certain infectious diseases.

During fiscal 2018, through our wholly-owned subsidiary, ADMA Bio Centers Georgia, Inc. ("ADMA Bio Centers"), we operated three FDA-licensed source plasma collection facilities located in the U.S., two of which were transferred to Biotest Pharmaceuticals Corporation ("BPC") on January 1, 2019, pursuant to the acquisition transaction described below. Our remaining source plasma collection facility located in Kennesaw, GA provides us with a portion of our blood plasma for the manufacture of our products and product candidates. We intend to open additional plasma collection centers in the U.S. during the next few years. A typical plasma collection center, such as those operated by ADMA Bio Centers, can collect approximately 30,000 to 50,000 liters of source plasma annually, which may be sold for different prices depending upon the type of plasma, quantity of purchase and market conditions at the time of sale. Plasma collected from ADMA Bio Centers' facilities that is not used to manufacture our products or product candidates is sold to third-party customers in the U.S., in other locations where plasma from ADMA Bio Centers is approved globally under supply agreements, or in the open "spot" market.

On June 6, 2017, we completed the acquisition of certain assets (the "Biotest Assets") of the Therapy Business Unit ("BTBU") of BPC (and, together with Biotest AG, "Biotest"), which included two FDA-licensed products, Nabi-HB and BIVIGAM, and a plasma fractionation facility located in Boca Raton, FL (the "Boca Facility") (the "Biotest Transaction"). BTBU was our third-party manufacturer for our then-lead pipeline product candidate, previously referred to as "RI-002." The Boca Facility is FDA-licensed and certified by the German Health Authority. In addition to the manufacture and sale of Nabi-HB and ASCENIV and the manufacture of BIVIGAM, we also provide contract manufacturing services for certain historical clients, including the potential sale of intermediate by-products.

Prior to the acquisition of BTBU and the FDA approval for ASCENIV, in July 2016 the FDA issued a Complete Response Letter ("CRL") to us for our Biologics License Application ("BLA") for RI-002. The RI-002 CRL reaffirmed the issues set forth in the November 2014 warning letter (the "Warning Letter") that had been issued by the FDA to Biotest related to certain compliance issues identified at the Boca Facility, but did not cite any concerns with the clinical safety or efficacy data for RI-002, nor did the FDA request any additional clinical studies be completed prior to FDA approval of RI-002. The FDA identified in the RI-002 CRL, among other things, certain outstanding inspection issues and deficiencies related to chemistry, manufacturing and controls and Good Manufacturing Practices at the Boca Facility and certain of our third-party vendors, and requested documentation of corrections for a number of these issues. The FDA had indicated in the RI-002 CRL that it could not grant final approval of the RI-002 BLA until, among other things, these deficiencies were resolved. Upon the completion of the Biotest Transaction, we gained control over the regulatory, quality, general operations and drug substance manufacturing process at the Boca Facility. In April 2018, the FDA inspected the Boca Facility and in July 2018 our FDA status with respect to the Boca Facility improved from Official Action Indicated to Voluntary Action Indicated, and we determined that this inspection of the Boca Facility was successfully closed out.

Our Products

ASCENIV (formerly referred to as RI-002)

ASCENIV is a plasma-derived, polyclonal, IVIG. ASCENIV is manufactured under a U.S. Department of Health and Human Services ("HHS") License No. 2019 using a process known as fractionation, using our unique, patented plasma donor screening methodology and tailored plasma pooling design, which blends normal source plasma and plasma from donors tested to have high levels of neutralizing titers to Respiratory Syncytial Virus ("RSV") using our proprietary microneutralization assay. ASCENIV contains naturally occurring polyclonal antibodies, and is indicated for the treatment of PIDD in adults and adolescents (12 to 17 years of age). Polyclonal antibodies are proteins that are used by the body's immune system to neutralize microbes, such as bacteria and viruses and prevent against infection and disease. ASCENIV is approved for the treatment of PIDD, having completed a pivotal Phase III clinical trial among fifty-nine patients treated for twelve months during the pivotal investigation and met the primary endpoint of no Serious Bacterial Infections ("SBIs") reported. Secondary efficacy endpoints further demonstrated the benefits of ASCENIV in the low incidence of infection, therapeutic antibiotic use, days missed from work/school/daycare and unscheduled medical visits and hospitalizations. We anticipate the commercial launch of ASCENIV during the second half of 2019. We believe this FDA approval better positions ADMA to further its mission to evaluate ASCENIV in immune-compromised patients infected with or at-risk for RSV infection. We look forward to working with the FDA and the immunology and infectious disease community on developing a clinical investigation to evaluate use of ASCENIV in this patient population in the near future.

Nabi-HB

Nabi-HB is a hyperimmune globulin that is rich in antibodies to the Hepatitis B virus. Nabi-HB is a purified human polyclonal antibody product collected from plasma donors who have been previously vaccinated with a Hepatitis B vaccine. Nabi-HB is indicated for the treatment of acute exposure to blood containing HBsAg, prenatal exposure of infants born to HBsAg-positive mothers, sexual exposure to HBsAg-positive persons and household exposure to persons with acute Hepatitis B virus infection in specific, listed settings. Hepatitis B is a potentially life-threatening liver infection caused by the Hepatitis B virus. It is a major global health problem. It can cause chronic infection and puts people at high risk of death from cirrhosis and liver cancer. Nabi-HB has a well-documented record of long-term safety and effectiveness since its initial market introduction. FDA approval for Nabi-HB was received on March 24, 1999. Biotest acquired Nabi-HB from Nabi Biopharmaceuticals in 2007. Production of Nabi-HB at the Boca Facility has continued under our leadership since the third quarter of 2017. Subsequent to the end of 2017, we received authorization from the FDA for the release of our first commercial batch of Nabi-HB for commercial distribution in the U.S.

BIVIGAM

BIVIGAM is an intravenous immune globulin indicated for the treatment of primary humoral immunodeficiency. This includes, but is not limited to, X-linked and congenital agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome and severe combined immunodeficiency. These primary immunodeficiencies ("PIs") are a group of genetic disorders. Initially thought to be very rare, it is now believed that as many as one in every 1,200-2,000 people has some form of PI. BIVIGAM contains a broad range of antibodies similar to those found in normal human plasma. These antibodies are directed against bacteria and viruses, and help to protect PI patients against serious infections. BIVIGAM is a purified, sterile, ready-to-use preparation of concentrated human Immunoglobulin G ("IgG") antibodies.

BIVIGAM is currently under FDA review for the PAS that we submitted to the FDA in June 2018 to amend BIVIGAM's FDA-approved BLA which, once approved, would enable us to relaunch and commercialize this product in the U.S. In December 2018, we received a CRL from the FDA in response to the PAS (the "BIVIGAM CRL"), and we have since received several information requests from the FDA, each containing a limited number of questions. We believe that all requests contained in the various information requests were addressable, and we have responded to all of them. To date we have not received a formal BIVIGAM CRL resubmission acknowledgement and have not received clarity on the FDA's intended classification or review timing. Although we believe that the FDA is actively reviewing the PAS submission and subsequent information request responses, we cannot provide any assurance or predict with certainty the schedule for when we will, if at all, receive authorization from the FDA with respect to the PAS. In addition, the anticipated relaunch of BIVIGAM is dependent upon the timing of certain FDA decisions, production slots available with our contracted fill/finish provider, approvals that may need to be obtained for product labeling as well as other commercial requirements and regulatory factors. Biotest had originally received FDA approval for BIVIGAM on December 19, 2012, prior to the acquisition of BTBU, and product sales commenced in the first quarter of 2013. In December 2016, Biotest temporarily suspended the commercial production of BIVIGAM in order to focus on the completion of planned improvements to the manufacturing process. ADMA resumed production of BIVIGAM during the fourth quarter of 2017.

RESULTS OF OPERATIONS

Critical Accounting Policies and Estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our consolidated financial statements, which have been prepared in accordance with Accounting Principles Generally Accepted in the United States of America ("U.S. GAAP"). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate these estimates and assumptions, including those described below. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates. Significant estimates include the fair value of assets acquired and liabilities assumed in a business combination, realizable value of accounts receivable, valuation of inventory, assumptions used in the fair value of awards granted under our equity incentive plans and warrants issued in connection with the issuance of notes payable and the valuation allowance for our deferred tax assets.

Some of the estimates and assumptions we have to make under U.S. GAAP require difficult, subjective and/or complex judgments about matters that are inherently uncertain and, as a result, actual results could differ from those estimates. Due to the estimation processes involved, the following summary of accounting policies and their application are considered to be critical to understanding our business operations, financial condition and results of operations. For a detailed discussion on the application of these and our other accounting policies, see Note 2 to the Consolidated Financial Statements included in the 2018 10-K.

Revenue Recognition

Revenues for the three months ended March 31, 2019 are comprised of (i) revenues from Nabi-HB, (ii) product revenues from the sale of human plasma collected from our plasma collection centers business segment; and (iii) license and other revenues primarily attributable to the out-licensing of RI-002 to Biotest to market and sell this product in Europe and selected countries in North Africa and the Middle East. Biotest has provided us with certain services and financial payments in accordance with the related Biotest license agreement and is obligated to pay us certain amounts in the future if certain milestones are achieved. Deferred revenue is amortized into income for a period of approximately 22 years from December 31, 2012, the term of the Biotest license agreement.

Product revenue is recognized when the customer is deemed to have control over the product. Control is determined based on when the product is shipped or delivered and title passes to the customer. Revenue is recorded in an amount that reflects the consideration we expect to receive in exchange. Revenue from the sale of Nabi-HB is recognized when the product reaches the customer's destination, and is recorded net of estimated rebates, price protection arrangements and customer incentives, including prompt pay discounts, wholesaler chargebacks and other wholesaler fees. These estimates are based on historical experience, and we believe that such estimates are reasonable. For revenues associated with contract manufacturing, control transfers to the customer and the performance obligation is satisfied when the customer takes possession of the product from the Boca Facility.

Product revenues from the sale of human plasma collected at our plasma collection centers are recognized at the time control of the product has been transferred to the customer, which generally occurs at the time of shipment. Product revenues are recognized at the time of delivery if we retain control of the product during shipment.

For the three months ended March 31, 2019, two customers represented an aggregate of 81% of our consolidated revenues, with Biolife Plasma Services, L.P. ("Biolife") and AmerisourceBergen representing 61%, and 20%, respectively, of our consolidated revenues. For the three months ended March 31, 2018, three customers represented an aggregate of 90% of our consolidated revenues, with BPC, McKesson Corporation ("McKesson") and AmerisourceBergen representing 58%, 17% and 15%, respectively, of our consolidated revenues.

Accounts Receivable

Accounts receivable are reported at realizable value, net of allowances for contractual credits and doubtful accounts, which are recognized in the period the related revenue is recorded. At March 31, 2019, four customers represented an aggregate of 96% of our total accounts receivable, with Biolife, AmerisourceBergen, McKesson and Cardinal Health representing approximately 32%, 29%, 20% and 15%, respectively, of our consolidated accounts receivable. At December 31, 2018, BPC, AmerisourceBergen and Cardinal Health accounted for 59%, 23% and 12%, respectively, of our consolidated accounts receivable.

Cost of Product Revenue

Cost of product revenue includes expenses related to process development as well as scientific and technical operations when these operations are attributable to marketed products. When the activities of these operations are attributable to new products in development, the expenses are classified as research and development expenses. Expenses associated with remediating the issues identified at the Boca Facility by the FDA prior to the closing of the Biotest Transaction for the three months ended March 31, 2019 and 2018 of approximately $0.1 million and $0.7 million, respectively, are expensed as incurred and are reflected in cost of product revenue. In addition, for the three months ended March 31, 2019, all operating expenses associated with the Boca Facility, other than the Nabi-HB production and contract manufacturing production that was capitalized into inventory, have been expensed as incurred.

Stock-Based Compensation

Stock-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the grantee's requisite vesting period on a straight-line basis. For the purpose of valuing stock options granted to our employees, directors and officers, we use the Black-Scholes option pricing model. We granted options to purchase an aggregate of 1,335,850 and 868,700 shares of common stock, $0.0001 par value per share ("Common Stock") during the three months ended March 31, 2019 and 2018, respectively. To determine the risk-free interest rate, we utilized the U.S. Treasury yield curve in effect at the time of the grant with a term consistent with the expected term of our awards. The expected term of the options granted is in accordance with Staff Accounting Bulletins 107 and 110, and is based on the average between vesting terms and contractual terms. The expected dividend yield reflects our current and expected future policy for dividends on our Common Stock. The expected stock price volatility for our stock options was calculated by examining the historical volatility of our Common Stock since our Common Stock became publicly traded in the fourth quarter of 2013.

Research and Development Expenses

Our research and development ("R&D") costs consist of clinical research organization costs, costs related to clinical trials, post-marketing commitment studies for BIVIGAM , assay development and testing, storage and transportation costs for high-titer plasma used in the historical manufacture of ASCENIV, as well as wages, benefits and stock-based compensation for employees directly related to R&D activities. All R&D costs are expensed as incurred.

Impairment of Long-Lived Assets

We assess the recoverability of our long-lived assets, which include property and equipment and definite-lived intangible assets, whenever significant events or changes in circumstances indicate impairment may have occurred. If indicators of impairment exist, projected future undiscounted cash flows associated with the asset are compared to its carrying amount to determine whether the asset's value is recoverable. Any resulting impairment is recorded as a reduction in the carrying value of the related asset in excess of fair value and a charge to operating results. For the three months ended March 31, 2019 and 2018, we determined that there was no impairment of our long-lived assets.

Goodwill is not amortized, but is assessed for impairment on an annual basis or more frequently if impairment indicators exist. We have the option to perform a qualitative assessment of goodwill to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount, including goodwill and other intangible assets. If we were to conclude that this is the case, then we must perform a goodwill impairment test by comparing the fair value of the reporting unit to its carrying value. An impairment charge is recorded to the extent the reporting unit's carrying value exceeds its fair value, with the impairment loss recognized not to exceed the total amount of goodwill allocated to that reporting unit. We did not recognize any impairment charges related to goodwill for the three months ended March 31, 2019 and 2018.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, Leases (Topic 842) ("ASU 2016-02"), which requires lessees to recognize assets and liabilities for the rights and obligations created by most leases on their balance sheet. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. ASU 2016-02 requires modified retrospective adoption for all leases existing at, or entered into after, the date of initial application, with an option to use certain transition relief. We adopted ASU 2016-02 on January 1, 2019 using the option to recognize the cumulative-effect adjustment, if any, as of the date of application, which was also January 1, 2019. As a result, there will be no restatement of comparative periods. We recognized right-to-use assets and corresponding lease liabilities of approximately $1.4 million at the date of adoption (see Note 12 to the consolidated financial statements). The right-to-use assets are reflected in Deposits and other assets in the accompanying consolidated balance sheet as of March 31, 2019. We also elected the "package of practical expedients", which permits us to not reassess under the new standard our prior conclusions about lease identification, lease classification and initial direct costs. In addition, we elected the short-term lease recognition exemption for all leases that qualify.

In July 2017, the FASB issued ASU No. 2017-11, Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815)" ("ASU 2017-11"). ASU 2017-11 changed the classification analysis of certain equity-linked financial instruments (or embedded features within such instruments) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) would no longer be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share ("EPS") in accordance with ASC 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. In addition, convertible instruments with embedded conversion options that have down round features are now subject to the specialized guidance for contingent beneficial conversion features in ASC 470-20, "Debt—Debt with Conversion and Other Options." ASU 2017-11 became effective for us on January 1, 2019, and this update did not have a significant impact on our consolidated financial statements.

