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, 2020

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)	(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)

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 Global Market

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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

As of May 4, 2020, there were 86,345,313 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 Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended. These statements include, among others, statements about:

- our ability to manufacture BIVIGAM on a commercial scale and commercialize this product as a result of the approval of the Prior Approval Supplement for BIVIGAM by the U.S. Food and Drug Administration (the "FDA") on May 9, 2019;
- our ability to manufacture ASCENIV on a commercial scale and commercialize this product as a result of the FDA approval of ASCENIV's Biologics License Application on April 1, 2019;
- our plans to develop, manufacture, market, launch and expand our 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 for our product candidates;
- our dependence upon our third-party customers and vendors and their compliance with applicable regulatory requirements;
- our ability to obtain adequate quantities of FDA-approved plasma with proper specifications;
- our plans to increase our supplies of source plasma, which include plasma collection center expansion and reliance of third-party supply agreements as well as any extensions to such agreements;
- the potential indications for our products and product candidates;
- potential investigational new product applications;
- the acceptability of any of our products, including Nabi-HB, BIVIGAM and ASCENIV, for any purpose, including FDA-approved indications, by physicians, patients or payers;
- our plans to evaluate the clinical and regulatory paths to grow the ASCENIV franchise through expanded FDA-approved uses;
- 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 concerning our products and product candidates;
- the comparability of results of our hyperimmune and immune globulin products to other comparably run hyperimmune and immune globulin clinical trials;
- the potential for ASCENIV and BIVIGAM to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease, Primary Humoral Immunodeficiency Disease ("PIDD" or "PI") or other immune deficiencies or any other condition for which the products may be prescribed or evaluated;
- 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 vertical integration strategy;
- our plans related to the expansion of our manufacturing capacity, yield improvements, supply-chain robustness, distribution and other collaborative agreements and the success of such endeavors;
- our estimates regarding revenues, expenses, capital requirements, timing to profitability and the need for and availability of additional financing;
- possible or likely reimbursement levels for our currently marketed products;
- estimates regarding market size, projected growth and sales of our existing products as well as our expectations of market acceptance of ASCENIV and BIVIGAM;
- potential effects of the coronavirus (COVID-19) pandemic on our business, financial condition, liquidity and results of operations, and our ability to continue operations in the same manner as previously conducted prior to the macroeconomic effects of the COVID-19 pandemic;
- future domestic and global 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 may be identified by the use of terms such as “anticipates,” “believes,” “can,” “continue,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” or “should” or the negative thereof or other variations thereof or comparable terminology. Our actual results could differ materially from those contained in the forward-looking statements due to the factors described in the sections entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2019 and in this Quarterly Report on Form 10-Q for the quarter ended March 31, 2020. 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, industry and future growth. These forward-looking statements speak only as of the dates such statements are made and we undertake no obligation to publicly update any forward-looking statements or to publicly announce revisions to any of the forward-looking statements, unless otherwise required by the federal securities laws.

PART I
FINANCIAL INFORMATION

Item 1. Financial Statements.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2020	December 31, 2019
ASSETS	(Unaudited)	
Current assets:		
Cash and cash equivalents	$ 101,235,699	$ 26,752,135
Accounts receivable, net	7,107,834	3,469,919
Inventories	52,288,803	53,064,734
Prepaid expenses and other current assets	4,855,344	2,533,593
Total current assets	165,487,680	85,820,381
Property and equipment, net	35,060,795	31,741,317
Intangible assets, net	2,980,636	3,159,474
Goodwill	3,529,509	3,529,509
Deposits and other assets	3,465,207	2,840,044
TOTAL ASSETS	$ 210,523,827	$ 127,090,725
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 9,152,239	$ 9,174,591
Accrued expenses and other current liabilities	4,419,043	4,481,395
Current portion of deferred revenue	142,834	142,834
Current portion of lease obligations	193,987	229,073
Total current liabilities	13,908,103	14,027,893
Senior notes payable, net of discount	81,212,090	68,291,163
Deferred revenue, net of current portion	2,225,823	2,261,532
Subordinated note payable, net of discount	14,916,837	14,908,053
Lease obligations, net of current portion	1,831,639	1,302,361
Other non-current liabilities	93,652	106,574
TOTAL LIABILITIES	114,188,144	100,897,576
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, 150,000,000 shares authorized, 86,345,313 and 59,318,355 shares issued and outstanding	8,635	5,932
Additional paid-in capital	380,288,833	290,903,772
Accumulated deficit	(283,961,785)	(264,716,555)
TOTAL STOCKHOLDERS' EQUITY	96,335,683	26,193,149
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 210,523,827	$ 127,090,725

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,	
	2020	**2019**
REVENUES:		
Product revenue	$ 10,164,036	$ 3,492,881
License revenue	35,708	35,708
Total Revenues	10,199,744	3,528,589
OPERATING EXPENSES:		
Cost of product revenue (exclusive of amortization expense shown below)	16,829,226	9,405,179
Research and development	1,528,738	870,635
Plasma center operating expenses	500,644	654,486
Amortization of intangible assets	178,838	211,235
Selling, general and administrative	7,932,084	5,595,470
Total operating expenses	26,969,530	16,737,005
LOSS FROM OPERATIONS	(16,769,786)	(13,208,416)
OTHER INCOME (EXPENSE):		
Interest and other income	248,068	127,399
Interest expense	(2,717,091)	(1,540,507)
Loss on extinguishment of debt	—	(9,962,495)
Gain on transfer of plasma center assets	—	11,527,421
Other expense, net	(6,421)	(11,357)
Other (expense) income, net	(2,475,444)	140,461
NET LOSS	$ (19,245,230)	$ (13,067,955)
BASIC AND DILUTED LOSS PER COMMON SHARE	$ (0.26)	$ (0.28)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:		
Basic and Diluted	73,781,507	46,353,068

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, 2020

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2019	59,318,355	$ 5,932	$ 290,903,772	$ (264,716,555)	$ 26,193,149
Stock-based compensation	—	—	676,548	—	676,548
Issuance of common stock, net of offering expenses	27,025,000	2,703	88,701,336	—	88,704,039
Exercise of stock options	1,958	—	7,177	—	7,177
Net loss	—	—	—	(19,245,230)	(19,245,230)
Balance at March 31, 2020	86,345,313	$ 8,635	$ 380,288,833	$ (283,961,785)	$ 96,335,683

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

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,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (19,245,230)	$ (13,067,955)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	788,838	805,330
Loss on disposal of fixed assets	976	391
Stock-based compensation	676,548	637,263
Gain on transfer of plasma center assets	—	(11,527,420)
Amortization of debt discount	429,711	244,767
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	(3,637,915)	82,037
Inventories	775,932	(25,310)
Prepaid expenses and other current assets	(2,321,751)	(289,134)
Deposits and other assets	(79,532)	179,644
Accounts payable	(22,356)	(420,601)
Accrued expenses	(1,930,591)	(762,541)
Other current and non-current liabilities	(45,882)	(70,442)
Net cash used in operating activities	(24,646,960)	(14,287,184)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(2,074,876)	(110,453)
Proceeds from the sale of property and equipment	2,000	
Net cash used in investing activities	(2,072,876)	(110,453)
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	12,500,000	45,000,000
Payment of debt issuance costs	—	(1,555,762)
Proceeds from the issuance of common stock, net of offering expenses	88,704,039	—
Proceeds from the exercise of stock options	7,177	—
Payments on finance lease obligations	(7,816)	(7,308)
Net cash provided by financing activities	101,203,400	4,177,063
Net increase (decrease) in cash and cash equivalents	74,483,564	(10,220,574)
Cash and cash equivalents, including restricted cash - beginning of period	26,752,135	26,754,852
Cash and cash equivalents - end of period	$ 101,235,699	$ 16,534,278

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 an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics for the treatment of immunodeficient patients at risk for infection and others at risk for 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 BPC Plasma, Inc. (formerly 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, ASCENIV, previously referred to as "RI-002." ADMA Bio Centers is the Company's source plasma collection business with a plasma collection facility located in the U.S., which holds an approved license with the U.S. Food and Drug Administration (the "FDA").

The Company has three FDA-approved products, all of which are currently marketed and commercially available: (i) BIVIGAM (Immune Globulin Intravenous, Human), an Intravenous Immune Globulin ("IVIG") product indicated for the treatment of Primary Humoral Immunodeficiency ("PI"), also known as Primary Immunodeficiency Disease ("PIDD"), and for which we received FDA approval on May 9, 2019 for the commercial re-launch of the product and commenced the commercial re-launch in August 2019; (ii) ASCENIV (Immune Globulin Intravenous, Human – slra 10% Liquid), an IVIG product indicated for the treatment of PI, for which we received FDA approval on April 1, 2019 and commenced first commercial sales in October 2019; and (iii) Nabi-HB (Hepatitis B Immune Globulin, Human), which is indicated for the treatment of acute exposure to blood containing Hepatitis B surface antigen ("HBsAg") and other listed exposures to Hepatitis B. The Company seeks to develop a pipeline of plasma-derived therapeutics, and its 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.

On June 6, 2017, ADMA completed the acquisition of certain assets (the "Biotest Assets") of BTBU, which included the FDA-licensed BIVIGAM and Nabi-HB immunoglobulin products, and an FDA-licensed plasma fractionation manufacturing facility located in Boca Raton, FL (the "Boca Facility") (the "Biotest Transaction"). In addition to its commercially available immunoglobulin products, the Company provides contract manufacturing services for certain clients and generates revenues from the sale of intermediate by-products that result from the immunoglobulin production process.