Three Months Ended March 31, 2019 Compared to Three Months Ended March 31, 2018

The following table presents a summary of the changes in our results of operations for the three months ended March 31, 2019, our first fiscal quarter, compared to the three months ended March 31, 2018:

	Three Months Ended March 31,		
	2019	2018	Increase (Decrease)
Revenues	$ 3,528,589	$ 4,042,006	$ (513,417)
Cost of product revenue (exclusive of amortization expense shown below)	9,405,179	12,242,748	(2,837,569)
Gross loss	(5,876,590)	(8,200,742)	2,324,152
Research and development expenses	870,635	965,571	(94,936)
Plasma center operating expenses	654,486	1,833,774	(1,179,288)
Amortization of intangibles	211,235	211,235	—
Selling, general and administrative expenses	5,595,470	5,321,181	274,289
Loss from operations	(13,208,416)	(16,532,503)	3,324,087
Interest expense	(1,540,507)	(1,323,152)	(217,355)
Loss on extinguishment of debt	(9,962,495)	—	(9,962,495)
Gain on transfer of plasma center assets	11,527,421	—	11,527,421
Interest and other income, net	116,042	33,513	82,529
Net loss	$ (13,067,955)	$ (17,822,142)	$ 4,754,187

Revenues

We recorded total revenues of $3.5 million during the three months ended March 31, 2019, as compared to $4.0 million during the three months ended March 31, 2018, a decrease of $0.5 million, or approximately 13%. The decrease is due to a $0.3 million decrease in Nabi-HB revenues related to the timing of customer shipment requests, and a $0.2 million decrease in source plasma revenue from our ADMA Bio Centers operations, mainly due to the expiration of our supply agreement with Biotest in 2018, as well as having only one FDA-approved plasma collection center operating during the first quarter of 2019, as compared to two FDA-approved plasma collection centers in the first quarter of 2018.

Cost of Product Revenue

Cost of product revenue was $9.4 million for the three months ended March 31, 2019, as compared to $12.2 million for the three months ended March 31, 2018, a decrease of $2.8 million. During the three months ended March 31, 2018, we produced three conformance lots of ASCENIV and one conformance lot of BIVIGAM which we charged to expense in the amount of $4.1 million, as compared to one lot of BIVIGAM charged to expense in 2019 in the amount of $0.8 million. In addition, remediation costs incurred at the Boca Facility decreased by $0.7 million in 2019 as compared to 2018. These amounts were partially offset by an increase in underabsorbed overhead in the amount $1.3 million.

Research and Development Expenses

R&D expenses totaled $0.9 million for the three months ended March 31, 2019, as compared to $1.0 million for the three months ended March 31, 2018. The decrease is primarily due to lower expenses associated with clinical studies and other R&D projects, as we continue to focus more of our business on commercial operations in 2019 as compared to the early part of 2018.

Plasma Center Operating Expenses

Plasma center operating expenses were $0.7 million for the three months ended March 31, 2019, as compared to $1.8 million for the three months ended March 31, 2018. Plasma center operating expenses consist of certain general and administrative plasma center costs, including rent, maintenance, utilities, compensation and benefits for center and administrative staff, advertising and promotion expenses and computer software fees related to donor collections. The decrease in plasma center operating expenses is attributable to the transfer of two of our plasma collection centers to BPC on January 1, 2019.

Amortization of Intangibles

Amortization expense pertains to the amortization of intangible assets acquired in the Biotest Transaction, and was $0.2 million for the three months ended March 31, 2019 and 2018.

Selling, General and Administrative Expenses

Selling, general and administrative ("SG&A") expenses were $5.6 million for the three months ended March 31, 2019, an increase of $0.3 million from the three months ended March 31, 2018. The increase was primarily due to higher legal and professional fees in 2019, as well as increase in stock-based compensation expense.

Loss from Operations

Our operating loss was $13.2 million for the three months ended March 31, 2019, as compared to $16.5 million for the three months ended March 31, 2018. The decrease in operating loss was mainly due to the reductions in cost of product revenue and plasma center operating expenses, partially offset by lower revenues.

Interest Expense

Interest expense was $1.5 million for the three months ended March 31, 2019, as compared to $1.3 million for the three months ended March 31, 2018. During the first quarter of 2019, we refinanced our senior debt, resulting in an increase in the outstanding principal balance from $30 million to $45 million (see "Liquidity and Capital Resources"), resulting in higher interest expense for the period. Subsequent to March 31, 2019, we borrowed an additional $27.5 million, which will result in additional interest expense in future periods.

Loss on Extinguishment of Debt

In connection with the foregoing refinancing of our senior credit facility, we incurred a loss on the extinguishment debt for the retirement of our previously existing credit facility, consisting of a $6.5 million prepayment penalty, and the write-off of $3.5 million of unamortized debt discount related to the previous credit facility.

Gain on Transfer of Plasma Center Assets

As part of the purchase price for the Biotest Transaction, we agreed to transfer our Marietta, GA and Norcross, GA plasma collection centers to BPC effective January 1, 2019. We had estimated the combined fair value of the two facilities to be $12.6 million, and we recorded a liability in our financial statements for this amount as of the date of the Biotest Transaction. On January 1, 2019, the two plasma collection facilities were transferred to BPC and we recorded a gain on this transfer in the amount of $11.5 million, which reflects the derecognition of the obligation to transfer ownership of the two facilities net of the carrying value of the assets associated with these facilities, primarily property and equipment and inventory, in the amount of $1.1 million.

Net Loss

Our net loss was $13.1 million for the three months ended March 31, 2019, as compared to $17.8 million for the three months ended March 31, 2018. The reduced net loss was the result of the lower operating expenses for the quarter in addition to the gain on the transfer of plasma center assets, largely offset by the loss on extinguishment of debt.

LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2019, we had working capital of $30.0 million, including cash and cash equivalents of $16.5 million, and stockholders' equity of $10.0 million, as compared to working capital of $34.9 million, including cash and cash equivalents of $22.8 million, and stockholders' equity of $19.8 million as of December 31, 2018. We have had limited revenue from operations, incurred an accumulated deficit of $229.5 million since inception, had negative cash flows from operations of $14.3 million and $16.4 million for the three months ended March 31, 2019 and 2018, respectively, and had negative cash flows from operations of $62.7 million and $37.3 million for the years ended December 31, 2018 and 2017, respectively. We have funded our operations to date primarily from the sale of our equity and debt securities, acquisition proceeds from the Biotest Transaction and loans from our primary stockholders.

We expect to continue to spend substantial amounts on product development, quality assurance, regulatory affairs, procurement of raw material plasma, building additional plasma centers, manufacturing, marketing, sales and conducting clinical trials for our product candidates and purchasing clinical trial materials from our suppliers, some of which may be required by the FDA. We currently anticipate that, based upon our projected revenue and expenditures for 2019, including continued implementation of our commercialization and expansion activities, the proceeds from the refinancing of our senior credit facility and corresponding release of funds from the debt service reserve account to us in February 2019 as discussed below, as well as certain other assumptions, our cash, projected revenue and accounts receivable, along with the $40.0 million we are able to draw down under our current senior credit facility, $12.5 million of which is subject to the approval of the PAS as discussed below, will be sufficient to fund our operations, as currently conducted, into the fourth quarter of 2019. In order to have sufficient cash to fund our operations thereafter and to continue as a going concern, we will need to raise additional capital by the fourth quarter of 2019. These estimates may change based upon how quickly we are able to obtain FDA approval for BIVIGAM, commercial manufacturing ramp-up activities and the various financing options being explored. We currently have no firm commitments for additional financing, and there can be no assurances that we will be able to secure additional financing on terms that are acceptable to us, or at all. Furthermore, if the assumptions underlying our estimated revenues and expenses are incorrect, we may have to raise additional capital sooner than currently anticipated.

Failure to secure any necessary financing in a timely manner and on commercially reasonable terms could have a material adverse effect on our business plan and financial performance and we could be forced to delay or discontinue our product development, clinical trial or commercialization activities, delay or discontinue the approval efforts for any of our potential products, or potentially cease operations. In addition, we could also be forced to reduce or forgo sales and marketing efforts and forgo attractive business opportunities. Due to numerous risks and uncertainties associated with FDA approval of BIVIGAM, ongoing remediation and capacity expansion efforts at the Boca Facility and potential future commercialization of our products and product candidates, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures required to fund our commercialization and other development activities. Our current estimates may be subject to change as circumstances regarding our business requirements evolve. We may decide to raise capital through public or private equity offerings and such financings may only be available on unattractive terms, resulting in significant dilution of stockholders' interests and, in such event, the value and potential future market price of our Common Stock may decline. We may also decide to obtain additional debt financing or a bank credit facility, subject to the restrictions contained in our current Credit Agreement, or to enter into corporate collaboration and licensing arrangements. The sale of additional equity or debt securities, if convertible, could result in dilution to our current stockholders. The incurrence of additional indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations or other future financing alternatives.

Our long-term liquidity depends upon our ability to raise additional capital, fund capacity expansion and commercial programs and achieve commercial status for our products and product candidates in order to generate sufficient revenues to cover our operating expenses and meet our obligations on a timely basis. We believe that we will continue to incur losses and negative cash flows from operating activities through the foreseeable future. As such, these conditions raise substantial doubt about our ability to continue as a going concern.

On February 11, 2019, (the "Perceptive Closing Date"), we and all of our subsidiaries entered into a Credit Agreement and Guaranty (the "Perceptive Credit Agreement") with Perceptive Credit Holdings II, LP, as the lender and administrative agent ("Perceptive"). The Perceptive Credit Agreement provides for a senior secured term loan facility in a principal amount of up to $72.5 million (the "Perceptive Credit Facility"), comprised of (i) a term loan made on the Perceptive Closing Date in the principal amount of $45.0 million, as evidenced by our issuance of a promissory note (the "Perceptive Tranche I Note") in favor of Perceptive on the Perceptive Closing Date (the "Perceptive Tranche I Loan"), and (ii) an additional term loan in the principal amount of up to $27.5 million, but no less than $10.0 million (the "Perceptive Tranche II Loan" and, together with the Perceptive Tranche I Loan, the "Initial Perceptive Loans"), which Perceptive Tranche II Loan was subject to the satisfaction of certain conditions. The Perceptive Credit Facility has a maturity date of March 1, 2022 (the "Perceptive Maturity Date"), subject to acceleration pursuant to the Perceptive Credit Agreement, including upon an Event of Default (as defined in the Perceptive Credit Agreement).

On the Perceptive Closing Date, we used $30.0 million of the Perceptive Tranche I Loan to terminate and pay in full all of the outstanding obligations under our previously existing credit agreement with Marathon Healthcare Finance Fund, L.P. ("Marathon") (the "Marathon Credit Facility") that we entered into in October 2017. We also (i) used $2.8 million of the Perceptive Tranche I Loan to pay a deferred facility fee to Marathon, (ii) used $6.5 million of the Perceptive Tranche I Loan to pay a prepayment penalty to Marathon, (iii) used $0.7 million of the Perceptive Tranche I Loan to pay outstanding accrued interest to Marathon and (iv) used proceeds of the Perceptive Tranche I Loan to pay certain fees and expenses incurred in connection with the Perceptive Credit Facility of approximately $1.5 million. In addition, on the Perceptive Closing Date, Marathon released the $4.0 million of cash held in a debt service reserve account, per the terms of the Marathon Credit Facility, to us.

On May 3, 2019, as a result of the FDA's approval of ASCENIV, we accessed the additional $27.5 million available under the Perceptive Credit Facility through the issuance of a promissory note evidencing the Perceptive Tranche II Loan. We intend to use the proceeds from the Perceptive Tranche II Loan (i) to support ASCENIV's commercial launch anticipated during the second half of 2019, (ii) to expand our plasma collection facility network; and (iii) for working capital and general corporate purposes, including the procurement of raw material inventory.

Also on May 3, 2019, we and Perceptive entered into an amendment to the Perceptive Credit Agreement (the "Perceptive Amendment") whereby Perceptive agreed to an additional commitment under the Perceptive Credit Facility in the principal amount of up to $12.5 million (the "Perceptive Tranche III Loan"). The Perceptive Tranche III Loan is subject to the satisfaction of certain conditions, including, but not limited to, FDA approval of the BIVIGAM PAS and no Material Adverse Changes (as defined in the Perceptive Credit Agreement) having occurred since December 31, 2018; provided that the Perceptive Tranche III Loan would not be made later than March 31, 2020. The Perceptive Tranche III Loan has terms that are substantially identical to those of the Initial Perceptive Loans. The Perceptive Tranche III Loan required us to pay certain proceeds of the Perceptive Tranche II Loan to Perceptive on May 3, 2019 as a facility fee. In addition, we issued a warrant (the "Perceptive Tranche III Warrant") to purchase 250,000 shares of our Common Stock to Perceptive with an exercise price equal to $4.64 per share, which represents the trailing 10-day volume weighted average price ("VWAP") of the Company's Common Stock as of May 2, 2019. The Perceptive Tranche III Warrant has an expiration date of May 3, 2029. Perceptive represented to us, among other things, that it was an "accredited investor" (as such term is defined in Rule 501(a) of Regulation D under the Securities Act of 1933, as amended (the "Securities Act")), and we issued the Perceptive Tranche III Warrant in reliance upon an exemption from registration contained in Section 4(2) under the Securities Act. The Perceptive Tranche III Warrant and the shares of Common Stock issuable thereunder may not be offered, sold, pledged or otherwise transferred in the U.S. absent registration or an applicable exemption from the registration requirements under the Securities Act.

Borrowings under the Perceptive Credit Agreement bear interest at a rate per annum equal to 7.5% plus the greater of (i) one-month LIBOR and (ii) 3.5%; provided, however, that upon, and during the continuance of, an Event of Default, the interest rate will automatically increase by an additional 400 basis points. On the last day of each month during the term of the Perceptive Credit Facility, we pay accrued interest to Perceptive. The rate of interest in effect as of the Perceptive Closing Date was 11.0%.

On the Perceptive Maturity Date, we will pay Perceptive the entire outstanding principal amount underlying the Perceptive Loans and any accrued and unpaid interest thereon. Prior to the Perceptive Maturity Date, there are no scheduled principal payments on the Perceptive Loans. We may prepay outstanding principal on the Perceptive Loans at any time and from time to time upon three business days' prior written notice, subject to the payment to Perceptive of, (A) any accrued but unpaid interest on the prepaid principal amount plus (B) a redemption premium amount equal to (i) 5.0% of the prepaid principal amount, if prepaid on or prior to the first anniversary of the Perceptive Closing Date, (ii) 4.0% of the prepaid principal amount, if prepaid after the first anniversary of the Perceptive Closing Date and on or prior to the second anniversary of the Perceptive Closing Date, or (iii) 3.0% of the prepaid principal amount, if prepaid after the second anniversary of the Perceptive Closing Date and on or prior to the third anniversary of the Perceptive Closing Date.