As of March 31, 2020, the Company had working capital of $151.6 million, including $101.2 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 will be sufficient to fund ADMA's operations, as currently conducted, into the second quarter of 2021. In order to have sufficient cash to fund its operations thereafter, the Company anticipates it will need to raise additional capital before the end of the second quarter of 2021. These estimates may change based upon the success of the Company's commercial sales of its products, manufacturing ramp-up activities, the acceptability of ADMA's immune globulin products by physicians, patients or payers and the various financing options that may be available to the Company. The Company currently has no firm commitments for additional financing, and there can be no assurance 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 approvals related to the Company's products or the labeled indications of such products, ongoing compliance requirements and capacity expansion efforts at the Company's Boca Facility and future commercialization of the Company's products, including the Company's ability to obtain adequate quantities of FDA-approved plasma with proper specifications on acceptable terms for use in the Company's manufacturing process, as well as the additional uncertainties surrounding the COVID-19 pandemic (see Note 9) the Company is unable to estimate with certainty the amounts of increased capital outlays and operating expenditures required to fund its commercial and development activities. The Company's current estimates may be subject to change as circumstances regarding its business requirements evolve. 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 commercialization, product development or clinical activities or delay or discontinue the approval efforts for any of the Company's products or product candidates. The Company has reported cumulative losses since inception in June 2004 through March 31, 2020 of $284.0 million. 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

The Company may decide to raise capital through public or private equity offerings or debt financings, or obtain a bank credit facility or enter into corporate collaboration and licensing arrangements. The sale of additional equity or debt securities, if convertible, could result in dilution to the Company's existing stockholders and, in such event, the market value 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. In addition, the Company is exploring additional contract manufacturing arrangements and other business development opportunities, which may provide additional liquidity to the Company.

There can be no assurance that the Company's approved products will be commercially viable, or that research and development, plant capacity expansion, plasma center build-outs or other capital improvements will be successfully completed or that any product developed in the future will be approved. The Company is subject to risks common to companies in the biotechnology and pharmaceutical manufacturing industries 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, 2019 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, 2020. The accompanying consolidated balance sheet as of December 31, 2019 was derived from the audited financial statements for the year ended December 31, 2019. 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 complete consolidated 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, 2020 and its results of operations, changes in equity and cash flows for the three months ended March 31, 2020.

During the three months ended March 31, 2020 and 2019, comprehensive loss was equal to the net loss amounts presented for the respective periods in the accompanying condensed 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.

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

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 realizable value of accounts receivable, valuation of inventory, assumptions used in projecting future liquidity and capital requirements, 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.

Fair value of financial instruments

The carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents, accounts receivable 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 subordinated note payable in the amount of $15.0 million as of March 31, 2020 and December 31, 2019, which is held by Biotest, a principal stockholder of the Company at the time the note was issued 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 is reported at realizable value, net of allowances for contractual credits and doubtful accounts, which are recognized in the period the related revenue is recorded. The Company extends credit to its customers based upon an evaluation of each customer's financial condition and credit history. Evaluations of the financial condition and associated credit risk of customers are performed on an ongoing basis. Based on these evaluations, the Company has concluded that the credit risk is minimal. At March 31, 2020, three customers accounted for an aggregate of 84% of the Company's total accounts receivable, and at December 31, 2019, two customers accounted for 89% of the Company's total accounts receivable.

Inventories

Inventories, including plasma intended for resale and plasma intended for internal use in the Company's manufacturing, commercialization or research and development activities, are carried at the lower of cost or net realizable value determined by the first-in, first-out method. Due to previous uncertainties surrounding certain prior submissions made to the FDA, all costs related to the production of BIVIGAM and ASCENIV prior to their FDA approval dates of May 9, 2019 and April 1, 2019, 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, 2020 and December 31, 2019 was $3.5 million. All of the Company's goodwill is attributable to the acquisition of 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. The Company's annual goodwill impairment test as of October 1, 2019 did not result in a goodwill impairment charge, and the Company did not record any impairment charges related to goodwill for the three months ended March 31, 2020 and 2019.

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

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, 2020 and 2019, the Company determined that there was no impairment of its long-lived assets.

Revenue recognition

Revenues for the three months ended March 31, 2020 and 2019 are comprised of (i) revenues from the sale of the Company's immunoglobulin products, ASCENIV, BIVIGAM and Nabi-HB, (ii) product revenues from the sale of human plasma collected from the Company's Plasma Collection Centers business segment, (iii) contract manufacturing revenue, (iv) revenues from the sale of intermediate by-products; and (v) license and other revenues primarily attributable to the out-licensing of ASCENIV to Biotest in 2012 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 the Company's immunoglobulin products 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 certain other assumptions, and the Company believes that such estimates are reasonable. For revenues associated with contract manufacturing and the sale of intermediates, control transfers to the customer and the performance obligation is satisfied when the customer takes possession of the product from the Boca Facility or from a third-party warehouse that is utilized by the Company.

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, 2020, three customers represented an aggregate of 82% of the Company's consolidated revenues. For the three months ended March 31, 2019, two customers represented an aggregate of 81% 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.

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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, 2020 and 2019, the following securities were excluded from the calculation of diluted loss per common share because of their anti-dilutive effects:

	For the Three Months Ended March 31,	
	2020	**2019**
Stock options	6,753,354	5,599,435
Restricted stock units	333,500	—
Warrants	2,138,160	1,888,160
	9,225,014	7,487,595

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 statement of operations as compensation expense based on their fair values at the date of grant. Compensation expense related to awards to employees and directors with service-based vesting conditions is recognized on a straight-line over the associated vesting period of the award based on the grant date fair value of the award. Stock options granted under the Company's equity incentive plans generally have a four-year vesting period and a term of 10 years. Pursuant to ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting (Topic 718)*, the Company has elected not to establish a forfeiture rate, as stock-based compensation expense related to forfeitures of unvested stock options is fully reversed at the time of forfeiture.

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, 2020 and December 31, 2019, and during the three months ended March 31, 2020 and 2019, the Company recognized no adjustments for uncertain tax positions.

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326)* ("ASU 2016-13"), which requires financial assets to be presented at the net amount expected to be collected, with an allowance for credit losses to be deducted from the amortized cost basis of the financial asset such that the net carrying value of the asset is presented as the amount expected to be collected. Under ASU 2016-13, the entity's statement of operations is required to reflect the measurement of credit losses for newly recognized financial assets, as well as expected increases or decreases in expected credit losses that have taken place during the period. For public business entities, ASU 2016-13 is effective for fiscal years beginning after December 15, 2019. The Company adopted ASU No. 2016-13, and the adoption of this update did not have a significant impact on the Company's consolidated financial statements.

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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. The Company recognized right-to-use assets of $1.4 million and corresponding lease liabilities of approximately $1.6 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.

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) will 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, 2020	December 31, 2019
Raw materials	$ 29,717,087	$ 33,381,806
Work-in-progress	17,139,411	14,455,665
Finished goods	5,432,305	5,227,263
Total inventories	$ 52,288,803	$ 53,064,734

Raw materials includes plasma and other materials expected to be used in the production of ASCENIV, BIVIGAM and Nabi-HB, as there are alternative uses for these materials that 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.

Work-in-process inventory primarily consists of bulk drug substance and unlabeled filled vials of the Company's immunoglobulin products. Finished goods inventory is comprised of immunoglobulin product inventory and related intermediates that are available for commercial sale, as well as plasma collected at the Company's plasma collection center which is expected to be sold to third-party customers.

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4. INTANGIBLE ASSETS

Intangible assets at March 31, 2020 and December 31, 2019 consist of the following:

	March 31, 2020			December 31, 2019		
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Trademark and other intangible rights related to Nabi-HB	$ 4,100,046	$ 1,659,542	$ 2,440,504	$ 4,100,046	$ 1,513,112	$ 2,586,934
Rights to intermediates	907,421	367,289	540,132	907,421	334,881	572,540
Customer contract	1,076,557	1,076,557	—	1,076,557	1,076,557	—
	$ 6,084,024	$ 3,103,388	$ 2,980,636	$ 6,084,024	$ 2,924,550	$ 3,159,474

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, 2020 and 2019 was $0.2 million. Estimated aggregate future aggregate amortization expense for the next five years is expected to be as follows:

Remainder of 2020	$ 536,514
2021	715,352
2022	715,352
2023	715,352
2024	298,066

5. PROPERTY AND EQUIPMENT

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

	March 31, 2020	December 31, 2019
Manufacturing and laboratory equipment	$ 9,524,749	$ 8,831,817
Office equipment and computer software	2,220,856	1,690,248
Furniture and fixtures	1,133,132	582,088
Construction in process	6,022,188	4,285,915
Leasehold improvements	1,673,084	1,673,084
Land	4,339,441	4,339,441
Buildings and building improvements	16,480,277	16,063,680
	41,393,727	37,466,273
Less: Accumulated depreciation	(6,332,932)	(5,724,956)
Total property and equipment, net	$ 35,060,795	$ 31,741,317

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 three 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, 2020 and 2019 of $0.6 million.

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6. DEBT

Senior Notes Payable

A summary of outstanding senior notes payable is as follows:

	March 31, 2020	December 31, 2019
Notes payable	$ 85,000,000	$ 72,500,000
Less:		
Debt discount	(3,787,910)	(4,208,837)
Senior notes payable	$ 81,212,090	$ 68,291,163

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, as amended, provides for a senior secured term loan facility in a principal amount of up to $85.0 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"), (ii) a term loan in the principal amount of up to $27.5 million (the "Perceptive Tranche II Loan") evidenced by the Company's issuance of a promissory note (the "Perceptive Tranche II Note") in favor of Perceptive on May 3, 2019; and (iii) a term loan in the principal amount of up to $12.5 million evidenced by the Company's issuance of a promissory note (the "Perceptive Tranche III Note") in favor of Perceptive on March 20, 2020 (the "Perceptive Tranche III Loan," and together with the Perceptive Tranche I Loan and the Perceptive Tranche II Loan, the "Perceptive Loans"). The Perceptive Tranche III Loan is the result of an amendment to the Perceptive Credit Agreement (the "Perceptive Amendment") that the Company and Perceptive entered into on May 3, 2019, and the Perceptive Tranche III Loan became available to the Company upon the approval of BIVIGAM on May 9, 2019. 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).

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 used proceeds from the Perceptive Tranche I Loan to: (i) pay a deferred facility fee to Marathon in the amount of $2.8 million, (ii) pay a prepayment penalty to Marathon in the amount of $6.5 million, (iii) pay outstanding accrued interest to Marathon in the amount of $0.7 million, and (iv) 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 to the Company that was held in a debt service reserve account per the terms of the Marathon Credit Facility. In connection with the Perceptive Amendment, the Company paid an additional facility fee to Perceptive in the amount of $0.1 million on May 3, 2019.

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 for the three months ended March 31, 2019 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. Accrued interest is payable to Perceptive on the last day of each month during the term of the Perceptive Credit Facility. The rate of interest in effect as of the Perceptive Closing Date and at March 31, 2020 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.

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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, report revenues for the trailing 12-month period that exceed the amounts set forth in the Perceptive Credit Agreement, which range from $7.0 million for the fiscal quarter ended June 30, 2019 to $55.0 million for the fiscal quarter ending December 31, 2021. At March 31, 2020, the Company was in compliance with all of the covenants contained in the Perceptive Credit Agreement.

As consideration for the Perceptive Credit Agreement, the Company issued to Perceptive a warrant to purchase 1,360,000 shares of the Company's common stock (the "Perceptive Warrant") on the Perceptive Closing Date. The Perceptive Warrant has an exercise price equal to $3.28 per share, which is equal to the trailing 10-day volume weighted average price ("VWAP") of the Company's common stock on the business day immediately prior to the Perceptive Closing Date multiplied by 1.15. The Company valued the Perceptive Warrant at $2.7 million as of the Perceptive Closing Date and it has an expiration date of February 11, 2029. In connection with the Perceptive Amendment, the Company issued an additional warrant (the "Perceptive Tranche III Warrant" and, together with the Perceptive Warrant, the "Perceptive Warrants") 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 VWAP of the Company's common stock as of May 2, 2019. The Perceptive Tranche III Warrant was valued by the Company at $0.9 million and has an expiration date of May 3, 2029. Perceptive has 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 Warrants in reliance upon an exemption from registration contained in Section 4(2) under the Securities Act. The Perceptive Warrants 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 Warrants, the Company recognized an aggregate discount on the Perceptive Tranche I Note and Perceptive Tranche II Note in the amount of $5.3 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 Warrants and the aggregate amount of fees and expenses associated with obtaining the Perceptive Credit Facility, the effective interest rate on the Perceptive Loans as of May 3, 2019 was approximately 14.1%.

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Subordinated Note Payable

A summary of the outstanding subordinated note payable is as follows:

	March 31, 2020	December 31, 2019
Subordinated note payable to Biotest	$ 15,000,000	$ 15,000,000
Less:		
Debt discount	(83,163)	(91,947)
Subordinated note payable	$ 14,916,837	$ 14,908,053

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, 2020.

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, 2020 and December 31, 2019.

Common Stock

As of March 31, 2020 and December 31, 2019, the Company was authorized to issue 150,000,000 shares of its common stock, $0.0001 par value per share, and 86,345,313 and 59,318,355 shares of common stock were outstanding as of March 31, 2020 and December 31, 2019, respectively. After giving effect to shares reserved for outstanding warrants and awards issued under the Company's equity incentive plans, as of March 31, 2020, there were 54,429,673 shares of common stock available for issuance.

On February 11, 2020, the Company completed an underwritten public offering of 23,500,000 shares of its common stock for gross proceeds of $82.3 million. On February 21, 2020, the Company sold an additional 3,525,000 shares pursuant to the underwriters' exercise of their option to purchase additional shares of the Company's common stock for additional gross proceeds of $12.3 million. The Company received net proceeds, after underwriting discounts and other expenses associated with the offering, of approximately $88.7 million.

Warrants

At March 31, 2020, the Company had outstanding warrants to purchase an aggregate of 2,138,160 shares of common stock, with a weighted average exercise price of $3.81 per share and expiration dates ranging between June 2022 and May 2029.

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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, 2020 and 2019:

	Three Months Ended March 31,	
	2020	**2019**
Expected term	5.8 - 6.3 years	5.8 - 6.3 years
Volatility	62%	61%
Dividend yield	0.0	0.0
Risk-free interest rate	0.47-1.68%	2.25-2.63%

During the three months ended March 31, 2020, the Company granted Restricted Stock Units ("RSUs") to members of the Company's Board of Directors and to certain management employees of the Company. The total RSUs granted during the period represent an aggregate of 341,000 shares of the Company's common stock, 7,500 of which were forfeited during the period. The RSUs vest semi-annually over a period of one year for directors and annually over a period of 4 years for employees. The market price of the Company's common stock as of the date the awards were granted ranged from $2.59 to $2.92 per share. At March 31, 2020, there were 333,500 RSUs outstanding.

During the three months ended March 31, 2020 and 2019, the Company granted options to purchase an aggregate of 1,158,900 and 1,335,850 shares of common stock, respectively, to its directors, employees and certain third party service providers. The weighted average remaining contractual life of stock options outstanding and expected to vest at March 31, 2020 is 7.2 years. The weighted average remaining contractual life of stock options exercisable at March 31, 2020 is 5.9 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, 2019	5,630,351	$ 4.76
Forfeited	(29,087)	$ 3.65
Expired	(4,852)	$ 4.60
Granted	1,158,900	$ 2.96
Exercised	(1,958)	$ 3.67
Balance at March 31, 2020	6,753,354	$ 4.46
Options exercisable	3,780,306	$ 5.29

Stock-based compensation expense for the three months ended March 31, 2020 and 2019 is as follows:

	2020	**2019**
Research and development	$ 93,574	$ 86,523
Plasma centers	7,244	11,540
Selling, general and administrative	523,889	498,471
Cost of product revenue	51,841	40,729
Total stock-based compensation expense	$ 676,548	$ 637,263

As of March 31, 2020, the Company had $5.7 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 2.7 years.

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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 set at $10,000. On November 7, 2019, an additional amendment was entered into between Areth and the Company to extend the term of this agreement through September 30, 2020, and to provide for automatic one-year renewals unless ADMA gives written notice of termination to Areth 60 days prior to the end of the term. Rent expense for the three months ended March 31, 2020 and 2019 amounted to $30,000. Areth is a company controlled by Dr. Jerrold B. Grossman, the Vice Chairman of the Company's Board of Directors, 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, 2020 and 2019.

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

In connection with the February 2020 public offering of the Company's common stock (see Note 7) on February 11, 2020: (i) Lawrence P. Guiheen, a director of the Company, purchased 20,000 shares of common stock, (ii) James Mond, the Company's Chief Scientific Officer and Chief Medical Officer, purchased 4,285 shares of common stock, (iii) Jerrold B. Grossman, the Company's Vice Chairman of the Board, purchased 22,857 shares of common stock directly and 22,857 shares indirectly through an entity he controls, (iv) Brian Lenz, the Company's Executive Vice President and Chief Financial Officer, purchased 7,142 shares of common stock, (v) Adam S. Grossman, the Company's President and Chief Executive Officer, purchased 28,571 shares of common stock directly and 57,143 shares indirectly through an entity he controls, and (vi) Perceptive Advisors, a principal stockholder of ADMA, purchased 4,563,700 shares of common stock through one of its affiliates, all at the public offering price of $3.50 per share.

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.

COVID-19 Pandemic

The Company is closely monitoring ongoing developments in connection with the COVID-19 pandemic, which has the potential to adversely impact several aspects of the Company's supply-chain operations, including procurement of raw materials and packaging materials, a portion of which are sourced internationally, and the testing of finished drug product that is required prior to its availability for commercial sale. Such testing has been performed to date by contract laboratories outside the United States.

To date, the COVID-19 pandemic has not had a material impact on the Company's financial condition or results of operations, and the Company does not believe that its production operations at the Boca Facility, the Company's contract fill/finishers or its plasma collection facility have been significantly impacted by the COVID-19 pandemic. As a result, the Company does not anticipate any material impairments with respect to any of its long-lived assets, including the Company's property and equipment, goodwill or intangible assets.

Although the COVID-19 pandemic has not, to date, materially adversely impacted the Company's capital and financial resources, because the Company is unable to determine the ultimate severity or duration of the pandemic or its long-term effects on, among other things, the global, national or local economies, the capital and credit markets or the Company's workforce, customers or our suppliers, at this time the Company is unable to predict whether COVID-19 will have a material adverse impact on the Company's business, financial condition, liquidity and results of operations.

Vendor and Licensor Commitments

Pursuant to the terms of a plasma purchase agreement with BPC dated as of November 17, 2011 (the "2011 Plasma Purchase Agreement"), the Company agreed to purchase from BPC an annual minimum volume of source plasma containing antibodies to RSV to be used in the manufacture of ASCENIV. The Company must purchase a to-be-determined and agreed upon annual minimum volume from BPC, but may also collect high-titer RSV plasma from up to five wholly-owned ADMA plasma collection facilities. During 2015, the Company and BPC amended the 2011 Plasma Purchase Agreement to allow the Company the ability to collect its raw material RSV high-titer plasma from other third-party collection organizations, thus allowing the Company to expand its reach for raw material supply as it approaches commercialization for ASCENIV. Unless terminated earlier, the 2011 Plasma Purchase Agreement expires in June 2027, after which it may be renewed for two additional five-year periods if agreed to by the parties. As part of the closing of the Biotest Transaction, the parties amended the 2011 Plasma Purchase Agreement to extend the initial term through the ten year anniversary of the closing date of the Biotest Transaction. On December 10, 2018, BPC assigned its rights and obligations under the 2011 Plasma Purchase Agreement to Grifols Worldwide Operations Limited ("Grifols") as its successor-in-interest, effective January 1, 2019. On January 1, 2019, Grifols and the Company entered into an additional amendment to the 2011 Plasma Purchase Agreement for the purchase of source plasma containing antibodies to RSV from Grifols. Pursuant to this amendment, until January 1, 2022, the Company may purchase RSV plasma from Grifols from the two plasma collection centers that were transferred to BPC on January 1, 2019 at a price equal to cost plus five percent (5%) (without any additional increase due to inflation).

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NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

On June 6, 2017, the Company and BPC entered into a Plasma Supply Agreement pursuant to which BPC supplies, on an exclusive basis subject to certain exceptions, to ADMA BioManufacturing an annual minimum volume of hyperimmune plasma that contain antibodies to the hepatitis B virus for the manufacture of Nabi-HB. The Plasma Supply Agreement has a 10-year term. On July 19, 2018, the Company and BPC entered into an amendment to the Plasma Supply Agreement to provide, among other things, that in the event BPC elects not to supply in excess of ADMA BioManufacturing's specified amount of Hepatitis B plasma and ADMA BioManufacturing is unable to secure Hepatitis B plasma from a third party at a price that is within a low double digit percentage of the price that ADMA BioManufacturing pays to BPC, then BPC shall reimburse ADMA BioManufacturing for the difference in price ADMA BioManufacturing incurs. On December 10, 2018, BPC assigned its rights and obligations under the Plasma Supply Agreement to Grifols, effective January 1, 2019.