All of our obligations under the Perceptive Credit Agreement are secured by a first-priority lien and security interest in substantially all of our tangible and intangible assets, including intellectual property and all of the equity interests in our subsidiaries. The Perceptive Credit Agreement contains certain representations and warranties, affirmative covenants, negative covenants and conditions that are customarily required for similar financings. The negative covenants restrict or limit our ability to, among other things and subject to certain exceptions contained in the Perceptive Credit Agreement, incur new indebtedness; create liens on assets; engage in certain fundamental corporate changes, such as mergers or acquisitions, or changes to our business activities; make certain Investments or Restricted Payments (each as defined in the Perceptive Credit Agreement); change our fiscal year; pay dividends; repay other certain indebtedness; engage in certain affiliate transactions; or enter into, amend or terminate any other agreements that have the impact of restricting our ability to make loan repayments under the Perceptive Credit Agreement. In addition, we must (i) at all times prior to the Maturity Date maintain a minimum cash balance of $3.0 million; and (ii) as of the last day of each fiscal quarter commencing with the fiscal quarter ending June 30, 2019, receive revenue for the trailing 12-month period in amounts set forth in the Perceptive Credit Agreement, which range from $7.0 million for the fiscal quarter ending June 30, 2019 to $55.0 million for the fiscal quarter ending December 31, 2021.

As consideration for the Perceptive Credit Agreement, we issued to Perceptive, on the Perceptive Closing Date, a warrant to purchase 1,360,000 shares of our Common Stock (the “Perceptive Warrant”). The Perceptive Warrant has an exercise price equal to $3.28 per share, which is equal to the trailing 10-day VWAP of our Common Stock on the business day immediately prior to the Perceptive Closing Date multiplied by 1.15. The Perceptive Warrant was valued by us at $2.7 million as of the Perceptive Closing Date, and has an expiration date of February 11, 2029. Perceptive represented to us, among other things, that it was an “accredited investor” (as such term is defined in Rule 501(a) of Regulation D under the Securities Act), and we issued the Perceptive Warrant in reliance upon an exemption from registration contained in Section 4(2) under the Securities Act. The Perceptive Warrant and the shares of Common Stock issuable thereunder may not be offered, sold, pledged or otherwise transferred in the U.S. absent registration or an applicable exemption from the registration requirements under the Securities Act.

On June 18, 2018, we completed an underwritten public offering of 9,623,430 shares of our Common Stock for gross proceeds of $46.0 million. We received net proceeds from this offering, after underwriters’ commissions and other offering expenses, of $42.9 million. The net proceeds have been and will continue to be used for (i) for continued remediation and ongoing improvement and enhancements at the Boca Facility, (ii) to submit the PAS for, and re-launch of, BIVIGAM, (iii) to resubmit the RI-002 BLA, (iv) for expenses associated with obtaining with FDA approval of our Kennesaw, GA plasma collection facility, and (v) for general corporate purposes, including capital expenditures.

On November 13, 2017, we completed an underwritten public offering of 19,523,255 shares of Common Stock for gross proceeds of $42.0 million. Net proceeds from this offering, after payment of underwriting discounts and offering expenses of $2.8 million, were $39.2 million. The proceeds from this offering were used for (i) the purchase of raw material inventory and the ramp-up of our manufacturing capabilities, (ii) continued remediation of the issues identified in the RI-002 CRL and the Warning Letter and completion of our internal quality management systems overhaul, (iii) capital expenditures for the Boca Facility, (iv) product launch and medical education campaigns, (v) the build-out of our Kennesaw, GA plasma collection facility, (vi) research and development activities for our plasma collection programs and specialty plasma products, and (vii) working capital needs and general corporate purposes, including expenses associated with improving the FDA inspection classification relative to the Warning Letter, filing the BIVIGAM PAS and obtaining marketing clearance for the relaunch of BIVIGAM and re-filing the RI-002 BLA.

In June 2017, we received $27.5 million in connection with the Biotest Transaction, comprised of $12.5 million in cash from BPC and an unsecured subordinated 6% note payable to Biotest in the amount of $15.0 million. The note has since been assigned from BPC to Biotest AG and matures on June 6, 2022. We are obligated to make semi-annual interest payments on the note, with all principal and unpaid interest due at maturity. The note is subordinate to all amounts outstanding under the Perceptive Credit Agreement.

Cash Flows

The following table sets forth a summary of our cash flows for the periods indicated:

	Three Months Ended March 31,	
	2019	**2018**
Net cash used in operating activities	$ (14,287,184)	$ (16,434,114)
Net cash used in investing activities	(110,453)	(549,246)
Net cash provided by (used in) financing activities	4,177,063	(4,377)
Net change in cash and cash equivalents	(10,220,574)	(16,987,737)
Cash and cash equivalents, including restricted cash - beginning of period	26,754,852	48,607,574
Cash and cash equivalents, including restricted cash - end of period	$ 16,534,278	$ 31,619,837

Net Cash Used in Operating Activities

Cash used in operations for the three months ended March 31, 2019 was $14.3 million, a decrease of $2.1 million from the same period of a year ago, mainly due to the decrease in our net loss. The following table illustrates the primary components of our cash flows from operations:

	Three Months Ended March 31,	
	2019	**2018**
Net loss	$ (13,067,955)	$ (17,822,142)
Non-cash expenses, gains and losses	87,118	1,564,464
Changes in accounts receivable	82,037	222,552
Changes in inventories	(25,310)	189,379
Changes in prepaid expenses and other current assets	(289,134)	(652,474)
Changes in accounts payable and accrued expenses	(1,183,142)	(114,114)
Other	109,202	178,221
Cash used in operations	$ (14,287,184)	$ (16,434,114)

Net Cash Used in Investing Activities

Net cash used in investing activities for the three months ended March 31, 2019 and 2018 was $0.1 million and $0.5 million, respectively, consisting of capital expenditures at the Boca Facility. Although we have no specific material commitments for capital expenditures as of March 31, 2019, we expect our total capital expenditures will be between $4.0 million and $6.0 million for the remainder of fiscal 2019.

Net Cash Provided by (Used in) Financing Activities

Cash provided by financing activities during the three months ended March 31, 2019 was $4.2 million, which was a result of the net proceeds received from the refinancing of our senior credit facility. Net cash used in financing activities for the three months ended March 31, 2018 of $4,000 was comprised of payments made under a capital lease obligation.

Effect of Inflation

Inflation or changing prices did not have a significant impact on our net sales, revenues or net loss in 2018 or 2017, or for the three months ended March 31, 2019.

Off-Balance Sheet Arrangements

None.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We designed our disclosure controls and procedures, as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, (the "Exchange Act"), to provide reasonable assurance that information required to be disclosed by us in reports we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the U.S. Securities and Exchange Commission's (the "SEC") rules and forms, and (ii) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

Under the supervision of and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures as of March 31, 2019. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures as of March 31, 2019 are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (ii) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding disclosures.

A control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. We do not expect that our disclosure controls and procedures or our internal control over financial reporting are able to prevent with certainty all errors and all fraud.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended March 31, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II
OTHER INFORMATION

Item 1. Legal Proceedings.

We may become subject to certain legal proceedings and claims arising in connection with the normal course of our business. In the opinion of management, there are currently no claims that would have a material adverse effect on our consolidated financial position, results of operations or cash flows.

Item 1A. Risk Factors

Described below are various risks and uncertainties that may affect our business. These risks and uncertainties are not the only ones we face. You should recognize that other significant risks and uncertainties may arise in the future, which we cannot foresee at this time. Also, the risks that we now foresee might affect us to a greater or different degree than expected. Certain risks and uncertainties, including ones that we currently deem immaterial or that are similar to those faced by other companies in our industry or business in general, may also affect our business. If any of the risks described below actually occur, our business, financial condition or results of operations could be materially and adversely affected. You should carefully consider the following risk factors and the section entitled "Special Note Regarding Forward-Looking Statements" before you decide to invest in our securities.

Risks Relating to our Business

To date, we have generated limited product revenues, have a history of losses and will need to raise additional capital to operate our business, which may not be available on favorable terms, if at all.

To date, we have generated a substantial portion of our revenues from the sale of plasma by our plasma collections facilities. Following completion of the Biotest Transaction, we began generating revenues from the sale of Nabi-HB, and we recorded additional revenue in connection with a contract manufacturing agreement. On April 1, 2019, the FDA approved ASCENIV, formerly referred to as RI-002, and we anticipate having the product available for commercial launch during the second half of 2019. Unless and until we receive approval from the FDA and other regulatory authorities for BIVIGAM and other products and product candidates in our pipeline, we do not expect to sell and generate revenue from the commercialization of BIVIGAM and other products and product candidates in our pipeline, and we will be required to raise additional funds through the sale of our equity and/or debt securities in order to establish a commercial sales force, develop our commercial infrastructure and recognize any significant revenues.

Our long-term liquidity will depend upon our ability to raise additional capital, fund and successfully implement our research and development and commercial programs, establish and build out a commercial sales force and commercial infrastructure and meet our ongoing obligations. If we are unable to successfully raise additional capital by the fourth quarter of 2019, we will likely not have sufficient cash flow and liquidity to fund our business operations as we currently operate, forcing us to potentially curtail our activities and significantly reduce or cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, resulting in significant dilution of stockholders' interests and, in such event, the value and potential future market price of our Common Stock may decline. In addition, if we raise additional funds through license arrangements or through the disposition of any of our assets, it may be necessary to relinquish potentially valuable rights to our product candidates or assets or grant licenses on terms that are not favorable to us.

Based upon our projected revenue and expenditures for fiscal 2019, including continued implementation of our commercialization and expansion activities and certain other assumptions, we currently believe that our cash, cash equivalents, projected revenue and accounts receivable, along with the additional funds we are able to draw down through our existing senior credit facility (see "Management's Discussion and Analysis of Financial Condition and Results of Operations"), will be sufficient to fund our operations, as currently conducted, into the fourth quarter of 2019. In order to have sufficient cash to fund our operations thereafter and to continue as a going concern, we will need to raise additional equity or debt financing by the fourth quarter of 2019. This timeframe may change based upon how quickly we are able to execute on our ADMA BioManufacturing operations, commercial manufacturing ramp-up activities and the various financing options we are exploring. These estimates may change based upon whether or when the FDA approves BIVIGAM or if any of our other assumptions change. We currently do not have arrangements to obtain additional financing. Any such financing could be difficult to obtain or only available on unattractive terms and could result in significant dilution to stockholders. Failure to secure necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business plan and financial performance and could delay, discontinue or prevent product development, clinical trials, commercialization activities or the approval of any of our potential products. In addition, we could be forced to reduce or forgo sales and marketing efforts and forgo attractive business opportunities.

Failure to timely and effectively remediate and close out the outstanding Warning Letter and other inspection issues and deficiencies at the Boca Facility will have a material adverse effect on our business. Failure of the FDA to adhere to its stated timelines in the Code of Federal Regulations, statements of internal policy or review timing goals, as well as any potential government shut-downs or unforeseen government office closings, may affect our ability to resolve the Warning Letter and other inspection and review issues within estimated timelines described.

Prior to the closing of the Biotest Transaction, BTBU was our third-party manufacturer for ASCENIV, formerly referred to as RI-002. In response to our BLA submission for RI-002 in 2015 (the "RI-002 BLA"), in July 2016 the FDA issued a CRL for RI-002 (the "RI-002 CRL"). The RI-002 CRL did not specify or request the need for any addition clinical trials or data; however, the RI-002 CRL reaffirmed the issues set forth in the Warning Letter issued to Biotest relating to inspection issues identified at the Boca Facility. The FDA identified in the RI-002 CRL, among other things, certain outstanding inspection issues and deficiencies related to CMC and Good Manufacturing Practices ("GMP") at the Boca Facility and at certain of our third-party vendors, and requested documentation of corrections for a number of these issues. The FDA indicated in the RI-002 CRL that it could not grant final approval of our RI-002 BLA until, among other things, these deficiencies are resolved. Following the completion of the Biotest Transaction, we gained control over the regulatory, quality, general operations and drug substance manufacturing process at the Boca Facility, and our highest priority has been to remediate the outstanding compliance issues at the Boca Facility as indicated in the Warning Letter. We have been working with a consulting firm consisting of quality management systems and biologics production subject matter experts with extensive experience in remediating compliance and inspection issues related to quality management systems that manages a robust team of subject matter experts in plasma derived products and biologic drugs to assist us in addressing all identified CMC and current good manufacturing practice ("cGMP") issues and deficiencies. Although we received FDA approval of our RI-002 BLA on April 1, 2019, we have not received a "Warning Letter close-out letter" from the FDA. We believe that we have successfully closed out the April 2018 FDA inspection of the Boca Facility, however there can be no assurances as to the timing by which the FDA may make any determinations post-inspection concerning our compliance status. There can also be no assurances that our ongoing efforts to remediate the Warning Letter and other inspection issues and deficiencies at the Boca Facility will be effective or whether the FDA will accept these efforts. Failure to timely remediate the issues identified in the Warning Letter and other inspection issues and deficiencies and/or receive approval from the FDA would have a material adverse effect on our business (including the ability to timely commercialize our products), prospects, financial condition and results of operations. Additionally, we are unable to control the timing of FDA inspections, responses, meeting requests, teleconference requests, requests for clarifications and similar regulatory communications as well as whether or not the FDA will change its requirements, guidance or expectations.

We are currently not profitable and may never become profitable.

We have a history of losses and expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we may never achieve or maintain profitability. For the years ended December 31, 2018 and 2017, we incurred net losses of $65.7 and $43.8 million, respectively, and for the three months ended March 31, 2019 and 2018, we incurred net losses of $13.1 million and $17.8 million, respectively. From our inception in 2004 through March 31, 2019, we have incurred an accumulated deficit of $229.5 million. Even if we succeed in developing and commercializing one or more of our products and product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures and anticipate that our operating expenses will increase substantially in the foreseeable future as we:

- seek regulatory approval for BIVIGAM;

- initiate commercialization and marketing efforts;
- implement additional internal systems, controls and infrastructure;
- hire additional personnel;
- expand and build out our plasma center network; and
- expand production capacity at the Boca Facility.

We also expect to experience negative cash flows for the foreseeable future as we fund our operating losses and capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the value of our securities.

Although our financial statements have been prepared on a going concern basis, we must raise additional capital by the second half of 2019 to fund our operations in order to continue as a going concern.

CohnReznick LLP, our independent registered public accounting firm, has included an explanatory paragraph in their opinion that accompanies our audited consolidated financial statements as of and for the year ended December 31, 2018, indicating that our current liquidity position and history of losses raise substantial doubt about our ability to continue as a going concern. If we are unable to improve our liquidity position we may not be able to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements. We may also be forced to make reductions in spending, including delaying or curtailing our clinical development, trials or commercialization efforts, or seek to extend payment terms with our vendors and creditors. Our ability to raise or borrow the capital needed to improve our financial condition may be hindered by a variety of factors, including market conditions and the availability of such financing on acceptable terms, if at all. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments that might result if we are unable to continue as a going concern and, therefore, be required to realize our assets and discharge our liabilities other than in the normal course of business, which could cause our security holders to suffer the loss of all or a substantial portion of their investment.

We anticipate that our principal sources of liquidity will only be sufficient to fund our activities, as currently conducted, into the fourth quarter of 2019. In order to have sufficient cash to fund our operations thereafter and to continue as a going concern, we will need to raise additional equity or debt financing by the fourth quarter of 2019. This time frame may change based upon how quickly we are able to execute on our quality management systems' remediation plans for the ADMA BioManufacturing operations, commercial manufacturing ramp-up activities and the various financing options we are exploring. In order to have sufficient cash to fund our operations thereafter, we will need to raise additional equity or debt capital, and we cannot provide any assurance that we will be successful in doing so. If our assumptions underlying our estimated expenses prove to be wrong, we may have to raise additional capital sooner than the fourth quarter of 2019.