On June 6, 2017, the Company and BPC entered into a Plasma Purchase Agreement (the "2017 Plasma

Purchase Agreement"), pursuant to which ADMA BioManufacturing purchases normal source plasma ("NSP") from BPC at agreed upon annual quantities and prices. The 2017 Plasma Purchase Agreement has an initial term of five years after which the 2017 Plasma Purchase Agreement may be renewed for additional two terms of two years each upon the mutual written consent of the parties. On July 19, 2018, the Company and BPC entered into an amendment to the 2017 Plasma Purchase Agreement to, among other things, provide agreed upon amounts of NSP to be supplied by BPC to ADMA BioManufacturing in calendar year 2019 at a specified price per liter, provided that ADMA BioManufacturing delivers a valid purchase order to BPC. Additionally, pursuant to the amendment to the 2017 Plasma Purchase Agreement, BPC agrees that, for calendar years 2020 and 2021, it shall supply no less than a high double digit percentage of ADMA BioManufacturing's requested NSP amounts, provided that such requested NSP amounts are within an agreed range, at a price per liter to be mutually determined. Furthermore, pursuant to the amendment to the 2017 Plasma Purchase Agreement, in the event BPC fails to supply ADMA BioManufacturing with at least a high double digit percentage of ADMA BioManufacturing's requested NSP amounts, BPC shall promptly reimburse ADMA BioManufacturing the difference in price ADMA BioManufacturing incurs due to BPC's election not to supply NSP to ADMA BioManufacturing in such amounts as requested. On December 10, 2018, BPC assigned its rights and obligations under the Plasma Purchase Agreement to Grifols, effective January 1, 2019.

The Company purchases substantially all of its raw material plasma from Grifols. For the three months ended March 31, 2020, plasma purchases from Grifols totaled approximately $2.0 million, representing approximately 46% of the Company's total inventory purchases. For the three months ended March 31, 2019, plasma purchases from BPC totaled $0.2 million, or approximately 11% of the Company's total inventory purchases.

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, as such 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.

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

In connection with the FDA's approval of ASCENIV on April 1, 2019, the Company is required to perform a pediatric study to evaluate the safety and efficacy of ASCENIV in children and adolescents. This study is required to be completed by June of 2023.

Employment contracts

The Company has entered into employment agreements with its executive management team consisting of its President and Chief Executive Officer, its Executive Vice President, Chief Medical Officer and Chief Scientific Officer and its Executive Vice President and Chief Financial Officer.

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, 2020. 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, commercial and development operations in Boca Raton, FL, acquired on June 6, 2017 (see Note 1). The Plasma Collection Centers segment consists of one FDA-licensed source plasma collection facility, with two additional plasma collection centers currently under construction. 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:

Three Months Ended March 31, 2020

	ADMA BioManufacturing	Plasma Collection Centers	Corporate	Consolidated
Revenues	$ 7,743,275	$ 2,420,761	$ 35,708	$ 10,199,744
Cost of product revenue	14,451,954	2,377,272	—	16,829,226
Loss from operations	(12,476,144)	(457,155)	(3,836,487)	(16,769,786)
Interest and other expense, net	(238,873)	—	(2,236,571)	(2,475,444)
Net loss	(12,715,017)	(457,155)	(6,073,058)	(19,245,230)
Capital expenditures	1,914,614	160,262	—	2,074,876
Depreciation and amortization expense	674,973	111,289	2,576	788,838
Total assets	104,645,897	5,376,807	100,501,123	210,523,827

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

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. 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.

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 2030. 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 of 13%. 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 lease expense and cash paid for the Company's operating leases for the three months ended March 31, 2020 and 2019 was $0.1 million.

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

In connection with the adoption of ASU 2016-02 on January 1, 2019 (see Note 2), the Company recognized right to use assets of $1.4 million and lease liabilities of approximately $1.6 million. On July 11, 2019, the Company entered into a new property lease where the Company intends to construct a new plasma collection facility, and the lease commencement date for this property was February 1, 2020. In connection with this lease the Company recognized a lease liability and corresponding right-to-use asset in the amount $0.5 million. The right-to-use assets are reflected in Deposits and other assets in the accompanying consolidated balance sheets. Including a finance lease the Company entered into in June 2018, the Company has aggregate lease liabilities of $2.0 million and $1.5 million as of March 31, 2020 and December 31, 2019, respectively, which are comprised primarily of the lease for the Company's plasma collection centers 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 7.5 years. Scheduled payments under the Company's lease obligations are as follows:

Remainder of 2020	$ 320,128
Year ended December 31, 2021	481,708
2022	480,982
2023	461,853
2024	417,721
Thereafter	978,007
Total payments	3,140,399
Less: imputed interest	(1,114,773)
Current portion	(193,987)
Balance at March 31, 2020	$ 1,831,639

As of April 15, 2020, the Company had entered into two additional property leases where the Company intends to construct new plasma collection facilities. The Company has not taken possession of these two leased properties and their lease commencement dates have not been determined. With the exception of advance deposits and initial months' rent totaling approximately $63,000, no payments have been made under these leases. The initial terms of each lease are from 10 to 11 years with monthly rental payments varying between approximately $13,000 and $27,000, including common area maintenance charges.

13. SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

Supplemental cash flow information for the three months ended March 31, 2020 and 2019 is as follows:

	2020	2019
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	$ 2,017,866	$ 1,369,939
Noncash Financing and Investing Activities:		
Equipment acquired reflected in accounts payable and accrued liabilities	$ 2,340,337	$ 35,823
Right-to-use assets obtained in exchange for lease obligations	$ 545,630	$ 1,404,281
Warrants issued in connection with notes payable	$ —	$ 2,699,208

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, 2019, filed on March 13, 2020 (the "2019 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 from our current expectations.

OVERVIEW

Our Business

ADMA Biologics, Inc. (the "Company," "ADMA," "we," "us" or "our") is an end-to-end commercial biopharmaceutical and specialty immunoglobulin company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics for the treatment of immunodeficient patients at risk for infection and others at risk for 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 U.S. Food and Drug Administration (the "FDA") approval, all of which are currently marketed and commercially available: (i) BIVIGAM (Immune Globulin Intravenous, Human), an Intravenous Immune Globulin ("IVIG") product indicated for the treatment of Primary Humoral Immunodeficiency ("PI"), also known as Primary Immunodeficiency Disease ("PIDD"), and for which we received FDA approval on May 9, 2019 for the commercial re-launch of the product and commenced the re-launch in August 2019; (ii) ASCENIV (Immune Globulin Intravenous, Human – slra 10% Liquid), previously referred to as RI-002, an IVIG product indicated for the treatment of PI, for which we received FDA approval on April 1, 2019 and commenced first commercial sales in October 2019; and (iii) Nabi-HB (Hepatitis B Immune Globulin, Human), which is indicated for the treatment of acute exposure to blood containing HBsAg and other listed exposures to Hepatitis B. 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.

Through ADMA Bio Centers, we currently operate one FDA-approved source plasma collection facility in the U.S., which provides us with a portion of our blood plasma for the manufacture of our products and product candidates, and we have two additional plasma collection centers currently under construction. We intend to open five to 10 additional plasma collection centers in the U.S. during the next three to five 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. and in other locations outside the U.S. where we are approved under supply agreements or in the open "spot" market.

We also sell plasma-derived intermediate fractions to certain customers, which are generated as part of our FDA-approved manufacturing process for IVIG products. In January 2020, we announced our entry into a five-year manufacturing and supply agreement to produce and sell these intermediate by-products, which are used as the starting raw material to produce other plasma-derived biologics. In addition, from time to time we provide contract manufacturing services for certain historical clients.

On June 6, 2017, we completed the acquisition of certain assets (the "Biotest Assets") of the Therapy Business Unit ("BTBU") of BPC Plasma, Inc. (formerly Biotest Pharmaceuticals Corporation) ("BPC" and, together with Biotest AG, "Biotest"), which included two FDA-licensed products, Nabi-HB and BIVIGAM, and an FDA-licensed plasma fractionation facility located in Boca Raton, FL (the "Boca Facility") (the "Biotest Transaction").

Our Products

BIVIGAM

BIVIGAM is a plasma-derived IVIG that 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 antibodies indicated for the treatment of PI, a group of genetic disorders. This includes, but is not limited to, the humoral immune defect in common variable immunodeficiency, X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome and severe combined immunodeficiency. These PIs are a group of genetic disorders. Based on recent estimates, these disorders are no longer considered to be very rare, with as many as one in every 1,200 people in the United States having some form of PI. BPC had originally received FDA approval for BIVIGAM on December 19, 2012, prior to our acquisition of BTBU, and product sales had commenced in the first quarter of 2013. On May 9, 2019, the FDA approved the Prior Approval Supplement (the "PAS") for the use of our IVIG manufacturing process, thereby enabling us to re-launch and commercialize this product in the United States. We resumed production of BIVIGAM during the fourth quarter of 2017 after the closing of the Biotest Transaction and commercial production is ongoing, using our FDA-approved IVIG manufacturing process under U.S. Department of Health and Human Services ("HHS") License No. 2019. The commercial re-launch and first commercial sales commenced in August of 2019.

ASCENIV

ASCENIV is a plasma-derived IVIG that contains naturally occurring polyclonal antibodies, which 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. We manufacture ASCENIV under HHS License No. 2019 using a process known as fractionation. As part of our proprietary manufacturing process for ASCENIV, we leverage 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 RSV using our proprietary microneutralization assay. We are able to identify the high titer plasma that meets our internal specifications for ASCENIV with our patented testing assay. This type of high titer plasma is typically found in less than 10% of the total donor collection samples we test.

ASCENIV is approved for the treatment of PIDD, a class of inherited genetic disorders that causes a deficient or absent immune system in adults and adolescents (12 to 17 years of age). Our pivotal Phase 3 clinical trial in 59 PIDD patients met the primary endpoint of no Serious Bacterial Infections reported during 12 months of treatment. 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 believe this clinical data together with the FDA approval for the treatment of PIDD better positions ADMA to further evaluate ASCENIV in immune-compromised patients infected with or at-risk for RSV infection. We plan to work with the FDA and the immunology and infectious disease community to design a clinical trial to evaluate the use of ASCENIV in this patient population in the near future. Commercial sales of ASCENIV commenced in October of 2019.