We have a limited operating history upon which to base an investment decision.

We have not demonstrated an ability to perform the functions necessary for the successful commercialization of ASCENIV. The successful development and commercialization of ASCENIV or any product candidate will require us or our collaborators to perform a variety of functions, including:

- undertaking product development and clinical trials;
- participating in regulatory approval processes;

- formulating and manufacturing products; and
- conducting sales and marketing activities once product approval is received.

Our operations thus far provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our securities.

Business interruptions could adversely affect our business.

Our operations, including our headquarters located in Ramsey, NJ, the Boca Facility and our Kennesaw, GA plasma collection facility, are vulnerable to interruption by fire, weather related events such as hurricanes, wind and rain, other acts of God, electric power loss, telecommunications failure, equipment failure and breakdown, human error, employee issues, product liability claims and events beyond our control. While we maintain several insurance policies with reputable carriers, which we believe are in acceptable amounts and contain market terms common within the industry which provide adequate coverage for a variety of these risks, including replacing or rebuilding a substantial part of our facilities, these policies are subject to the insurance carriers' final determination of compensation to us. In addition, our disaster recovery plans for our facilities may not be adequate and we do not have an alternative manufacturing facility or contractual arrangements with other manufacturers in the event of a casualty to or destruction of any of our facilities. If we are required to rebuild or relocate any of our facilities, a substantial investment in improvements and equipment would be necessary. We carry only a limited amount of business interruption insurance, which may not sufficiently compensate us for losses that may occur. As a result, any significant business interruption could adversely affect our business and results of operations.

Product candidates require extensive clinical data analysis and regulatory review and may require additional testing. Clinical trials and data analysis can be very expensive, time-consuming and difficult to design and implement. The conduct of preclinical studies and clinical trials is subject to numerous risks and results of the studies and trials are highly uncertain. If we are unsuccessful in obtaining regulatory approval for any of our product candidates or if any of our product candidates do not provide positive results, we may be required to delay or abandon development of such product, which would have a material adverse impact on our business.

Continuing product development requires additional and extensive clinical testing. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming. Furthermore, failure can occur at any stage of the process, and we could encounter problems that cause us to abandon our product development programs and related INDs or biologics license applications, or to repeat clinical trials. The commencement and completion of clinical trials for any current or future development product candidate may be delayed by several factors, including:

- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

We cannot be certain as to what type and how many clinical trials the FDA, or equivalent foreign regulatory agencies, will require us to conduct before we may successfully gain approval to market any of our product candidates. Prior to approving a new drug or biologic, the FDA generally requires that the effectiveness of the product candidate (which is not typically fully investigated until Phase 3) be demonstrated in two adequate and well-controlled clinical trials. However, if the FDA or an equivalent foreign regulatory authority determines that our Phase 3 clinical trial results do not demonstrate a statistically significant, clinically meaningful benefit with an acceptable safety profile, or if a relevant regulator requires us to conduct additional Phase 3 clinical trials in order to gain approval, we will incur significant additional development costs and commercialization of these products would be prevented or delayed and our business would be adversely affected.

In addition, the FDA or an independent institutional review board may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our IND submissions or the conduct of these trials. Therefore, we cannot provide any assurance or predict with certainty the schedule for future clinical trials. In the event we do not ultimately receive regulatory approval for our product candidates, we may be required to terminate development of such product candidates. If we fail to obtain regulatory approval to market and sell our product candidates, or if approval is delayed, we will be unable to generate revenue from the sale of these products, our potential for generating positive cash flow will be diminished and the capital necessary to fund our operations will increase.

If the results of our clinical trials do not support our product candidate claims, completing the development of such product candidate may be significantly delayed or we may be forced to abandon development of such product candidate altogether.

We cannot be certain that the clinical trial results of our product candidates will support our product candidates' claims. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay our ability to commercialize our product candidates and generate product revenues. In addition, our clinical trials involve a relatively small patient population. Because of the small sample size, the results of these clinical trials may not be indicative of future results. In addition, certain portions of our clinical trials and product testing for our product candidates may be performed outside of the U.S., and therefore, may not be performed in accordance with standards normally required by the FDA and other regulatory agencies.

If we do not obtain the necessary U.S. or worldwide regulatory approvals to commercialize our product candidates, we will not be able to sell our product candidates.

If we cannot obtain regulatory approval for our product candidates, we will not be able to generate revenue from such product candidates. As a result, our sources of revenue may continue to be from a product mix consisting only of plasma collection and sales revenues, revenues generated from sales of our FDA-approved commercial products, revenues generated from ongoing contract manufacturing for third parties and revenues generated from the sales of manufacturing intermediates. We cannot assure you that we will receive the approvals necessary to commercialize any product candidate we may acquire or develop in the future. In order to obtain FDA approval of any product candidate requiring FDA approval, our clinical development must demonstrate that the product candidate is safe for humans and effective for its intended use, and we must successfully complete an FDA BLA review. Obtaining FDA approval of a product candidate generally requires significant research and testing, referred to as preclinical studies, as well as human tests, referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in products that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the product approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies, or may require additional CMC or other data and information, and the development and provision of this data and information may be time-consuming and expensive. There are numerous FDA personnel assigned to review different aspects of a BLA, and uncertainties can be presented by their ability to exercise judgment and discretion during the review process. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive product revenues from, our product candidate;
- impose costly procedures on us; and

- diminish any competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately reject our product candidate's BLA. In addition, the FDA could determine that we must test additional subjects and/or require that we conduct further studies with more subjects. We may never obtain regulatory approval for any future potential product candidate or label expansion activity. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by leaving us without the ability to generate additional accretive revenues. There is no guarantee that we will ever be able to develop or acquire other product candidates. In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize any products or product candidates outside the U.S. Foreign regulatory approval processes generally include all of the risks and uncertainties associated with the FDA approval procedures described above. We cannot assure you that we will receive the approvals necessary to commercialize any product candidate for sale outside the U.S.

Although we have received approval from the FDA to market ASCENIV for PIDD, our ability to market ASCENIV for alternative indications could be limited, unless additional clinical trials are conducted.

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the Internet and off-label promotion. The FDA generally does not allow drugs to be promoted for "off-label" uses — that is, uses that are not described in the product's labeling and that differ from those that were approved by the FDA. Generally, the FDA limits approved uses to those studied by a company in its clinical trials. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. Although we have received approval from the FDA to market ASCENIV for PIDD, we cannot be sure whether we will be able to obtain FDA approval for any desired future indications for ASCENIV.

While physicians in the U.S. may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product's labeling, and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote our products is narrowly limited to those indications that are specifically approved by the FDA. "Off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U.S. generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. Although recent court decisions suggest that certain off-label communications, such as truthful and non-misleading speech, may be protected under the First Amendment, the scope of any such protection is unclear, and there are still significant risks in this area as it is unclear how these court decisions will impact the FDA's enforcement practices, and there is likely to be substantial disagreement and difference of opinion regarding whether any particular statement is truthful and not misleading. Furthermore, there are still significant risks in this area in part due to potential False Claims Act exposure. Moreover, while we intend to promote our products consistent with what we believe to be the approved indication for our drugs, the FDA may disagree. If the FDA determines that our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines related to promotion and advertising may cause the FDA to issue warning letters or untitled letters, bring an enforcement action against us, suspend or withdraw an approved product from the market, require a recall or institute fines or civil fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our reputation and our business.

With the approval of ASCENIV, there can be no assurance that we will be successful in developing and expanding commercial operations or balancing our research and development activities with our commercialization activities.

With the approval of ASCENIV, we plan to commercialize this product, while also continuing our research and development activities. There can be no assurance that we will be able to successfully manage the balance of our research and development operations with our planned commercialization activities. Potential investors should be aware of the problems, delays, expenses and difficulties frequently encountered by companies balancing development of product candidates, which can include problems such as unanticipated issues relating to clinical trials and receipt of approvals from the FDA and foreign regulatory bodies, with commercialization efforts, which can include problems related to managing manufacturing and supply, reimbursement, marketing challenges, development of a comprehensive compliance program, and other related and additional costs. Our product candidates will require significant additional research and clinical trials, and we will need to overcome significant regulatory burdens prior to commercialization in the United States and other countries. In addition, we may be required to spend significant funds on building out our commercial operations. There can be no assurance that after the expenditure of substantial funds and efforts, we will successfully develop and commercialize any of our product candidates, generate any significant revenues or ever achieve and maintain a substantial level of sales of our products.

We depend on third-party researchers, developers and vendors to develop, manufacture and test ASCENIV and our other products, and such parties are, to some extent, outside of our control.

We depend on independent investigators and collaborators, such as universities and medical institutions, contract laboratories, clinical research organizations, contract manufacturers and consultants to conduct our preclinical, clinical trials, CMC testing and other activities under agreements with us. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs. These investigators may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our product-development programs, or if their performance is substandard, the approval of our FDA application(s), if any, and our introduction of new products, if any, will be delayed. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist our competitors at our expense, our competitive position would be harmed. Additionally, any change in the regulatory compliance status of any of our vendors may impede our ability to receive approval for our product candidates.

Historically a single customer has accounted for a significant amount of our total revenue and, collectively with two other customers, represented 87% of our total revenue for the year ended December 31, 2018. For the three months ended March 31, 2019, two customers represented an aggregate of 81% of our total revenue, and therefore the loss of any of these customers could have a material adverse effect on our business, results of operations and financial condition.

Historically, a significant amount of our total revenue is attributable to a single customer, BPC. For the year ended December 31, 2018, BPC, McKesson and AmerisourceBergen represented 56%, 16% and 15%, respectively, of our total revenue. For the three months ended March 31, 2019, Biolife and AmerisourceBergen represented 61% and 20%, respectively, of our total revenue.

The loss of any key customers or a material change in the revenue generated by any of these customers could potentially have a material adverse effect on our business, results of operations and financial condition. The initial term of our Amended and Restated Plasma Supply Agreement with BPC, pursuant to which we supplied BPC with normal source plasma, expired by its terms on December 31, 2018 and was not renewed. Factors that could influence our relationships with our customers include, among other things:

- our ability to sell our products at competitive prices;
- our ability to maintain features and quality standards for our products sufficient to meet the expectations of our customers; and
- our ability to produce and deliver a sufficient quantity of our products in a timely manner to meet our customers' requirements.

Additionally, an adverse change in the financial condition of Biolife, McKesson Corporation or AmerisourceBergen could have a material adverse effect on our business and results of operations.

Issues with product quality and compliance could have a material adverse effect upon our business, subject us to regulatory actions and cause a loss of customer confidence in us or our products.

Our success depends upon the quality of our products. Quality management plays an essential role in meeting customer requirements, preventing defects, improving our products and services and assuring the safety and efficacy of our products. Our future success depends on our ability to maintain and continuously improve our quality management program. A quality or safety issue may result in failure to obtain product approval, adverse inspection reports, warning letters, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses. An inability to address a quality or safety issue by us or by a third-party vendor in an effective and timely manner may also cause negative publicity, a loss of customer confidence in us or our current or future products, which may result in the loss of sales and difficulty in successfully commercializing our current products and launching new products.

If physicians, payers and patients do not accept and use our current products or our future product candidates, our ability to generate revenue from these products will be materially impaired.

Even if the FDA approves a product made by ADMA Biologics, such as ASCENIV, physicians, payers and patients may not accept and use it. Acceptance and use of our products will depend on a number of factors including:

- perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our products;
- cost-effectiveness of our products relative to competing products;
- availability of reimbursement for our products from government or other healthcare payers; and
- the effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

The failure of our current and future products to find market acceptance would harm our business and could require us to seek additional financing or make such financing difficult to obtain on favorable terms, if at all.

Industry and other market data used in our periodic reports filed with the SEC and our other materials, including those undertaken by us or our engaged consultants, may not prove to be representative of current and future market conditions or future results.

Our periodic reports filed with the SEC and our other materials include statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties and surveys and studies we commissioned regarding the market potential for our current products and product candidates. Although we believe that such information has been obtained from sources believed to be reliable, neither the sources of such data, nor we, can guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. With respect to the information from third-party consultants, the results of this data represent the independent consultants' own methodologies, assumptions, research, analysis, projections, estimates, composition of respondent pool, presentation of data and adjustments, each of which may ultimately prove to be incorrect, and cause actual results and market viability to differ materially from those presented in any such report or other materials. Readers should not place undue reliance on this information.

Our long-term success may depend on our ability to supplement our existing product portfolio through new product development or the in-license or acquisition of other new products, product candidates and label expansion of existing products, and if our business development efforts are not successful, our ability to achieve profitability may be adversely impacted.

Our current product development portfolio consists primarily of ASCENIV and label expansion activities for Nabi-HB and BIVIGAM. We have initiated small scale preclinical activities to potentially expand our current portfolio through new product development efforts or to in-license or acquire additional products and product candidates. If we are not successful in developing or acquiring additional products and product candidates, we will have to depend on our ability to raise capital for, and the successful development and commercialization of, ASCENIV, as well as the revenue we may generate from the sale of Nabi-HB, BIVIGAM, contract manufacturing, and intermediates and plasma attributable to the operations of ADMA Bio Centers, to support our operations.

Our ADMA Bio Centers operations collect information from donors in the U.S. that subjects us to consumer and health privacy laws, which could create enforcement and litigation exposure if we fail to meet their requirements.

Consumer privacy is highly protected by federal and state law. The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, impose, among other things, obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information held by covered entities and business associates. A "covered entity" is the primary type of HIPAA-regulated entity. Health plans/insurers, health care providers engaging in standard transactions (insurance/health plan claims and encounters, payment and remittance advice, claims status, eligibility, enrollment/disenrollment, referrals and authorizations, coordination of benefits and premium payments), and health care clearinghouses (switches that convert data between standard and non-standard data sets) are covered entities. A "business associate" provides services to covered entities (directly or as subcontractors to other business associates) involving arranging, creating, receiving, maintaining, or transmitting protected health information ("PHI") on a covered entity's behalf. In order to legally provide access to PHI to service providers, covered entities and business associates must enter into a "business associate agreement" ("BAA") with the service provider PHI recipient. Among other things, HITECH made certain aspects of the HIPAA's rules (notably the Security Rule) directly applicable to business associates – independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal court to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. The Department of Health and Human Services Office of Civil Rights ("OCR") has increased its focus on compliance and continues to train state attorneys general for enforcement purposes. OCR has recently increased both its efforts to audit HIPAA compliance and its level of enforcement, with one recent penalty exceeding $5 million.

While we are not a covered entity or business associate subject to HIPAA, even when HIPAA does not apply, according to the U.S. Federal Trade Commission (the "FTC"), failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule. In addition, states impose a variety of laws protecting consumer information, with certain sensitive information such as HIV/Sexually Transmitted Disease status subject to heightened standards. In addition, federal and state privacy, data security, and breach notification laws, rules and regulations, and other laws apply to the collection, use and security of personal information, including social security number, driver's license numbers, government identifiers, credit card and financial account numbers. Some state privacy and security laws apply more broadly than HIPAA and associated regulations. For example, California recently enacted legislation – the California Consumer Privacy Act, or CCPA – which goes into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Legislators have stated that they intend to propose amendments to the CCPA before it goes into effect, and the California Attorney General will issue clarifying regulations. Although the law includes limited exceptions, including for certain information collected as part of clinical trials as specified in the law, it may regulate or impact our processing of personal information depending on the context. It remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted. We could be subject to enforcement action and litigation exposure if we fail to adhere to these data privacy and security laws.