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. In early 2018, we received authorization from the FDA for the release of our first commercial batch of Nabi-HB for commercial distribution in the U.S. and we continue to manufacture Nabi-HB under HHS License No. 2019.

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 realizable value of accounts receivable, valuation of inventory, assumptions used in projecting future liquidity and capital requirements, 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 elsewhere in this Quarterly Report on Form 10-Q.

Revenue Recognition

Revenues for the three months ended March 31, 2020 and 2019 are comprised of (i) revenues from the sale of our FDA-approved immunoglobulin products, (ii) product revenues from the sale of human plasma collected from our Plasma Collection Centers business segment, (iii) product revenues from the sale of intermediate fractions, (iv) contract manufacturing revenue from certain clients; and (v) license revenues attributable to the out-licensing of ASCENIV in December 2012 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 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 we expect to receive in exchange. Revenue from the sale of immunoglobulin products is generally recognized when the product reaches the customer's destination, and is recorded net of distributor fees, 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 certain other assumptions, and we believe that such estimates are reasonable. For revenues associated with contract manufacturing and sales of our intermediates, control transfers to the customer and the performance obligation is satisfied when the customer takes possession of the product from the Boca Facility or a third-party warehouse that is utilized by the Company.

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. Payments received from customers where the foregoing revenue recognition criteria have not been satisfied are recorded as deferred revenue, which is reflected as a liability in our consolidated balance sheets.

For the three months ended March 31, 2020, three customers represented an aggregate of 82% of our consolidated revenues, with BioCARE, Inc. ("BioCare"), Biolife Plasma Services, L.P. ("Biolife") and Reliance Life Sciences Pvt Limited ("Reliance") representing approximately 43%, 24%, 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.

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. Costs of production for ASCENIV and BIVIGAM prior to their FDA approval dates of April 1, 2019 and May 9, 2019, respectively, were not capitalized into inventory but were instead expensed as incurred.

Stock-Based Compensation

All equity-based payments, including grants of stock options and restricted stock units ("RSUs") are recognized at their estimated fair value at the grant date, and compensation expense is recognized on a straight-line basis over the grantee's requisite vesting period. During the three months ended March 31, 2020, we granted RSUs to our Board of Directors and certain members of our management and employees representing an aggregate of 341,000 shares of common stock, 7,500 of which were forfeited during the period. 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 1,158,900 and 1,335,850 shares of common stock during the three months ended March 31, 2020 and 2019, 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 SEC 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. We will continue to analyze the expected stock price volatility and expected term assumptions and will adjust our Black-Scholes option pricing assumptions as appropriate. In accordance with Accounting Standards Update ("ASU") No. 2016-09, *Improvements to Employee Share-Based Payment Accounting (Topic 718)*, we have elected not to establish a forfeiture rate, as stock-based compensation expense related to forfeitures of unvested stock options is fully reversed at the time of forfeiture.

Research and Development Expenses

Our research and development ("R&D") costs consist of clinical research organization costs, costs related to clinical trials, studies for potentially extending a product's approved and labeled expiration dating and other potential label expansions, post-marketing commitment studies for BIVIGAM and ASCENIV, wages, benefits and stock-based compensation for employees directly related to research and development activities and, prior to April 1, 2019, assay development and testing, storage and transportation costs for high-titer plasma used in the manufacture of ASCENIV. All research and development 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 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, 2020 and 2019, 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 the reporting unit associated with the goodwill is less than its carrying amount, including goodwill and other intangible assets. If we 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 years ended March 31, 2020 and 2019.

Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2016-13, *Financial Instruments – Credit Losses (Topic 326)* ("ASU 2016-13"), which requires financial assets to be presented at the net amount expected to be collected, with an allowance for credit losses to be deducted from the amortized cost basis of the financial asset such that the net carrying value of the asset is presented as the amount expected to be collected. Under ASU 2016-13, the entity's statement of operations is required to reflect the measurement of credit losses for newly recognized financial assets, as well as expected increases or decreases in expected credit losses that have taken place during the period. For public business entities, ASU 2016-13 is effective for fiscal years beginning after December 15, 2019. We adopted ASU No. 2016-13, and the adoption of this update did not have a significant impact on our consolidated financial statements.

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) no longer would 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.

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 became 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 was no restatement of comparative periods. We recognized right-to-use assets of approximately $1.4 million and corresponding lease liabilities of approximately $1.6 million at the date of adoption. 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 or embedded leases that qualify.

Three Months Ended March 31, 2020 Compared to Three Months Ended March 31, 2019

The following table presents a summary of the changes in our results of operations for the three months ended March 31, 2020, our first fiscal quarter, compared to the three months ended March 31, 2019:

	Three Months Ended March 31,		
	2020	2019	Increase (Decrease)
Revenues	$ 10,199,744	$ 3,528,589	$ 6,671,155
Cost of product revenue (exclusive of amortization expense shown below)	16,829,226	9,405,179	7,424,047
Gross loss	(6,629,482)	(5,876,590)	(752,892)
Research and development expenses	1,528,738	870,635	658,103
Plasma center operating expenses	500,644	654,486	(153,842)
Amortization of intangibles	178,838	211,235	(32,397)
Selling, general and administrative expenses	7,932,084	5,595,470	2,336,614
Loss from operations	(16,769,786)	(13,208,416)	(3,561,370)
Interest expense	(2,717,091)	(1,540,507)	(1,176,584)
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	241,647	116,042	125,605
Net loss	$ (19,245,230)	$ (13,067,955)	$ (6,177,275)

Revenues

We recorded total revenues of $10.2 million during the three months ended March 31, 2020, as compared to $3.5 million during the three months ended March 31, 2019, an increase of $6.7 million, or approximately 189%. The increase is mainly due to increased sales and production throughput of our immunoglobulin products generated by our Boca Facility manufacturing operations in 2020 totaling $6.4 million, and to a $0.3 million increase in plasma revenues generated by our plasma collection facility in 2020 as compared to the same period of a year ago. Our revenues for the first quarter of 2020 as compared to the first quarter of 2019 were favorably impacted by the FDA approvals of BIVIGAM and ASCENIV on May 9, 2019 and April 1, 2019, respectively, and by the manufacturing and supply agreement we entered into in January 2020 to produce and sell intermediate fractions to a certain customer.

Cost of Product Revenue

Cost of product revenue was $16.8 million for the three months ended March 31, 2020, as compared to $9.4 million for the three months ended March 31, 2019, an increase of $7.4 million. The increase reflects $3.9 million in production costs incurred for the manufacture of BIVIGAM conformance lots at an increased plasma pool production scale which pertains to our planned capacity expansion and other production initiatives and investments at the Boca Facility. Because we will require a new PAS from the FDA before the inventory comprising these conformance lots will be available for commercial sale, these costs were expensed as incurred and were not capitalized into inventory. We also experienced increased costs of product revenue in 2020 of approximately $3.9 million related to the increased sales of our immunoglobulin products and $0.9 million related to the increased plasma sales, partially offset by a decrease in unabsorbed manufacturing expenses at the Boca Facility in the amount of $1.9 million related to increased production during the first quarter of 2020 as compared with the first quarter of 2019.

Research and Development Expenses

R&D expenses totaled $1.5 million for the three months ended March 31, 2020, as compared to $0.9 million for the three months ended March 31, 2019. The increase represents $0.4 million of costs incurred during 2020 for a study we commenced to potentially extend ASCENIV's approved and labeled expiration dating, and to increased expenses for clinical studies related to post-marketing commitments for BIVIGAM, an obligation we assumed in the Biotest Transaction, partially offset by the absence in 2020 of RSV assay and other testing, storage and transportation costs for high-titer plasma used in the manufacture of ASCENIV. As a result of the approval of ASCENIV by the FDA on April 1, 2019, we no longer charge these costs to R&D expense, but instead reflect those costs as part of the cost of the raw material plasma.

Plasma Center Operating Expenses

Plasma center operating expenses were $0.5 million for the three months ended March 31, 2020, as compared to $0.7 million for the three months ended March 31, 2019. 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 mainly attributable to increased absorption of plasma center operating expenses into inventory resulting from higher source plasma collections at our plasma collection facility in 2020 as compared to 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, 2020 and 2019.

Selling, General and Administrative Expenses

Selling, general and administrative (“SG&A”) expenses were $7.9 million for the three months ended March 31, 2020, an increase of $2.3 million from the three months ended March 31, 2019. The increase was mainly due to increases in employee compensation expenses of $1.4 million related to staffing increases in support of our commercialization efforts for BIVIGAM’s relaunch and ASCENIV’s launch and the overall growth in the size and scope of our operations, as well as higher information technology consulting expenses of $0.4 million and $0.4 million in increased insurance expense.

Loss from Operations

Our operating loss was $16.8 million for the first quarter of 2020, as compared to $13.2 million for the first quarter of 2019. The $3.6 million increase in operating loss was mainly due to the increases in SG&A and R&D expenses and to the conformance lot production in 2020, partially offset by the increase in revenues and reductions in unabsorbed manufacturing expenses.

Interest Expense

Interest expense was $2.7 million for the three months ended March 31, 2020, as compared to $1.5 million for the three months ended March 31, 2019. The increase is mainly due to additional loan proceeds we received from our senior lender in May of 2019, when we drew down $27.5 million from our senior credit facility, and to the refinancing of our senior debt in February of 2019, which resulted in an increase in the outstanding principal balance at the time of the transaction from $30 million to $45 million (see “Liquidity and Capital Resources”).

Non-recurring Expenses in the Three Months Ended March 31, 2019

In connection with the foregoing refinancing of our senior credit facility in the first quarter of 2019, we incurred a loss on the extinguishment debt of approximately $10.0 million 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.

As part of the purchase price for the Biotest Assets, 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 $19.2 million for the three months ended March 31, 2020, as compared to $13.1 million for the three months ended March 31, 2019. The increase in net loss of $6.2 million was primarily due to the increase in operating loss for the quarter of $3.6 million and to the $1.2 million of higher interest expense.