We may not realize the strategic and financial benefits currently anticipated from the Biotest Transaction.

We may not realize all of the strategic and financial benefits currently anticipated from the Biotest Transaction. For example, we may not be able to [officially] resolve the outstanding issues at the Boca Facility that resulted in the Warning Letter. As part of the remediation of the Warning Letter, in December 2016 BTBU temporarily suspended the production of BIVIGAM in order to focus on the completion of planned improvements to the manufacturing process. As a result, BIVIGAM was not available for sale or distribution throughout fiscal 2017. If we are unable to address the underlying concerns at the Boca Facility that resulted in the Warning Letter and the CRL in July 2016 that identified deficiencies and inspection issues related to certain of our third-party contract manufacturers, including BPC, and provide requested documentation of corrections for a number of these issues, we will not be able to obtain approval for our June 2018 PAS submission for BIVIGAM drug substance and resolve the matters addressed in the corresponding BIVIGAM CRL issued in December 2018, which could disrupt our business operations and the timing of our commercialization efforts and may have a material adverse effect on our financial condition and operating results. In April 2018, the FDA inspected the Boca Facility and in July 2018 our FDA status resulted improved from OAI to VAI and this inspection of the Boca Facility has been successfully closed-out as indicated on the FDA's website inspection database. In April 2019, the FDA approved ASCENIV and we anticipate having the product available for commercial launch during the second half of 2019. However, the FDA has yet to inform us that the outstanding issues set forth in the Warning Letter have been officially resolved.

Through the Biotest Transaction, we assumed a contract manufacturing agreement related to the fractionation of plasma provided by one of our third-party customers that includes certain minimum production requirements. If we are unable to meet our contractual obligations under this agreement, we may be liable for the payment of liquidated damages. If we are unable to resolve these issues, such failure could have a material adverse effect on us.

There is also uncertainty as to whether the combined business will be able to operate at a profitable level in the future given the relatively small size of the Biotest Assets and the competitive environment in which we operate. Furthermore, there is no assurance and no definitive timeline as to when or if the Warning Letter will be [officially] resolved by the FDA. These factors could have a material adverse effect on us.

We may not be successful in integrating the Biotest Assets into our business.

The Biotest Transaction involves the integration of two businesses that previously have operated independently with principal offices in two distinct locations. We are expending significant management attention and resources to integrate the two companies following completion of the Biotest Transaction. The failure to integrate successfully and to manage successfully the challenges presented by the integration process may result in the combined company's failure to achieve some or all of the anticipated benefits of the Biotest Transaction.

Potential difficulties that may be encountered in the integration process include, but are not limited to, the following:

- using our cash and other assets efficiently to develop the business on a post-Biotest Transaction basis;
- appropriately managing the liabilities of our Company on a post-Biotest Transaction basis;
- potential unknown or currently unquantifiable liabilities associated with the Biotest Transaction and the operations of our Company on a post-Biotest Transaction basis;
- potential unknown and unforeseen expenses, delays or regulatory conditions associated with the Biotest Transaction; and
- performance shortfalls in one or both of the businesses as a result of the diversion of the applicable management's attention caused by completing the Biotest Transaction and integrating the business.

Delays in the integration process could adversely affect the combined company's business, financial results, financial condition and stock price following the Biotest Transaction. Even if the combined company were able to integrate the business operations successfully, there can be no assurance that this integration will result in the realization of the full benefits of synergies, innovation and operational efficiencies that may be possible from this integration or that these benefits will be achieved within a reasonable period of time.

By completing the Biotest Transaction, we transferred assets that have historically generated substantially all of our revenue.

As part of the consideration paid to acquire the Biotest Assets, we transferred to BPC ownership of two of our licensed plasma collection facilities in the U.S. and certain related assets and liabilities. These plasma collection facilities, which were transferred on January 1, 2019, have historically been the source of substantially all of our revenue. Plasma collection centers are expensive to construct, time-consuming and this industry is subject to market saturation and increasing competition from companies with substantially greater financial resources than us. Although we have completed construction of, and received FDA approval for our plasma collection facility in Kennesaw, GA, there can be no assurances that we will generate similar revenues as historically reported from the plasma collection facilities we transferred to BPC on January 1, 2019 or that we will successfully expand and build out our plasma center network.

The Biotest Transaction exposes us to liabilities, a release of claims and competition that could have a material adverse effect on our business, financial condition, results of operations and stock price.

As part of the consideration for the Biotest Transaction, we agreed to assume certain liabilities of BPC related to BTBU. Because we agreed to assume liabilities related to the Biotest Assets, we are exposed to liabilities that are not within our control and we cannot predict the extent to which these liabilities may arise in the future. Any liabilities that may arise could have a material adverse effect on our business, financial condition, results of operations and stock price.

The Purchase Agreement contains indemnification undertakings by the parties thereto for certain losses, including, among other things, indemnification for any losses arising from breaches of its representations, warranties, covenants and agreements in the Purchase Agreement. In connection with the Biotest Transfer Agreement, we granted a full release to Biotest from any and all past, present or future indemnification claims arising under or in connection with the Purchase Agreement. Significant indemnification claims by BPC or its affiliates or breaches by BPC or its affiliates of any indemnity obligations which would have been owed to us under the Purchase Agreement prior to the release granted in the Biotest Transfer Agreement could have a material adverse effect on our business, financial condition, results of operations and stock price.

As part of the consideration for the Biotest Transaction, the parties also agreed to a mutual release, pursuant to which the parties agreed not to bring any suit, action or claim for any breach or default under the existing manufacturing and supply agreement or master services agreement prior to the closing of the Biotest Transaction. This release remains effective from and after the closing of the Biotest Transaction. Without this release, we would have otherwise been permitted to bring a claim against BPC related to the Warning Letter that could have possibly entitled us to remedies in the event that we are unable to resolve the Warning Letter. The inability to seek these remedies could have a material adverse effect on our business, financial condition, results of operations and stock price.

In addition, while the Purchase Agreement contains certain non-compete clauses, such clauses do not prohibit either the Biotest Guarantors (as defined therein) or their other affiliates from directly or indirectly (other than through BPC) competing with BTBU after the closing of the Biotest Transaction. Such competition could result in the loss of existing or new customers, price reductions, reduced operating margins and loss of market share, which could have a material adverse effect on our business, financial condition, results of operations and stock price.

If our due diligence investigation for the Biotest Transaction was inadequate and/or the representations, warranties and indemnification given to us by BPC was inadequate, then it could result in a material adverse effect on our business.

Even though we believe that we conducted a reasonable and customary due diligence investigation of BTBU and we received market representations, warranties and indemnities from Biotest and BPC, we cannot be sure that our due diligence investigation uncovered all material or non-material issues that may be present. There also can be no assurances that we received access to or had the ability to diligence certain information, as well as appropriate representations and or warranties, that it would be possible to uncover all material issues through customary due diligence, or that issues outside of our control will not later arise or that all material issues which are or could have been discovered would otherwise be covered by the representations and warranties of Biotest and BPC and therefore indemnifiable. In connection with the Biotest Transfer Agreement, we granted a full release to Biotest from any and all past, present or future indemnification claims arising under or in connection with the Master Purchase Agreement with Biotest, dated as of January 21, 2017. If we failed to identify any important issues, or if it were not possible to uncover all material issues, any such material issue could result in a material adverse effect on our business, financial condition, results of operations and stock price.

Our Credit Agreement and Guaranty, as amended (the "Credit Agreement"), with our secured lender, Perceptive Credit Holdings II, LP ("Perceptive") is subject to acceleration in specified circumstances, which may result in Perceptive taking possession and disposing of any collateral.

On May 3, 2019, we amended the Credit Agreement with Perceptive which provides for a senior secured term loan facility in an aggregate amount of up to $85.0 million (collectively, the "Credit Facility"), comprised of (i) an initial term loan made on February 11, 2019 with an outstanding principal amount of $45.0 million (the "Initial Term Loan"), (ii) a second term loan made on May 3, 2019 with an outstanding principal amount of $27.5 million (the "Second Term Loan"), and (iii) a third term loan in the principal amount of $12.5 million (the "Third Term Loan", and, together with the Initial Term Loan and the Second Term Loan, the "Loans"). The Loans each have a maturity date of March 1, 2022, subject to acceleration pursuant to the Credit Agreement, including upon an Event of Default (as defined in the Credit Agreement). The Loans are secured by substantially all of our assets, including our intellectual property. Events of Default include, among others, non-payment of principal, interest, or fees, violation of covenants, inaccuracy of representations and warranties, bankruptcy and insolvency events, material judgments, cross-defaults to material contracts and events constituting a change of control. In addition to an increase in the rate of interest on the Loans of 4% per annum, the occurrence of an Event of Default could result in, among other things, the termination of commitments under the Credit Facility, the declaration that all outstanding Loans are immediately due and payable in whole or in part, and Perceptive taking immediate possession of, and selling, any collateral securing the Loans.

Developments by competitors may render our products or technologies obsolete or non-competitive.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our current products and any future product we may develop will have to compete with other marketed therapies. In addition, other companies may pursue the development of pharmaceuticals that target the same diseases and conditions that we are targeting. We face competition from pharmaceutical and biotechnology companies in the U.S. and abroad. In addition, companies pursuing different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater financial resources, larger research and development staffs and facilities, longer product development history in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures or other collaborations.

If we are unable to protect our patents, trade secrets or other proprietary rights, if our patents are challenged or if our provisional patent applications do not get approved, our competitiveness and business prospects may be materially damaged.

As we move forward in clinical development we are also uncovering novel aspects of our products and are drafting patents to cover our inventions. We rely on a combination of patent rights, trade secrets and nondisclosure and non-competition agreements to protect our proprietary intellectual property, and we will continue to do so. There can be no assurance that our patent, trade secret policies and practices or other agreements will adequately protect our intellectual property. Our issued patents may be challenged, found to be over-broad or otherwise invalidated in subsequent proceedings before courts or the USPTO. Even if enforceable, we cannot provide any assurances that they will provide significant protection from competition. The processes, systems, and/or security measures we use to preserve the integrity and confidentiality of our data and trade secrets may be breached, and we may not have adequate remedies as a result of any such breaches. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. There can be no assurance that the confidentiality, nondisclosure and non-competition agreements with employees, consultants and other parties with access to our proprietary information to protect our trade secrets, proprietary technology, processes and other proprietary rights, or any other security measures relating to such trade secrets, proprietary technology, processes and proprietary rights, will be adequate, will not be breached, that we will have adequate remedies for any breach, that others will not independently develop substantially equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets or proprietary knowledge. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

We could lose market exclusivity of a product earlier than expected.

In the pharmaceutical and biotechnology industries, the majority of an innovative product's commercial value is realized during its market exclusivity period. In the U.S. and in some other countries, when market exclusivity expires and generic versions are approved and marketed or when biosimilars are introduced (even if only for a competing product), there are usually very substantial and rapid declines in a product's revenues.

Market exclusivity for our products is based upon patent rights and certain regulatory forms of exclusivity. The scope of our patent rights may vary from country to country and may also be dependent on the availability of meaningful legal remedies in a country. The failure to obtain patent and other intellectual property rights, or limitations on the use or loss of such rights, could be material to us. In some countries, basic patent protections for our products may not exist because certain countries did not historically offer the right to obtain specific types of patents and/or we (or our licensors) did not file in those markets. In addition, the patent environment can be unpredictable and the validity and enforceability of patents cannot be predicted with certainty. Absent relevant patent protection for a product, once the data exclusivity period expires, generic versions can be approved and marketed.

Patent rights covering ASCENIV may become subject to patent litigation. In some cases, manufacturers may seek regulatory approval by submitting their own clinical trial data to obtain marketing approval or choose to launch a generic product "at risk" before the expiration of our patent rights/or before the final resolution of related patent litigation. Enforcement of claims in patent litigation can be very costly, time-consuming and no assurance can be given that we will prevail. In addition, any such litigation may divert our management's attention from our core business and reduce the resources available for our clinical development, manufacturing and marketing activities, and consequently have a material and adverse effect on our business and prospects, regardless of the outcome.

There is no assurance that ASCENIV, or any other of our products for which we are issued a patent, will enjoy market exclusivity for the full time period of the respective patent.

Third parties could obtain patents that may require us to negotiate licenses to conduct our business, and there can be no assurance that the required licenses would be available on reasonable terms or at all.

We may not be able to operate our business without infringing third-party patents. Numerous U.S. and foreign patents and pending patent applications owned by third parties exist in fields that relate to the development and commercialization of immune globulins. In addition, many companies have employed intellectual property litigation as a way to gain a competitive advantage. It is possible that infringement claims may occur as the number of products and competitors in our market increases. In addition, to the extent that we gain greater visibility and market exposure as a public company, we face a greater risk of being the subject of intellectual property infringement claims. We cannot be certain that the conduct of our business does not and will not infringe intellectual property or other proprietary rights of others in the U.S. and in foreign jurisdictions. If our products, methods, processes and other technologies are found to infringe third-party patent rights, we could be prohibited from manufacturing and commercializing the infringing technology, process or product unless we obtain a license under the applicable third-party patent and pay royalties or are able to design around such patent. We may be unable to obtain a license on terms acceptable to us, or at all, and we may not be able to redesign our products or processes to avoid infringement. Even if we are able to redesign our products or processes to avoid an infringement claim, our efforts to design around the patent could require significant time, effort and expense and ultimately may lead to an inferior or more costly product and/or process. Any claim of infringement by a third party, even those without merit, could cause us to incur substantial costs defending against the claim and could distract our management from our business. Furthermore, if any such claim is successful, a court could order us to pay substantial damages, including compensatory damages for any infringement, plus prejudgment interest and could, in certain circumstances, treble the compensatory damages and award attorney fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. A court also could enter orders that temporarily, preliminarily or permanently prohibit us, our licensees, if any, and our customers from making, using, selling, offering to sell or importing one or more of our products or practicing our proprietary technologies or processes, or could enter an order mandating that we undertake certain remedial activities. Any of these events could seriously harm our business, operating results and financial condition.

If we are unable to successfully manage our growth, our business may be harmed.

Our success will depend on the expansion of our commercial and manufacturing activities, supply of plasma and overall operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources. To manage this growth, we must expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business could be harmed.

The loss of one or more key members of our management team could adversely affect our business.

Our performance is substantially dependent on the continued service and performance of our management team, who have extensive experience and specialized expertise in our business. In particular, the loss of Adam S. Grossman, our President and Chief Executive Officer, could adversely affect our business and operating results. We do not have "key person" life insurance policies for any members of our management team. We have employment agreements with each of our executive officers; however, the existence of an employment agreement does not guarantee retention of members of our management team and we may not be able to retain those individuals for the duration of or beyond the end of their respective terms. The loss of services of key personnel, or the inability to attract and retain additional qualified personnel, could result in delays in development or approval of our product candidates and diversion of management resources.

Cyberattacks and other security breaches could compromise our proprietary and confidential information, which could harm our business and reputation.

In the ordinary course of our business, we generate, collect and store proprietary information, including intellectual property and business information. The secure storage, maintenance, and transmission of and access to this information is important to our operations and reputation. Computer hackers may attempt to penetrate our computer systems and, if successful, misappropriate our proprietary and confidential information including e-mails and other electronic communications. In addition, an employee, contractor, or other third party with whom we do business may attempt to obtain such information, and may purposefully or inadvertently cause a breach involving such information. While we have certain safeguards in place to reduce the risk of and detect cyber-attacks, including a company-wide cybersecurity policy, our information technology networks and infrastructure may be vulnerable to unpermitted access by hackers or other breaches, or employee error or malfeasance. Any such compromise of our data security and access to, or public disclosure or loss of, confidential business or proprietary information could disrupt our operations, damage our reputation, provide our competitors with valuable information and subject us to additional costs, which could adversely affect our business.

If we are unable to hire and retain a substantial number of qualified personnel, our ability to sustain and grow our business may be harmed.

We will need to hire additional qualified personnel with expertise in commercialization, sales, marketing, medical affairs, reimbursement, government regulation, formulation and manufacturing and finance and accounting. In particular, over the next 12-24 months, we expect to hire several new employees devoted to commercialization, sales, marketing, medical and scientific affairs, regulatory affairs, quality control, financial, general and operational management. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot assure you that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success and any failure to do so successfully may have a material adverse effect on us.

We currently collect human blood plasma at our ADMA Bio Centers facility, and if we cannot maintain FDA approval for this facility or obtain FDA approval for additional facilities which we create or acquire rights to, we may be adversely affected and may not be able to sell or use this human blood plasma for future commercial purposes.

We intend to maintain FDA approval of our ADMA Bio Centers collection facility in Kennesaw, GA for the collection of human blood plasma and we may seek other governmental and regulatory approvals for this facility. We also plan to grow through the creation and licensing of additional ADMA Bio Centers facilities in various regions of the U.S. Collection facilities are subject to FDA and potentially other governmental and regulatory inspections and extensive regulation, including compliance with current cGMP, FDA and other government approvals, as applicable. Failure to comply with applicable governmental regulations or to receive applicable approvals for our future facilities may result in enforcement actions, such as adverse inspection reports, warning letters, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, costly litigation, refusal of regulatory authority approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses, any of which may significantly delay or suspend our operations for these locations, potentially having a materially adverse effect on our ability to manufacture our products or offer for sale plasma collected at the affected site(s).

We currently manufacture our current marketed products, pipeline products, and products for third parties in our manufacturing and testing facilities, and if we or our vendors cannot maintain appropriate FDA status for these facilities, we may be adversely affected, and may not be able to sell, manufacture or commercialize these products.

We currently operate under the Warning Letter due to issues identified by the FDA in their prior inspections while the Boca Facility was under Biotest's operational control. We engaged a leading consulting firm with extensive experience in remediating compliance and inspection issues related to quality management systems and which manages a robust team of subject matter experts in plasma derived products and biologic drugs to assist us in addressing all identified CMC and cGMP issues and deficiencies. We continue to work with the FDA to resolve the Warning Letter classification. Although we have improved our compliance status at the Boca Facility, there are no assurances we will be able to maintain compliance with all FDA or other regulations. Our third-party vendors may perform activities for themselves or other clients and we may not be privy to all regulatory findings or issues discovered by the FDA or other regulatory agencies. Such findings, which are out of our control, may adversely affect our ability to continue to work with these vendors, or our ability to release commercial drug product or perform necessary testing or other actions for us or our clients, which may be required in order to remain FDA compliant or commercialize our products.

We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.

The testing and marketing of medical products entail an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, either alone or with collaborators.

Many of our business practices are subject to scrutiny by federal and state regulatory authorities, as well as to lawsuits brought by private citizens under federal and state laws. Failure to comply with applicable law or an adverse decision in lawsuits may result in adverse consequences to us.

The laws governing our conduct in the U.S. are enforceable on the federal and state levels by criminal, civil and administrative penalties. Violations of laws such as the Federal Food, Drug, and Cosmetic Act, the Social Security Act (including the Anti-Kickback Statute), the Public Health Service Act and the Federal False Claims Act, and any regulations promulgated under the authority of the preceding, may result in jail sentences, fines or exclusion from federal and state programs, as may be determined by Medicare, Medicaid and the Department of Health and Human Services and other regulatory authorities as well as by the courts. Similarly, the violation of applicable laws, rules and regulations of the State of Florida with respect to the manufacture of our products and product candidates may result in jail sentences, fines or exclusion from applicable state programs. There can be no assurance that our activities will not come under the scrutiny of federal and/or state regulators and other government authorities or that our practices will not be found to violate applicable laws, rules and regulations or prompt lawsuits by private citizen "relators" under federal or state false claims laws.

For example, under the Anti-Kickback Statute and similar state laws and regulations, the offer or payment of anything of value for patient referrals, or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease, or ordering of any time or service reimbursable in whole or in part by a federal health care program is prohibited. This places constraints on the marketing and promotion of products and on common business arrangements, such as discounted terms and volume incentives for customers in a position to recommend or choose products for patients, such as physicians and hospitals, and these practices can result in substantial legal penalties, including, among others, exclusion from the Medicare and Medicaid programs. Arrangements with referral sources such as purchasers, group purchasing organizations, physicians and pharmacists must be structured with care to comply with applicable requirements. Legislators and regulators may seek to further restrict the scope of financial relationships that are considered appropriate. For example, HHS issued a proposed rule in February 2019, which aims to eliminate certain Anti-Kickback Statute safe harbor protection for drug rebates. Also, certain business practices, such as payments of consulting fees to healthcare providers, sponsorship of educational or research grants, charitable donations, interactions with healthcare providers that prescribe products for uses not approved by the FDA and financial support for continuing medical education programs, must be conducted within narrowly prescribed and controlled limits to avoid any possibility of wrongfully influencing healthcare providers to prescribe or purchase particular products or as a reward for past prescribing. Under the Patient Protection and Affordable Care Act (“ACA”) and the companion Health Care and Education Reconciliation Act, which together are referred to as the “Healthcare Reform Law”, payments and transfers of value by pharmaceutical manufacturers subject to this “Sunshine Act” and its implementing regulations to U.S.–licensed physicians and teaching hospitals, must be tracked and reported, and will be publicly disclosed. Such “applicable manufacturers” are also required to report certain ownership interests held by physicians and their immediate family members. In 2018, the Sunshine Act was extended to require tracking and reporting of payments and transfers of value to physician assistants, nurse practitioners, and other mid-level practitioners (with reporting requirements going into effect in 2022 for payments and transfers of value made in 2021). A number of states have similar laws in place. Additional and stricter prohibitions could be implemented by federal and state authorities. Where such practices have been found to be improper incentives to use such products, government investigations and assessments of penalties against manufacturers have resulted in substantial damages and fines. Many manufacturers have been required to enter into consent decrees or orders that prescribe allowable corporate conduct.

Failure to satisfy requirements under the Federal Food, Drug, and Cosmetic Act can also result in penalties, as well as requirements to enter into consent decrees or orders that prescribe allowable corporate conduct. In addition, while regulatory authorities generally do not regulate physicians' discretion in their choice of treatments for their patients, they do restrict communications by manufacturers on unapproved uses of approved products or on the potential safety and efficacy of unapproved products in development. Companies in the U.S., Canada and the European Union cannot promote approved products for other indications that are not specifically approved by the competent regulatory authorities such as the FDA in the U.S., nor can companies promote unapproved products. In limited circumstances, companies may disseminate to physicians information regarding unapproved uses of approved products or results of studies involving investigational products. If such activities fail to comply with applicable regulations and guidelines of the various regulatory authorities, we may be subject to warnings from, or enforcement action by, these authorities. Furthermore, if such activities are prohibited, it may harm demand for our products. Promotion of unapproved drugs or devices or unapproved indications for a drug or device is a violation of the Federal Food, Drug, and Cosmetic Act and subjects us to civil and criminal sanctions. Furthermore, sanctions under the Federal False Claims Act have recently been brought against companies accused of promoting off-label uses of drugs, because such promotion induces the use and subsequent claims for reimbursement under Medicare and other federal programs. Similar actions for off-label promotion have been initiated by several states for Medicaid fraud. The Healthcare Reform Law significantly strengthened provisions of the Federal False Claims Act, the Anti-Kickback Statute that applies to Medicare and Medicaid, and other health care fraud provisions, leading to the possibility of greatly increased qui tam suits by relators for perceived violations. Violations or allegations of violations of the foregoing restrictions could materially and adversely affect our business.

We are required to report detailed pricing information, net of included discounts, rebates and other concessions, to the Centers for Medicare & Medicaid Services (“CMS”) for the purpose of calculating national reimbursement levels, certain federal prices and certain federal and state rebate obligations. Inaccurate or incomplete reporting of pricing information could result in liability under the False Claims Act, the federal Anti-Kickback Statute and various other laws, rules and regulations.

We will need to establish systems for collecting and reporting this data accurately to CMS and institute a compliance program to assure that the information collected is complete in all respects. If we report pricing information that is not accurate to the federal government, we could be subject to fines and other sanctions that could adversely affect our business. If we choose to pursue clinical development and commercialization in the European Union or otherwise market and sell our products outside of the U.S., we must obtain and maintain regulatory approvals and comply with regulatory requirements in such jurisdictions. The approval procedures vary among countries in complexity and timing. We may not obtain approvals from regulatory authorities outside the U.S. on a timely basis, if at all, which would preclude us from commercializing products in those markets.

In addition, some countries, particularly the countries of the European Union, regulate the pricing of prescription pharmaceuticals. In these countries, pricing discussions with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Such trials may be time-consuming and expensive, and may not show an advantage in efficacy for our products. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, in either the U.S. or the European Union, we could be adversely affected.

Also, under the U.S. Foreign Corrupt Practices Act, the U.S. has increasingly focused on regulating the conduct by U.S. businesses occurring outside of the U.S., generally prohibiting remuneration to foreign officials for the purpose of obtaining or retaining business. To enhance compliance with applicable health care laws, and mitigate potential liability in the event of noncompliance, regulatory authorities such as the U.S. Health and Human Services Department Office of Inspector General (the “OIG”) have recommended the adoption and implementation of a comprehensive health care compliance program that generally contains the elements of an effective compliance and ethics program described in Section 8B2.1 of the U.S. Sentencing Commission Guidelines Manual. Increasing numbers of U.S.-based pharmaceutical companies have such programs. We will need to adopt healthcare compliance and ethics programs that would incorporate the OIG's recommendations and train our employees. Such a program may be expensive and may not provide assurance that we will avoid compliance issues.

We are also required to comply with the applicable laws, rules, regulations and permit requirements of the various states in which our business operates, including the State of Florida where our manufacturing facility is located. These regulations and permit requirements are not always in concert with applicable federal laws, rules and regulations regulating our business. Although compliant with applicable federal requirements, we may be required to comply with additional state laws, rules, regulations and permits. Failure to appropriately comply with such state requirements could result in temporary or long-term cessation of our manufacturing operations, as well as fines and other sanctions. Any such penalties may have a material adverse effect on our business and results of operations.

We are subject to extensive and rigorous governmental regulation, including the requirement of FDA and other federal, state and local business regulatory approval before our products and product candidates may be lawfully marketed, and our ability to obtain regulatory approval of our products and product candidates from the FDA in a timely manner, access the public markets and obtain necessary capital in order to properly capitalize and continue our operations may be hindered by inadequate funding for the FDA, the SEC and other state and local government agencies.

Both before and after the approval of our products, our products, our operations, our facilities, our suppliers and our contract research organizations are subject to extensive regulation by federal, state and local governmental authorities in the U.S. and other countries, with regulations differing from country to country. In the U.S., the FDA regulates, among other things, the pre-clinical testing, clinical trials, manufacturing, safety, efficacy, potency, labeling, storage, record keeping, quality systems, advertising, promotion, sale and distribution of therapeutic products. Failure to comply with applicable requirements could result in, among other things, one or more of the following actions: notices of violation, untitled letters, warning letters, complete response letters, fines and other monetary penalties, unanticipated expenditures, delays in approval or refusal to approve a product or product candidate, product recall or seizure, interruption of manufacturing or clinical trials, operating restrictions, injunctions and criminal prosecution. Our products and product candidates cannot be lawfully marketed in the U.S. without FDA and other federal, state and local business regulatory approval. Any failure to receive the marketing approvals necessary to commercialize our product or product candidates could harm our business.

The regulatory review and approval process of governmental authorities is lengthy, expensive and uncertain. For example, in December 2016, BPC, the owner of BIVIGAM prior to the Biotest Transaction in June 2017, temporarily suspended the commercial production of BIVIGAM in order to focus on the completion of planned improvements to the manufacturing process. We resumed production of BIVIGAM utilizing our optimized IVIG manufacturing process with two conformance lots in the fourth quarter of 2017 and a third conformance lot in the first quarter of 2018. During the first half of 2018, we qualified and filled the BIVIGAM conformance batches and the product is on stability. In June 2018, we filed a drug substance PAS with the FDA for BIVIGAM to include the ADMA optimization improvements for BIVIGAM and to seek FDA authorization which would enable us to resume commercial scale manufacturing and relaunch and commercialize this product. On December 19, 2018, we received the BIVIGAM CRL for our PAS submission for BIVIGAM drug substance. The BIVIGAM CRL requested certain additional information and clarifications relating to CMC matters contained in our PAS submission for drug substance, including complete resolution of certain manufacturing related deviations, information pertaining to how certain in-process manufacturing samples are taken, as well as updates on certain stability data previously submitted. As the information we believed necessary to address and respond to the matters raised in the BIVIGAM CRL was readily available in our files, on January 7, 2019 we announced that our responses to the BIVIGAM CRL were submitted to the FDA for further review. Subsequent to the January 7, 2019 resubmission to the FDA, we received an information request for a limited number of questions. We believe that all requests contained in the recently received FDA information request were addressable and we have responded to the FDA. To date, we have not received a formal BIVIGAM CRL resubmission acknowledgment and we have not received formal clarity on the FDA's intended review timing. We can confirm that the FDA is actively reviewing our BIVIGAM CRL resubmission and information request responses, however we cannot provide any assurance or predict with certainty the schedule for when we will, if at all, receive authorization from the FDA with respect to our PAS for BIVIGAM.

Additionally, the ability of the FDA and other federal, state and local business regulatory agencies to review and approve products and product candidates can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA and other federal, state and local business regulatory agencies have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for products and product candidate submissions to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including in December 2018 and January 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown reoccurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions and other reporting requirements, including our drug substance PAS for BIVIGAM, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

The manufacturing processes for plasma-based biologics are complex and involve biological intermediates that are susceptible to contamination and impurities.

Plasma is a raw material that is susceptible to damage and contamination and may contain human pathogens, any of which would render the plasma unsuitable as raw material for further manufacturing. For instance, improper storage of plasma, by us or third-party suppliers, may require us to destroy some of our raw material. If unsuitable plasma is not identified and discarded prior to the release of the plasma to the manufacturing process, it may be necessary to discard intermediate or finished product made from that plasma or to recall any finished product released to the market, resulting in a charge to cost of product revenue. The manufacture of our plasma products is an extremely complex process of fractionation, purification, filling and finishing. Our products can become non-releasable or otherwise fail to meet our stringent specifications or regulatory agencies' specifications through a failure in one or more of these process steps. We may detect instances in which an unreleased product was produced without adherence to our manufacturing procedures or plasma used in our production process was not collected or stored in a compliant manner consistent with our cGMP or other regulations. Such an event of noncompliance would likely result in our determination that the implicated products should not be released or maybe replaced or withdrawn from the market and therefore should be destroyed. Once manufactured, our plasma-derived products must be handled carefully and kept at appropriate temperatures. Our failure, or the failure of third parties that supply, ship or distribute our products, to properly care for our products may require that those products be destroyed. Even if handled properly, biologics may form or contain particulates or have other issues or problems after storage which may require products to be destroyed or recalled. While we expect to write off small amounts of work-in-progress in the ordinary course of business due to the complex nature of plasma, our processes and our products, unanticipated events may lead to write-offs and other costs materially in excess of our expectations and the reserves we have established for these purposes. Such write-offs and other costs could cause material fluctuations in our results of operations.