IMPACT OF THE COVID-19 CRISIS

We are closely monitoring ongoing developments in connection with the COVID-19 global pandemic, which has the potential to adversely impact several aspects of our commercial and manufacturing operations, including but not limited to potential disruptions to our supply-chain operations, including procurement of raw materials and packaging materials, a portion of which are sourced internationally, and testing of finished drug product that is required prior to its availability for commercial sale. Such testing has been performed to date by contract laboratories outside the United States. In addition, travel and other restrictions that have been implemented in the United States could impact our commercial launch efforts with respect to any of our products, including BIVIGAM and ASCENIV, as trade shows, industry and medical conferences and other events we had been planning to utilize and exhibit and attend with our staff to increase awareness of our products by physicians and payers have been cancelled outright or otherwise rescheduled in response to the pandemic.

To date, the COVID-19 pandemic has not had a significant impact on our financial condition or results of operations. As of the date of this report, we do not believe that the operations and immunoglobulin production at our Boca Facility, our contract fill/finishers or our plasma collection facility have been significantly impacted by the COVID-19 pandemic. As a result, as of the date of this report, we currently do not anticipate any material impairments with respect to any of our long-lived assets, including our property and equipment, goodwill or intangible assets.

Although the COVID-19 pandemic has not, to date, materially adversely impacted our capital and financial resources, due to the economic uncertainty that has resulted from the pandemic, and the potential impact of such to our stakeholders, we are unable to predict with certainty any potential impacts to our business. Additionally, because we are unable to determine the ultimate severity or duration of the outbreak or its long-term effects on, among other things, the global, national or local economies, the capital and credit markets, our workforce, our customers or our suppliers, at this time we are unable to predict whether the COVID-19 crisis will have a material adverse impact on our business, financial condition, liquidity and results of operations.

LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2020, we had working capital of $151.6 million, including cash and cash equivalents of $101.2 million, and stockholders' equity of $96.3 million, as compared to working capital of $71.8 million, including cash and cash equivalents of $26.8 million, and stockholders' equity of $26.2 million as of December 31, 2019. We have incurred an accumulated deficit of $284.0 million since inception, had negative cash flows of $24.6 million and $14.3 million for the three months ended March 31, 2020 and 2019, respectively, and had negative cash flows from operations of $76.2 million and $62.7 million for the years ended December 31, 2019 and 2018, 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 procurement of raw material plasma and other raw materials necessary to scale up our manufacturing operations, commercial product launches, capacity expansion at the Boca Facility, building additional plasma collection facilities, product development, quality assurance, regulatory affairs and conducting clinical trials for our product candidates and purchasing clinical trial materials, some of which may be required by the FDA. In addition, our end-to-end production cycle from procurement of raw materials to commercial release of finished product can take between seven and 12 months, requiring substantial investments in raw material plasma and other manufacturing materials. We expect that we will not be able to generate a sufficient amount of product revenue to achieve profitability before 2021 and, as a result, we expect that we will need to finance our operations through additional equity or debt financings or corporate collaboration and licensing arrangements. Based upon our current projected revenue and expenditures, including capital expenditures and continued implementation of our commercialization and expansion activities, we currently believe that our cash, cash equivalents, projected revenue and accounts receivable will be sufficient to fund our operations, as currently conducted, into the second quarter of 2021. In order to have sufficient cash to fund our operations thereafter, we anticipate raising additional capital before the end of the second quarter of 2021. These estimates and timeframe may change based upon the success of our commercial manufacturing ramp-up activities, the acceptability and reimbursement of BIVIGAM and ASCENIV by physicians, patients or payers, and the various financing options that may be available to us. 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 our assumptions underlying our estimated expenses and revenues are incorrect, we may have to raise additional capital sooner than currently anticipated.

Our long-term liquidity depends upon our ability to raise additional capital, fund capacity expansion and commercial programs and generate sufficient revenues from our products, several of which have only recently achieved commercial status, to cover our operating expenses and meet our obligations on a timely basis. The COVID-19 pandemic has negatively affected the global economy and created significant volatility and disruption of financial markets. 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 capacity expansion, commercialization, product development or clinical trial activities, delay or discontinue the approval efforts for any of our product candidates, 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 the COVID-19 pandemic, FDA reviews and approvals related to our products, patient/payer acceptance of our products, ongoing compliance and maintenance requirements and capacity expansion efforts at the Boca Facility, 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 and are also subject to the effect of potential new government orders, policies and procedures that we must comply with which are outside of our control. As such, these factors raise substantial doubt about the Company's ability to continue as a going concern.

We may decide to raise capital through public or private equity offerings or debt financings, or obtain a bank credit facility or enter into corporate collaboration and licensing arrangements. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders and, in such event, the market value of our common stock may decline. The incurrence of additional indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations or other financing alternatives. In addition, we are exploring additional contract manufacturing arrangements and other business development opportunities, which may provide additional liquidity to us.

On March 20, 2020, we drew down the third and final tranche of our existing Credit Agreement and Guaranty, dated February 11, 2019, as amended (the "Credit Agreement"), with Perceptive Credit Holdings II, LP and we received proceeds of $12.5 million which are being used for general corporate purposes. Borrowings under the Credit Agreement bear interest at a rate per annum equal to the sum of 7.5% (the "Applicable Margin") 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 Applicable Margin shall automatically increase by an additional 400 basis points.

In February 2020, we completed an underwritten public offering of 27,025,000 shares of our common stock and received net proceeds, after underwriting discounts and other expenses associated with the offering, of approximately $88.7 million. The proceeds from this offering are expected to be used (i) for the procurement of raw materials for the manufacturing of BIVIGAM and ASCENIV; (ii) to support the ongoing commercial sales of BIVIGAM and ASCENIV; (iii) to expand the manufacturing capacity of our Boca Facility and enhance our supply chain capabilities; (iv) to expand our plasma collection facility network; (v) for research and development and business development opportunities; and (vi) for general corporate purposes and other capital expenditures.

Cash Flows

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

	Three Months Ended March 31,	
	2020	2019
Net cash used in operating activities	$ (24,646,960)	$ (14,287,184)
Net cash used in investing activities	(2,072,876)	(110,453)
Net cash provided by financing activities	101,203,400	4,177,063
Net change in cash and cash equivalents	74,483,564	(10,220,574)
Cash and cash equivalents, including restricted cash - beginning of period	26,752,135	26,754,852
Cash and cash equivalents - end of period	$ 101,235,699	$ 16,534,278

Net Cash Used in Operating Activities

Cash used in operations for the three months ended March 31, 2020 was $24.6 million, an increase of $10.4 million from the same period of a year ago, mainly due to increases in net loss and accounts receivable. The following table illustrates the primary components of our cash flows from operations:

	Three Months Ended March 31,	
	2020	2019
Net loss	$ (19,245,230)	$ (13,067,955)
Non-cash expenses, gains and losses	1,860,365	87,118
Changes in accounts receivable	(3,637,915)	82,037
Changes in inventories	775,932	(25,310)
Changes in prepaid expenses and other current assets	(2,321,751)	(289,134)
Changes in accounts payable and accrued expenses	(1,952,947)	(1,183,142)
Other	(125,414)	109,202
Cash used in operations	$ (24,646,960)	$ (14,287,184)

Net Cash Used in Investing Activities

Net cash used in investing activities for the three months ended March 31, 2020 and 2019 was $2.1 million and $0.1 million, respectively, primarily consisting of capital expenditures at the Boca Facility. Although we have no specific material commitments for capital expenditures as of March 31, 2020, we expect our total capital expenditures will be between $10.0 million and $15.0 million for the remainder of fiscal 2020.

Net Cash Provided by Financing Activities

Cash provided by financing activities during the three months ended March 31, 2020 was $101.2 million, which is comprised of the net proceeds received from our February 2020 equity offering in the amount of $88.7 million and the $12.5 million of loan proceeds received from the Tranche III Loan under our senior credit facility. Net cash provided by financing activities for the three months ended March 31, 2019 of $4.2 million reflects the refinancing of the Marathon Credit Facility with the Perceptive Credit Facility in February of 2019.

Effect of Inflation

Inflation or changing prices did not have a significant impact on our net sales, revenues or net loss for the three months ended March 31, 2020 or in 2019 or 2018.

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, 2020. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures as of March 31, 2020 were 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, 2020 that have materially affected, or are 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 material pending legal proceedings 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 significant risks and uncertainties that may affect our business. These risks and uncertainties are not the only ones we face. 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.

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.

Prior to the second half of 2019, we 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 our plasma-derived immune globulins which include: Nabi-HB, BIVIGAM, ASCENIV, intermediate fractions and the contract manufacturing of plasma-derived products for a third-party. On May 9, 2019 we received approval from the FDA for BIVIGAM, and the commercial re-launch of this product commenced in August 2019. On April 1, 2019, the FDA approved ASCENIV, formerly referred to as RI-002, and the first commercial sales of this product took place in October 2019. In October 2019, we generated initial sales of our plasma-derived intermediate fractions.

Our long-term liquidity depends upon our ability to grow our commercial programs, expand our commercial operations at the Boca Facility, improve our supply-chain capabilities, improve production yields, provide more control and visibility for timing of commercial product releases, raise additional capital, fund and successfully implement our research and development and commercial programs, establish and build out a commercial sales force, medical affairs organization and commercial infrastructure and meet our ongoing obligations.

We currently anticipate, based upon our projected revenue and expenditures, that our current cash, cash equivalents and accounts receivable, will be sufficient to fund our operations into the second quarter of 2021. This time frame may change based upon how quickly we are able to execute on our commercialization efforts and operational initiatives. However, if the assumptions underlying our estimated revenues and expenses prove to be incorrect, we may have to raise additional capital sooner than we currently expect. We anticipate that we will not be able to generate a sufficient amount of product revenue to achieve profitability before 2021 and, as a result, we anticipate that we will need 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 commercialization efforts as well as product development activities. 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.

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 into fiscal 2021, and we may never achieve or maintain profitability. For the three months ended March 31, 2020 and 2019, we incurred net losses of $19.2 million and $13.1 million, respectively. For the years ended December 31, 2019 and 2018, we incurred net losses of $48.3 million and $65.7 million, respectively. From our inception in 2004 through March 31, 2020, we have incurred an accumulated deficit of $284.0 million. We expect that we will not be able to generate a sufficient amount of product revenue to achieve profitability before 2021 and, as a result, we expect that we will need to finance our operations through additional equity or debt financings or corporate collaboration and licensing agreements. 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:

- expand 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.