Furthermore, contamination of our products could cause investors, consumers, or other third parties with whom we conduct business to lose confidence in the reliability of our manufacturing procedures, which could adversely affect our revenues. In addition, faulty or contaminated products that are unknowingly distributed could result in patient harm, threaten the reputation of our products and expose us to product liability damages and claims from companies for whom we do contract manufacturing.

Our ability to continue to produce safe and effective products depends on the safety of our plasma supply, testing by third parties and manufacturing processes against transmittable diseases.

Despite overlapping safeguards, including the screening of donors and other steps to remove or inactivate viruses and other infectious disease causing agents, the risk of transmissible disease through blood plasma products cannot be entirely eliminated. For example, since plasma-derived therapeutics involves the use and purification of human plasma, there has been concern raised about the risk of transmitting human immunodeficiency virus (“HIV”), prions, West Nile virus, H1N1 virus or "swine flu" and other blood-borne pathogens through plasma-derived products. There are also concerns about the future transmission of H5N1 virus, or "bird flu." In the 1980s, thousands of hemophiliacs worldwide were infected with HIV through the use of contaminated Factor VIII. Other producers of Factor VIII, though not us, were defendants in numerous lawsuits resulting from these infections. New infectious diseases emerge in the human population from time to time. If a new infectious disease has a period during which time the causative agent is present in the bloodstream but symptoms are not present, it is possible that plasma donations could be contaminated by that infectious agent. Typically, early in an outbreak of a new disease, tests for the causative agent do not exist. During this early phase, we must rely on screening of donors for behavioral risk factors or physical symptoms to reduce the risk of plasma contamination. Screening methods are generally less sensitive and specific than a direct test as a means of identifying potentially contaminated plasma units. During the early phase of an outbreak of a new infectious disease, our ability to manufacture safe products would depend on the manufacturing process' capacity to inactivate or remove the infectious agent. To the extent that a product's manufacturing process is inadequate to inactivate or remove an infectious agent, our ability to manufacture and distribute that product would be impaired. If a new infectious disease were to emerge in the human population, or if there were a reemergence of an infectious disease, the regulatory and public health authorities could impose precautions to limit the transmission of the disease that would impair our ability to procure plasma, manufacture our products or both. Such precautionary measures could be taken before there is conclusive medical or scientific evidence that a disease poses a risk for plasma-derived products. In recent years, new testing and viral inactivation methods have been developed that more effectively detect and inactivate infectious viruses in collected plasma. There can be no assurance, however, that such new testing and inactivation methods will adequately screen for, and inactivate, infectious agents in the plasma used in the production of our products.

We could become supply-constrained and our financial performance would suffer if we cannot obtain adequate quantities of FDA-approved source plasma with proper specifications or other necessary raw materials.

In order for plasma to be used in the manufacturing of our products, the individual centers at which the plasma is collected must be licensed by the FDA and approved by the regulatory authorities of any country in which we may wish to commercialize our products. When we open a new plasma center, and on an ongoing basis after licensure, it must be inspected by the FDA for compliance with cGMP and other regulatory requirements. Therefore, even if we are able to construct new plasma collection centers to complement our Kennesaw, GA plasma collection facility, an unsatisfactory inspection could prevent a new center from being licensed or risk the suspension or revocation of an existing license. We do not and will not have adequate plasma to manufacture our products. Therefore, we are reliant on the purchase of plasma from third parties to manufacture our products. We can give no assurances that appropriate plasma will be available to us on commercially reasonable terms, or at all, to manufacture our products. In order to maintain a plasma center's license, its operations must continue to conform to cGMP and other regulatory requirements. In the event that we determine that plasma was not collected in compliance with cGMP, we may be unable to use and may ultimately destroy plasma collected from that center, which would be recorded as a charge to cost of product revenue. Additionally, if non-compliance in the plasma collection process is identified after the impacted plasma has been pooled with compliant plasma from other sources, entire plasma pools, in-process intermediate materials and final products could be impacted. Consequently, we could experience significant inventory impairment provisions and write-offs which could adversely affect our business and financial results. We plan to increase our supplies of plasma for use in the manufacturing processes through increased purchases of plasma from third-party suppliers as well as collections from our existing ADMA Bio Centers plasma collection facility. This strategy is dependent upon our ability to maintain a cGMP compliant environment in our plasma facility and to expand production and attract donors to our facility. There is no assurance that the FDA will inspect and license any of our unlicensed plasma collection facilities which we may, in the future, construct, in a timely manner consistent with our production plans. If we misjudge the readiness of a center for an FDA inspection, we may lose credibility with the FDA and cause the FDA to more closely examine all of our operations. Such additional scrutiny could materially hamper our operations and our ability to increase plasma collections. Our ability to expand production and increase our plasma collection facility to more efficient production levels may be affected by changes in the economic environment and population in selected regions where ADMA Bio Centers operates its current or future plasma facilities, by the entry of competitive plasma centers into regions where ADMA Bio Centers operates such centers, by misjudging the demographic potential of individual regions where ADMA Bio Centers expects to expand production and attract new donors, by unexpected facility related challenges, or by unexpected management challenges at selected plasma facilities held by us from time to time.

Our ability to commercialize our products, alone or with collaborators, will depend in part upon the extent to which reimbursement will be available from governmental agencies, health administration authorities, private health maintenance organizations and health insurers and other healthcare payers, and also depends upon the approval, timing and representations by the FDA or other governmental authorities for our product candidates. As the FDA BLA review process is ongoing, we are subject to information requests and communications from the FDA on a routine basis and may not have clarity on any or all specific aspects of the approval timing, language, name, claims and any other future requirements that may be imposed by the FDA or other governmental agencies for marketing, authorization and ultimately financial reimbursement for patient utilization.

Our ability to generate product revenues will be diminished if our products sell for inadequate prices or patients are unable to obtain adequate levels of coverage. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products, as well as to the timing, language, specifications and other details pertaining to the approval of such products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for products. Even if one of our product candidates is approved by the FDA, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover such product. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for one of our products, once approved, market acceptance of such product could be reduced. Prices in many countries, including many in Europe, are subject to local regulation and certain pharmaceutical products, such as plasma-derived products, are subject to price controls in several of the world's principal markets, including many countries within the European Union. In the U.S., where pricing levels for our products are substantially established by third-party payers, including Medicare, if payers reduce the amount of reimbursement for a product, it may cause groups or individuals dispensing the product to discontinue administration of the product, to administer lower doses, to substitute lower cost products or to seek additional price-related concessions. These actions could have a negative effect on our financial results, particularly in cases where our products command a premium price in the marketplace, or where changes in reimbursement induce a shift in the site of treatment. The existence of direct and indirect price controls and pressures over our products could materially adversely affect our financial prospects and performance.

The new biosimilar pathway established as part of healthcare reform may make it easier for competitors to market biosimilar products.

The Healthcare Reform Law introduced an abbreviated licensure pathway for biological products that are demonstrated to be biosimilar to an FDA-licensed biological product. A biological product may be demonstrated to be "biosimilar" if data shows that, among other things, the product is "highly similar" to an already-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. The law provides that a biosimilar application may be submitted as soon as four years after the reference product is first licensed, and that the FDA may not make approval of an application effective until 12 years after the reference product was first licensed. Since the enactment of the law, the FDA has issued several guidance documents to assist sponsors of biosimilar products in preparing their approval applications. The FDA approved the first biosimilar product in 2015, and has since approved a number of biosimilars. As a result of the biosimilar pathway in the U.S., we expect in the future to face greater competition from biosimilar products, including a possible increase in patent challenges.

The implementation of the Healthcare Reform Law in the U.S. may adversely affect our business.

Through the March 2010 adoption of the Healthcare Reform Law in the U.S., substantial changes are being made to the current system for paying for healthcare in the U.S., including programs to extend medical benefits to millions of individuals who currently lack insurance coverage. The changes contemplated by the Healthcare Reform Law are subject to rule-making and implementation timelines that extend for several years, and this uncertainty limits our ability to forecast changes that may occur in the future. However, implementation has already begun with respect to certain significant cost-saving measures under the Healthcare Reform Law, for example with respect to several government healthcare programs, including Medicaid and Medicare Parts B and D, that may cover the cost of our future products, and these efforts could have a material adverse impact on our future financial prospects and performance. For example, in order for a manufacturer's products to be reimbursed by federal funding under Medicaid, the manufacturer must enter into a Medicaid rebate agreement with the Secretary of the U.S. Department of Health and Human Services and pay certain rebates to the states based on utilization data provided by each state to the manufacturer and to CMS and pricing data provided by the manufacturer to the federal government. The states share these savings with the federal government, and sometimes implement their own additional supplemental rebate programs. Under the Medicaid drug rebate program, the rebate amount for most branded drug products was previously equal to a minimum of 15.1% of the Average Manufacturer Price ("AMP") or the AMP less Best Price, whichever is greater. Effective January 1, 2010, the Healthcare Reform Law generally increased the size of the Medicaid rebates paid by manufacturers for single source and innovator multiple source (brand name) drug products from a minimum of 15.1% to a minimum of 23.1% of AMP, subject to certain exceptions. For non-innovator multiple source (generic) products, the rebate percentage is increased from a minimum of 11.0% to a minimum of 13.0% of AMP. In 2010, the Healthcare Reform Law also newly extended this rebate obligation to prescription drugs covered by Medicaid managed care organizations. These increases in required rebates may adversely affect our future financial prospects and performance. In order for a pharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. As the 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.

Effective in 2011, the Healthcare Reform Law imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs. These fees may adversely affect our future financial prospects and performance. The Healthcare Reform Law established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation through 2019.

The Healthcare Reform Law also creates new rebate obligations for our products under Medicare Part D, a partial, voluntary prescription drug benefit created by the U.S. federal government primarily for persons 65 years old and over. The Part D drug program is administered through private insurers that contract with CMS. Beginning in 2011, the Healthcare Reform Law generally requires that in order for a drug manufacturer's products to be reimbursed under Medicare Part D, the manufacturer must enter into a Medicare Coverage Gap Discount Program agreement with the Secretary of the U.S. Department of Health and Human Services, and reimburse each Medicare Part D plan sponsor an amount equal to 50% savings for the manufacturer's brand name drugs and biologics which the Part D plan sponsor has provided to its Medicare Part D beneficiaries who are in the "donut hole" (or a gap in Medicare Part D coverage for beneficiaries who have expended certain amounts for drugs). The Part D plan sponsor is responsible for calculating and providing the discount directly to its beneficiaries and for reporting these amounts paid to CMS's contractor, which notifies drug manufacturers of the rebate amounts it must pay to each Part D plan sponsor. The rebate requirement could adversely affect our future financial performance, particularly if contracts with Part D plans cannot be favorably renegotiated or the Part D plan sponsors fail to accurately calculate payments due in a manner that overstates our rebate obligation. Regarding access to our products, the Healthcare Reform Law established and provided significant funding for a Patient-Centered Outcomes Research Institute to coordinate and fund Comparative Effectiveness Research (“CER”). While the stated intent of CER is to develop information to guide providers to the most efficacious therapies, outcomes of CER could influence the reimbursement or coverage for therapies that are determined to be less cost-effective than others. Should any of our products be determined to be less cost effective than alternative therapies, the levels of reimbursement for these products, or the willingness to reimburse at all, could be impacted, which could materially impact our future financial prospects and results.

There have been repeated attempts by Congress to repeal or change the Healthcare Reform Law. Further, on January 20, 2017, the new administration signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the Healthcare Reform Law that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. More recently, the United States District Court for the Northern District of Texas struck down the Healthcare Reform Law, deeming it unconstitutional given that Congress repealed the individual mandate in 2017. This decision has been stayed pending outcome of an appeal to the Fifth Circuit Court of Appeals. Although there is no immediate impact on the ACA, we will continue to evaluate the effect that the Healthcare Reform Law and its possible repeal and replacement, or potential total revocation by the Supreme Court of the United States, has on our business.

Developments in the worldwide economy may adversely impact our business.

The difficult economic environment may adversely affect demand for our products. ASCENIV is expected to be sold to hospitals, specialty pharmacies and clinicians in the U.S. As a result of loss of jobs, patients may lose medical insurance and be unable to purchase our products or may be unable to pay their share of deductibles or co-payments. Hospitals adversely affected by the economy may steer patients to less costly therapies, resulting in a reduction in demand, or demand may shift to public health hospitals, which may purchase at a lower government price.

Risks Relating to our Finances, Capital Requirements and Other Financial Matters

We require additional funding and may be unable to raise capital when needed, which would force us to delay, curtail or eliminate one or more of our research and development programs or commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. For the three months ended March 31, 2019 and 2018, we had negative cash flows from operations of $14.3 million and $16.4 million, respectively, and for the years ended December 31, 2018 and 2017, we had negative cash flows from operations of approximately $62.7 million and $37.3 million, respectively. We expect to continue to spend substantial amounts on product development, including commercialization activities, procuring raw material plasma, manufacturing, conducting potential future clinical trials for our product candidates and purchasing clinical trial materials from our suppliers, conducting commercial launch activities and potential post-marketing studies. We currently anticipate, based upon our projected revenue and expenditures, as well as the additional funds we are able to draw down under the Credit Agreement, that our current cash, cash equivalents and accounts receivable will be sufficient to fund our operations, as currently conducted, into the fourth quarter of 2019. In order to have sufficient cash to fund our operations thereafter and to continue as a going concern, we will need to raise additional equity or debt financing by the fourth quarter of 2019. This time frame may change based upon how quickly we are able to execute on our operational initiatives and the various financing options we are exploring**.** However, if the assumptions underlying our estimated expenses prove to be incorrect, we may have to raise additional capital sooner than we currently expect. Until such time, if ever, as we can generate a sufficient amount of product revenue to achieve profitability, we expect to continue to finance our operations through additional equity or debt financings or corporate collaboration and licensing arrangements. If we are unable to raise additional capital as needed, we will have to delay, curtail or eliminate our product development activities, including conducting clinical trials for our product candidates and purchasing clinical trial materials from our suppliers, as well as future commercialization efforts.

Raising additional funds by issuing securities or through licensing or lending arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights.

To the extent that we raise additional capital by issuing equity securities, the share ownership of existing stockholders will be diluted. Any future debt financing may involve covenants that, among other restrictions, limit our ability to incur liens or additional debt, pay dividends, redeem or repurchase our Common Stock, make certain investments or engage in certain merger, consolidation or asset sale transactions. In addition, if we raise additional funds through licensing arrangements or the disposition of any of our assets, it may be necessary to relinquish potentially valuable rights to our product candidates or grant licenses on terms that are not favorable to us.

Our cash, cash equivalents and short-term investments could be adversely affected if the financial institutions in which we hold our cash, cash equivalents and short-term investments fail.

We regularly maintain cash balances at third-party financial institutions in excess of the Federal Deposit Insurance Corporation insurance limit. While we monitor the cash balances in our operating accounts on a daily basis and adjust the balances as appropriate, these balances could be impacted, and there could be a material adverse effect on our business, if one or more of the financial institutions with which we deposit cash fails or is subject to other adverse conditions in the financial or credit markets. To date, we have experienced no loss or lack of access to our invested cash or cash equivalents; however, we can provide no assurance that access to our invested cash and cash equivalents will not be impacted by adverse conditions in the financial and credit markets.

If we fail to maintain proper and effective internal control over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our Common Stock.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 (the “Sarbanes-Oxley Act”) and related rules, our management is required to report on the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), we have been required to upgrade, and may need to implement further upgrades, to our financial, information and operating systems, implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff.

Our ability to use our net operating loss carryforwards (“NOLs”) may be limited.

We have incurred substantial losses during our history. As of December 31, 2018, we had federal and state NOLs of $108.5 million and $72.3 million, respectively. These NOLs will begin to expire at various dates beginning in 2027, if not limited by triggering events prior to such time. Under the provisions of the Internal Revenue Code, changes in our ownership, in certain circumstances, will limit the amount of federal NOLs that can be utilized annually in the future to offset taxable income. In particular, Section 382 of the Internal Revenue Code (“Section 382”) imposes limitations on a company’s ability to use NOLs upon certain changes in such ownership. If we are limited in our ability to use our NOLs in future years in which we have taxable income, we will pay more taxes than if we were able to fully utilize our NOLs. The Biotest Transaction on June 6, 2017 resulted in a change in ownership of ADMA under Section 382 and as result, we were required to write off $57.6 million of federal NOLs. We may experience ownership changes in the future as a result of subsequent changes in our stock ownership that we cannot predict or control that could result in further limitations being placed on our ability to utilize our federal NOLs.

The Tax Cuts and Jobs Act (the "TCJA") could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law the TCJA, which significantly reforms the Internal Revenue Code. The TCJA, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses generated after December 31, 2017 to 80% of current year taxable income and elimination of net operating loss carrybacks, immediate deductions for certain new investments instead of deductions for depreciation expense over time and modifying or repealing many business deductions and credits. Federal net operating losses arising in taxable years ending after December 31, 2017 will be carried forward indefinitely pursuant to the TCJA. We continue to examine the impact this tax reform legislation may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the TCJA is uncertain and our business and financial condition could be adversely affected. The impact of this tax reform on holders of our Common Stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our Common Stock.

Risks Associated with our Common Stock

The market price of our Common Stock may be volatile and may fluctuate in a way that is disproportionate to our operating performance.

Our stock price may experience substantial volatility as a result of a number of factors, including:

- sales or potential sales of substantial amounts of our Common Stock;
- our ability to successfully leverage the anticipated benefits and synergies from the Biotest Transaction, including optimization of the combined businesses, operations and products and services, including the nature, strategy and focus of the combined company and the management and governance structure of the combined company;
- delay or failure in initiating or completing preclinical or clinical trials or unsatisfactory results of these trials;
- delay in a decision by federal, state or local business regulatory authority;
- the timing of acceptance, third-party reimbursement and sales of ASCENIV;
- our ability to resume the manufacturing of BIVIGAM once the deficiencies identified in the CRL have been resolved by us to the satisfaction of the FDA;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions;
- developments concerning our licensors or third-party vendors;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- conditions in the pharmaceutical or biotechnology industries;
- governmental regulation and legislation;

- variations in our anticipated or actual operating results; and

- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations.

Many of these factors are beyond our control. The stock markets in general, and the market for pharmaceutical and biotechnology companies in particular, have historically experienced extreme price and volume fluctuations. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors could reduce the market price of our Common Stock, regardless of our actual operating performance.

An investment in our Common Stock is extremely speculative and there can be no assurance of any return on any such investment.

An investment in our Common Stock is extremely speculative and there is no assurance that investors will obtain any return on their investment. Investors will be subject to substantial risks involved in an investment in us, including the risk of losing their entire investment.

Sales of a substantial number of shares of our Common Stock, or the perception that such sales may occur, may adversely impact the market price of our Common Stock.

As of April 1, 2019, most of our 46,353,068 outstanding shares of Common Stock, as well as a substantial number of shares of our Common Stock underlying outstanding warrants, were available for sale in the public market, subject to certain restrictions with respect to sales of our Common Stock by our affiliates, either pursuant to Rule 144 ("Rule 144") under the Securities Act of 1933, as amended (the "Securities Act"), or under effective registration statements. Pursuant to the Stockholders' Agreement, until December 6, 2020, subject to certain limited exceptions, sales of the 10,109,534 shares of Common Stock held by The Biotest Divestiture Trust (the "Biotest Trust") (as successor-in-interest to BPC) may not exceed 15% of the issued and outstanding Common Stock of ADMA in any twelve-month period; provided, however, that if our market capitalization increases to double our market capitalization immediately following the closing of the Biotest Transaction, then the Biotest Trust may sell up to 20% of our issued and outstanding Common Stock in any twelve-month period; provided, further, that (x) if our market capitalization increases to triple our market capitalization immediately following the closing of the Biotest Transaction, or (y) upon the one-year anniversary of the Biotest Trust holding less than a 25% economic interest in us, which occurred on May 14, 2018 following the transfer of the NV Biotest Shares to us, then the Biotest Trust may sell any amount of its equity interests in us at any time (subject to applicable securities laws). Sales of a substantial number of shares of our Common Stock, or the perception that such sales may occur, may adversely impact the market price of our Common Stock.

Our affiliates control a substantial amount of our shares of Common Stock. Provisions in our Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation"), our Amended and Restated Bylaws (the "Bylaws") and Delaware law might discourage, delay or prevent a change in control of our Company or changes in our management and, therefore, depress the trading price of our Common Stock.

As of April 1, 2019, the Biotest Trust, our directors and executive officers and their affiliates beneficially owned approximately 40% of the outstanding shares of our Common Stock. Additionally, on November 14, 2018, the standstill provisions contained in that certain Stockholders Agreement, dated as of June 6, 2017, by and between us and BPC, as amended by that certain Share Transfer, Amendment and Release Agreement, dated as of May 14, 2018, with BPC, Biotest AG and the Biotest Trust, which prohibited the Biotest Trust from, among other things, acquiring more than (i) 50%, less one share, of our issued and outstanding shares of capital stock on an as-converted basis, or (ii) 30% of the issued and outstanding shares of Common Stock, terminated and are of no further force and effect. Such event could result in the Biotest Trust acquiring additional shares of our Common Stock or taking other actions with the goal of acquiring additional shares of our Common Stock.

Provisions of our Certificate of Incorporation, our Bylaws and Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of our Company or changes in our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interests. These provisions include:

- the inability of stockholders to call special meetings;
- the ability of our Board of Directors (the "Board") to institute a stockholder rights plan, also known as a poison pill, that would work to dilute our stock,
- classification of our Board and limitation on filling of vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our Company; and
- authorization of the issuance of "blank check" preferred stock, with such designation rights and preferences as may be determined from time to time by the Board, without any need for action by stockholders.

In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years, has owned 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our Common Stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that you could receive a premium for your Common Stock in an acquisition. In addition, as a result of the concentration of ownership of our shares of Common Stock, our stockholders may, from time to time, observe instances where there may be less liquidity in the public markets for our securities.

We have never paid and do not intend to pay cash dividends in the foreseeable future. As a result, capital appreciation, if any, will be your sole source of gain.

We have never paid cash dividends on any of our capital stock and we currently intend to retain future earnings, if any, to fund the development and growth of our business. In addition, the terms of existing and future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our Common Stock will be your sole source of gain for the foreseeable future.

If we fail to adhere to the strict listing requirements of the Nasdaq Capital Market ("Nasdaq"), we may be subject to delisting. As a result, our stock price may decline and our Common Stock may be delisted. If our stock were no longer listed on Nasdaq, the liquidity of our securities likely would be impaired.

Our Common Stock currently trades on Nasdaq under the symbol "ADMA." If we fail to adhere to Nasdaq's strict listing criteria, including with respect to stock price, our market capitalization and stockholders' equity, our stock may be delisted. This could potentially impair the liquidity of our securities not only in the number of shares that could be bought and sold at a given price, which may be depressed by the relative illiquidity, but also through delays in the timing of transactions and the potential reduction in media coverage. As a result, an investor might find it more difficult to dispose of our Common Stock. We believe that current and prospective investors would view an investment in our Common Stock more favorably if it continues to be listed on Nasdaq. Any failure at any time to meet the Nasdaq continued listing requirements could have an adverse impact on the value of and trading activity of our Common Stock. Although we currently satisfy the listing criteria for Nasdaq, if our stock price declines dramatically, we could be at risk of failing to meet the Nasdaq continued listing criteria.

Penny stock regulations may affect your ability to sell our Common Stock.

Because the price of our Common Stock currently trades below $5.00 per share, our Common Stock is subject to Rule 15g-9 under the Exchange Act, which imposes additional sales practice requirements on broker dealers which sell these securities to persons other than established customers and accredited investors. Under these rules, broker-dealers who recommend penny stocks to persons other than established customers and "accredited investors" must make a special written suitability determination for the purchaser and receive the purchaser's written agreement to a transaction prior to sale, which includes an acknowledgement that the purchaser's financial situation, investment experience and investment objectives forming the basis for the broker-dealer's suitability determination are accurately stated in such written agreement. Unless an exception is available, the regulations require the delivery, prior to any transaction involving a penny stock, of a disclosure schedule explaining the penny stock market and the associated risks. The additional burdens imposed upon broker-dealers by these requirements could discourage broker-dealers from effecting transactions in our Common Stock and may make it more difficult for holders of our Common Stock to sell shares to third parties or to otherwise dispose of them.

We will continue to incur increased costs now that we are no longer an "emerging growth company."

Effective January 1, 2019, we ceased to be an "emerging growth company" as defined by the Jumpstart Our Business Startups Act (the "JOBS Act"). The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for qualifying public companies. As an "emerging growth company," we took advantage of certain benefits afforded to "emerging growth companies" under Section 7(a)(2)(B) of the Securities Act, which included delaying the adoption of new or revised accounting standards applicable to public companies until such standards would otherwise apply to private companies. As an emerging growth company, we were also exempt from the requirement to have our independent registered public accounting firm provide an attestation report on our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act ("Section 404").

Consequently, we have, and will continue to, incur increased costs related to our compliance with Section 404 of the Sarbanes-Oxley Act ("Section 404"). For example, in 2018, our Audit Committee retained the services of AC Lordi, a Sarbanes-Oxley advisor, to assist with our internal controls over financial reporting and information technology relating to Section 404. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our Common Stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Our Board may, without stockholder approval, issue and fix the terms of shares of preferred stock and issue additional shares of Common Stock adversely affecting the rights of holders of our Common Stock.

Our Certificate of Incorporation authorizes the issuance of up to 10,000,000 shares of "blank check" preferred stock, with such designation rights and preferences as may be determined from time to time by the Board. Currently, our Certificate of Incorporation authorizes the issuance of up to 75,000,000 shares of Common Stock, of which, as of April 10, 2019, 21,159,337 shares remain available for issuance and may be issued by us without stockholder approval (exclusive of 7,487,595 shares of our Common Stock which were subject to outstanding stock options, warrants or other convertible securities as of April 10, 2019), and up to 8,591,160 shares of non-voting common stock, all of which were reacquired by us in May 2018 pursuant to the Biotest Transfer Agreement and were subsequently retired and are no longer available for issuance.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits

See the Exhibit Index immediately following the signature page of this Quarterly Report on Form 10-Q.

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.

ADMA Biologics, Inc.

Date: May 8, 2019

By: /s/ Adam S. Grossman
Name: Adam S. Grossman
Title: President and Chief Executive Officer

Date: May 8, 2019

By: /s/ Brian Lenz
Name: Brian Lenz
Title: Executive Vice President and Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
4.1	Note, dated February 11, 2019, issued by the Company to Perceptive Credit Holdings II, LP (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the SEC on February 12, 2019).
4.2	Warrant to Purchase Stock, dated February 11, 2019, issued by the Company to Perceptive Credit Holdings II, LP (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K, filed with the SEC on February 12, 2019).
10.1+	Transition Services Agreement, dated as of January 1, 2019, by and between the Company and Biotest Pharmaceuticals Corporation (incorporated herein by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K, filed with the SEC on March 13, 2019).
10.2	Fifth Amendment to Plasma Purchase Agreement, effective as of January 1, 2019, by and between ADMA Biologics, Inc. and Grifols Worldwide Operations Limited (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on January 2, 2019).
10.3	Amended and Restated Employment Agreement, dated as of January 29, 2019, by and between ADMA Biologics, Inc. and Adam Grossman (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on January 29, 2019).
10.4	Amended and Restated Employment Agreement, dated as of January 29, 2019, by and between ADMA Biologics, Inc. and Dr. James Mond (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on January 29, 2019).
10.5	Amended and Restated Employment Agreement, dated as of January 29, 2019, by and between ADMA Biologics, Inc. and Brian Lenz (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed with the SEC on January 29, 2019).
10.6	Credit Agreement and Guaranty, dated as of February 11, 2019, by and among ADMA Biologics, Inc., ADMA Plasma Biologics, Inc., ADMA Bio Centers Georgia Inc., ADMA BioManufacturing, LLC, and Perceptive Credit Holdings II, LP (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on February 12, 2019).
10.7	Security Agreement, dated as of February 11, 2019, by and among ADMA Biologics, Inc., ADMA Plasma Biologics, Inc., ADMA Bio Centers Georgia Inc., ADMA BioManufacturing, LLC, and Perceptive Credit Holdings II, LP (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on February 12, 2019).
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following materials from ADMA Biologics, Inc.'s Form 10-Q for the quarter ended March 31, 2019, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets as of March 31, 2019 (Unaudited) and December 31, 2018, (ii) Condensed Consolidated Statements of Operations (Unaudited) for the three months ended March 31, 2019 and 2018, (iii) Condensed Consolidated Statement of Changes in Stockholders' Equity (Unaudited) for the three months ended March 31, 2019 and 2018, (iv) Condensed Consolidated Statements of Cash Flows (Unaudited) for the three months ended March 31, 2019 and 2018, and (v) Notes to (Unaudited) Condensed Consolidated Financial Statements.

* Filed herewith.

** In accordance with SEC Release 33-8238, Exhibit 32.1 and 32.2 are being furnished and not filed.

+ Confidential treatment has been granted with respect as to certain portions of this exhibit. Such portions have been redacted and submitted separately to the SEC.

Exhibit 31.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Adam S. Grossman, certify that:

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

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

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

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

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, 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 this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth 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 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: May 8, 2019

By: /s/ Adam S. Grossman
Name: Adam S. Grossman
Title: President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brian Lenz, certify that:

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

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

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

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

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, 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 this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth 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 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: May 8, 2019

By: /s/ Brian Lenz
Name: Brian Lenz
Title: Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of ADMA Biologics, Inc., a Delaware corporation (the "Company"), on Form 10-Q for the quarter ended March 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Adam S. Grossman, President and Chief Executive Officer of the Company, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 8, 2019

By: /s/ Adam S. Grossman
Name: Adam S. Grossman
Title: President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of ADMA Biologics, Inc., a Delaware corporation (the "Company"), on Form 10-Q for the quarter ended March 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Brian Lenz, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 8, 2019

By: /s/ Brian Lenz
Name: Brian Lenz
Title: Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)