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. These factors raise substantial doubt about our ability to continue as a going concern. Our failure to achieve or maintain profitability could negatively impact the value of our securities.

The COVID-19 pandemic and efforts to reduce its spread has significantly affected worldwide economic conditions, and could have a material adverse impact on our business, liquidity, financial condition and results of operations

The COVID-19 pandemic has the potential to adversely impact several aspects of our commercial and manufacturing operations, including but not limited to potential disruptions to our supply-chain operations, including procurement of raw materials and packaging materials, a portion of which are sourced internationally, and the testing of finished drug product that is required prior to its availability for commercial sale. Such testing has been performed to date by contract laboratories outside the United States. In addition, travel and other restrictions that have been implemented in the United States could impact our commercial launch efforts with respect to any of our products, including BIVIGAM and ASCENIV, as trade shows, industry and medical conferences and other events we had been planning to utilize and exhibit and attend with our staff to increase awareness of our products by physicians and payers have been cancelled outright or otherwise rescheduled in response to the pandemic.

The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, operations, or financial condition, or on healthcare systems or the global economy as a whole. Although the COVID-19 pandemic has not adversely affected our capital and financial resources to date, the pandemic’s effects could have a material impact on our ability to access the capital markets as needed and on our operations and business, including those of the third parties on which we rely. Because we are unable to determine the ultimate severity or duration of the pandemic or its effects on, among other things, the global, national or local economies, the capital and credit markets, our workforce, our customers or our suppliers, at this time we are unable to predict whether COVID-19 will have a material adverse impact on our business, financial condition, liquidity and results of operations.

We contract with third parties for the filling, packaging, testing and labeling of the drug substance we manufacture. This reliance on third parties carries the risk that the services upon which we rely may not be performed in a timely manner or according to our specifications, which could delay the availability of our finished drug product and could adversely affect our commercialization efforts and our revenues.

Third-party fill/finish providers may not perform as agreed or in accordance with FDA requirements. Any significant problem that our fill/finish providers experience could delay or interrupt our supply of finished drug product until the service provider cures the problem or until we locate, negotiate for, validate and receive FDA approval for an alternative provider (when necessary), if one is available. Failure to obtain the needed fill/finish services could have a material and adverse effect on our business, financial condition, results from operations and prospects.

Although in the future we plan to build our own fill/finish suite within the Boca Facility, we also intend to continue to utilize third parties to supplement our fill/finish process for final drug substance and we may, in any event, never be successful in developing our own fill/finish suite. Our anticipated reliance on a limited number of third-party manufacturers exposes us to the following risks:

- we may be unable to identify contract fill/finishers on acceptable terms or at all because the number of potential service providers is limited and the FDA must inspect and qualify any contract manufacturers for current cGMP compliance as part of our marketing application;
- a new fill/finisher would have to be educated in, or develop substantially equivalent processes for, the production of our products and product candidates;
- our contracted fill/finishers' resources and level of expertise with plasma-derived biologics may be limited, and therefore they may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to deliver our finished drug product;
- our third-party fill/finishers might be unable to timely provide finished drug product in sufficient quantity to meet our commercial needs;
- contract manufacturers may not be able to execute our inspection procedures and required tests appropriately;
- contract manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations, and we do not have control over third-party providers' compliance with these regulations;
- our third-party fill-finishers could breach or terminate their agreements with us; and
- our contract fill/finishers may have unacceptable or inconsistent drug product quality success rates and yields, and we have no direct control over our contract fill/finishers' ability to maintain adequate quality control, quality assurance and qualified personnel.

Each of these risks could delay or prevent the completion of our finished drug product and the release of finished drug product by the FDA, which could result in higher costs or adversely impact the commercialization of our products. In addition, our contract fill/finishers and our other third-party vendors may source their materials and supplies globally, and are therefore subject to supply disruptions in the event of fire, weather related events such as hurricanes, wind and rain, other acts of God or force majeure events or global health occurrences and emergencies, including the COVID-19 pandemic.

The estimates of market opportunity and forecasts of market and revenue growth included in our filings may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business could fail to grow at similar rates, if at all.

Market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate, including as a result of changing circumstances during the ongoing COVID-19 pandemic. In particular, the size and growth of the overall U.S. IVIG and source plasma markets are subject to significant variables that can be difficult to measure, estimate or quantify. Our business depends on, among other things, successful commercialization of our existing products, market acceptance of such products and ensuring that our products are safe and effective. Further, there can be no assurance that we will be able to generate the revenue that we believe our products and plasma facilities are capable of generating. As a result, we may not be able to accurately forecast or predict revenue. For these reasons, the estimates and forecasts in our filings relating to revenue generation and growth may prove to be inaccurate. Even if the markets in which we compete meet our size estimates and forecasted growth, our business could fail to grow at similar rates, if at all.

Even though we operate under our own FDA-issued license, we may not be able to officially resolve or receive a final close-out letter with respect to the Warning Letter issued to Biotest's License #1792 for the Boca Facility.

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 Biologics License Application ("BLA") submission for RI-002 in 2015 (the "RI-002 BLA"), in July 2016 the FDA issued a Complete Response Letter ("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 a November 2014 warning letter (the "Warning Letter") that the FDA had issued to BPC related to certain compliance and other inspection issues and deficiencies identified at the Boca Facility. The FDA identified in the RI-002 CRL, among other things, certain outstanding inspection issues and deficiencies related to chemistry, manufacturing and control ("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 were resolved. In response to the Warning Letter, in December 2016, BTBU temporarily suspended the production of BIVIGAM 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, 2018, and until August 2019.

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 was to remediate the outstanding compliance issues at the Boca Facility as indicated in the Warning Letter. We worked with a leading consulting firm with extensive experience in remediating compliance and inspection issues related to quality management systems that managed 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. In April 2018, the FDA inspected the Boca Facility and, in July 2018, our FDA status improved from Official Action Indicated ("OAI") to Voluntary Action Indicated ("VAI"), and this inspection of the Boca Facility has been successfully closed out as indicated on the FDA's website inspection database. The FDA subsequently approved ASCENIV in April 2019 and BIVIGAM in May 2019, and, on July 2, 2019, notified us that the licenses for BIVIGAM and Nabi-HB had been revoked from BPC's U.S. License No. 1792, with respect to which the Warning Letter was issued, and transferred and issued to our U.S. License No. 2019. The commercial re-launch and first commercial sales of BIVIGAM under our ownership occurred in August 2019. Commercial sales of ASCENIV commenced in October 2019. Although we received FDA approval of our RI-002 BLA on April 1, 2019 and the FDA has transferred the BIVIGAM and Nabi-HB licenses to us, neither we nor BPC has 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, and we believe that as result of the FDA's transfer of the BIVIGAM and Nabi-HB licenses to us, we have neither a right nor an obligation to close out the Warning Letter, which applied to BPC's U.S. License No. 1792. Consequently, we may not be able to officially close out the Warning Letter issued to Biotest under their license #1792 related to the Boca Facility.

There can be no assurance that the FDA will not in the future determine that our efforts to remediate the underlying concerns at the Boca Facility that resulted in the Warning Letter and the CRL in July 2016 have not been effective. 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. If the FDA determines that we have not remediated the issues identified in the Warning Letter or any other inspection issues and deficiencies, any failure of ours to address or provide requested documentation of corrections for these issues could disrupt our business operations and the timing of our commercialization efforts and could have a material adverse effect on our financial condition and operating results.

Business interruptions could adversely affect our business.

Our operations, including our headquarters located in Ramsey, NJ, the Boca Facility and our plasma collection facilities, are vulnerable to interruption by fire, weather related events such as hurricanes, wind and rain, other acts of God or force majeure events, electric power loss, telecommunications failure, equipment failure and breakdown, human error, employee issues, global health occurrences, such as COVID-19, and emergencies, product liability claims and events beyond our control. While we maintain several insurance policies with reputable carriers that provide partial coverage for a variety of these risks, including replacing or rebuilding a part of our facilities, these policies are subject to the insurance carriers' final determination of compensation to us and we may not have adequate coverage if we need to rebuild or replace our inventory, infrastructure, business income or our entire facility. 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.

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.

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. 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, delays or setbacks 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 evolving COVID-19 pandemic may directly or indirectly affect the pace of enrollment in clinical trials as patients may be restricted in traveling to and accessing healthcare facilities and physicians' offices. Additionally, such healthcare facilities and offices have their limited resources directed towards treating patients with COVID-19 symptoms. 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
- inability or unwillingness of medical investigators to follow our clinical protocols; and
- temporary suspension resulting from the COVID-19 pandemic.

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 that still require FDA approval. 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 and maintain the necessary U.S. or international regulatory approvals to commercialize a product candidate, we will not be able to sell that product candidate, which would make it difficult for us to recover the costs of researching and developing such product candidate.

If we are not be able to generate revenue from our products and product candidates, 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, diversion of resources for FDA review during the ongoing COVID-19 pandemic 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 as a treatment for PIDD, our ability to market or seek approval for ASCENIV for alternative indications could be limited, unless additional clinical trials are conducted successfully and the FDA approves a BLA or other required submission for review.

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 as a treatment 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. 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 and stockholders 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, including supply chain constraints directly or indirectly caused by the ongoing COVID-19 pandemic and government responses thereto, reimbursement, marketing challenges, development of a comprehensive compliance program, and other related and additional costs. For example, the raw material plasma we collect and procure to manufacture ASCENIV using our patented proprietary microneutralization assay is comprised of plasma collected from donors which contains high titer antibodies to RSV. This high titer plasma which meets our internal specifications for the manufacture of ASCENIV that we are able to identify with our patented testing assay amounts to less than 10% of the total donor collection samples we test. 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 U.S. 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 products and product candidates, 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, contract fill/finishers 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 or the impact that the ongoing COVID-19 pandemic will have on such third parties. 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.

We may be unable to successfully expand our manufacturing processes to fulfill demand for our products or increase our production capabilities through the addition of new equipment, including if we do not obtain the requisite validation from the FDA.

We currently anticipate expanding the manufacturing capacity of our Boca Facility by approximately 50% or more. We also anticipate expanding our production capabilities through the addition of a fill-finish machine at our Boca Facility. Following the expansion of any of our manufacturing processes or the addition of new equipment, such as the fill-finish machine, we will need to validate the expanded facility and equipment and have it inspected by the FDA. Given the significant delays that may result during the validation process, including due to any diverted FDA attention during the COVID-19 pandemic, we may experience a significant supply shortage of our products or our production capabilities may be limited until completion of and validation of our facility expansion and new manufacturing equipment.

Our products, and any additional products for which we may obtain marketing approval in the future, could be subject to post-marketing restrictions or withdrawal from the market and we could be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products following approval.

Our products, and any additional products for which we may obtain marketing approval in the future, could be subject to post-marketing restrictions, new FDA guidance, or other regulatory actions, such as withdrawal from the market. Such products, as well as the manufacturing processes, post-marketing studies and measures, labeling, advertising and promotional activities for such products, among other things, are subject to ongoing regulatory compliance requirements, and oversight, review, and inspection by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, adherence with labeling and promotional requirements and restrictions, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding safeguarding the drug supply chain as well as the distribution of samples to physicians and recordkeeping. For example, the FDA's approval of our PAS to allow for the commercial relaunch of BIVIGAM requires us to conduct specified post-marketing studies related to our manufacturing controls and processes, and submit specified post-marketing reports to the FDA. If, during the post marketing period (after marketing approval) previously unknown adverse events or other potential concerns regarding our products or their manufacturing processes emerge, or we are observed in any way to fail to comply with the numerous regulatory requirements to which we are subject, those circumstances may yield various results, including:

- restrictions on such products or manufacturing processes;
- restrictions on the labeling or marketing of a product;

- restrictions on product distribution or use;
- requirements to conduct further post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- restrictions on coverage by third-party payers;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Historically, a few customers have accounted for a significant amount of our total revenue and accounts receivable and the loss of any of these customers could have a material adverse effect on our business, results of operations and financial condition.

For the three months ended March 31, 2020, three customers represented an aggregate of 82% of our consolidated revenues, with BioCare, Biolife and Reliance representing approximately 43%, 24%, and 15%, respectively, of our consolidated revenues. For the year ended December 31, 2019, three customers represented an aggregate of 70% of our consolidated revenues, with BioCare, Biolife and Sanofi representing approximately 26%, 24%, and 20%, respectively, of our consolidated revenues.

As of March 31, 2020, three customers represented a total of 84% of our consolidated accounts receivable, with BioCare, Reliance and Biolife representing approximately 57%, 16% and 11%, respectively, of our consolidated accounts receivable. At December 31, 2019, BioCare represented 77% of our consolidated accounts receivable and McKesson represented 13% of our consolidated accounts receivable.

The loss of any key customers or a material change in the revenue generated by any of these customers could 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, and we fulfilled our commitment under our supply agreement with Sanofi during the year ended December 31, 2019. Moreover, we anticipate deriving increased revenue from BioCare over the next few years. 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
- our ability to produce and deliver a sufficient quantity of our products in a timely manner to meet our customers' requirements; and

- the impact of the ongoing COVID-19 pandemic and government responses thereto on our customers and their businesses, operations and financial condition.

Additionally, an adverse change in the financial condition of BioCare, Biolife, Reliance, McKesson, Cardinal Health or AmerisourceBergen could negatively affect revenue derived from such customer, which in turn 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 us, physicians, payers and patients may not accept and use it. Acceptance and use of our products depends 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 or 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.

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 label expansion activities for Nabi-HB, BIVIGAM and ASCENIV. 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 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, healthcare 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 healthcare 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 HHS 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 $5.0 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 went 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. 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 neither be successful in integrating the Biotest Assets into our business nor realize the strategic and financial benefits currently anticipated from the Biotest Transaction.

The Biotest Transaction involves the integration of two businesses that previously have operated independently with principal offices in two distinct locations. We continue to expend 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. 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.

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.

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, which exposes us 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 Master Purchase and Sale Agreement, dated as of January 21, 2017 (the "Master 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 Master Purchase Agreement. In connection with the Share Transfer, Amendment and Release Agreement among us, BPC, Biotest AG, Biotest US Corporation and The Biotest Divestiture Trust (the "Biotest Trust") (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. 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 Master 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 Master 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 were 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. 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.

The Perceptive Credit Facility is subject to acceleration in specified circumstances, which may result in Perceptive taking possession and disposing of any collateral.

On February 11, 2019 (the "Perceptive Closing Date"), we entered into the Perceptive Credit Agreement with Perceptive Credit Holdings II, LP, as the lender and administrative agent ("Perceptive"). The Perceptive Credit Agreement, as amended, provides for a senior secured term loan facility in a principal amount of up to $85.0 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 in favor of Perceptive on the Perceptive Closing Date (the "Perceptive Tranche I Loan"), (ii) a term loan in the principal amount of $27.5 million evidenced by our of a promissory note in favor of Perceptive on May 3, 2019 (the "Perceptive Tranche II Loan"); and (iii) an additional commitment in the principal amount of up to $12.5 million (the "Perceptive Tranche III Loan," and together with the Perceptive Tranche I Loan and the Perceptive Tranche II Loan, the "Perceptive Loans") which we drew down on March 20, 2020. The Perceptive Loans each have a maturity date of March 1, 2022, subject to acceleration pursuant to the Perceptive Credit Agreement, including upon an Event of Default (as defined in the Perceptive Credit Agreement). The Perceptive 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 Perceptive Loans of 4% per annum, the occurrence of an Event of Default could result in, among other things, the termination of commitments under the Perceptive 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 Perceptive 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 U.S. Patent and Trademark Office. 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 our products 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 IG. 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. Our ability to accomplish each of these factors may be negatively impacted as a consequence of the COVID-19 pandemic. 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. Further, while many of our employees and certain suppliers with whom we do business operate in a remote working environment during the COVID-19 pandemic, the risk of cybersecurity attacks and data breaches, particularly through phishing attempts, may be increased as we and third-parties with whom we interact leverage our IT infrastructure in unanticipated ways during the ongoing COVID-19 pandemic. 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 cyberattacks, 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, quality control, 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, finance and 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, particularly if the COVID-19 pandemic causes significant changes in the competitive market for such personnel or travel restrictions related to COVID-19 prevent qualified personnel from applying for employment. 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 that 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 building 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.

The FDA had identified issues in the Warning Letter resulting from their prior inspections while the Boca Facility was under BPC's operational control. We engaged a leading consulting firm with extensive experience in remediating compliance and inspection issues related to quality management systems that managed 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. 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 to 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 and maintain 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 HHS 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 healthcare 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 healthcare 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 healthcare laws, and mitigate potential liability in the event of noncompliance, regulatory authorities such as the HHS Office of Inspector General (the "OIG") have recommended the adoption and implementation of a comprehensive healthcare 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 now FDA-approved 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 improvements for BIVIGAM and to seek FDA authorization which would enable us to resume commercial scale manufacturing and re-launch 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. On May 9, 2019, we received FDA approval for 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 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, testing, 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, test, 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 the timing of receiving the testing results, 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 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, such as COVID-19, 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. Further, the COVID-19 pandemic has resulted in, and may continue to result in, significant constraints in raw material supply across various different industries. It is possible that in the future, the COVID-19 pandemic and government responses thereto will have an adverse effect on our ability to source plasma from donors in quantity and quality sufficient for our manufacturing processes. 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.

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 HHS 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 HHS, 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 U.S. 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 U.S. 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.

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, 2020 and 2019, we had negative cash flows from operations of $24.6 million and $14.3 million, respectively, and for the years ended December 31, 2019 and 2018, we had negative cash flows from operations of approximately $76.2 million and $62.7 million, respectively. We expect to continue to spend substantial amounts on procurement of raw material plasma and other raw materials necessary to scale up our manufacturing operations, commercial product launches, capacity expansion at the Boca Facility, building additional plasma collection facilities, product development, quality assurance, regulatory affairs and conducting clinical trials for our product candidates and purchasing clinical trial materials, some of which may be required by the FDA. We expect that we will not be able to generate a sufficient amount of product revenue to achieve profitability before 2021 and, as a result, we expect that we will need to finance our operations through additional equity or debt financings or corporate collaboration and licensing agreements. We currently anticipate, based upon our projected revenue and expenditures, as well as the additional funds we are able to draw down under the Perceptive Credit Facility, that our current cash, cash equivalents and accounts receivable will be sufficient to fund our operations, as currently conducted, into the second quarter of 2021. In order to have sufficient cash to fund our operations thereafter, we will need to raise additional equity or debt financing before the end of the second quarter of 2021. This time frame may change based upon how quickly we are able to execute on our operational initiatives and the various financing options that may be available to us in 2021**.** 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, including due to widespread liquidity constraints or significant market instability that could result from the COVID-19 pandemic, we will have to delay, curtail or eliminate our commercialization efforts or our product development activities.

We may not have cash available to us in amounts sufficient to enable us to make interest or principal payments on our indebtedness when due.

The Perceptive Credit Facility provides for term loans of up to an aggregate principal amount of $85.0 million, all of which has been drawn down and is currently outstanding. Borrowings under the Perceptive Credit Facility 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. We are required to make monthly payments of interest during the term of the Perceptive Credit Facility of approximately $0.8 million, with all principal and unpaid interest due at maturity. The Perceptive Credit Facility has a maturity date of March 1, 2022, subject to acceleration pursuant to the Perceptive Credit Agreement, including upon an Event of Default. All of our obligations under the Perceptive Credit Facility are secured by a first-priority lien and security interest in substantially all of our and our subsidiaries' tangible and intangible assets, including intellectual property, and all of the equity interests in our subsidiaries.

In addition, we have $15.0 million in principal amount of indebtedness outstanding under an unsecured subordinated note issued by ADMA BioManufacturing to Biotest on June 6, 2017, which note bears interest at a rate of 6.0% per annum and matures on June 6, 2022. We are obligated to make semi-annual interest payments to Biotest, with all principal and unpaid interest due at maturity.

Our current cash, cash equivalents and accounts receivable will not be sufficient to repay all of our current outstanding debt obligations as they mature. If we are unable to obtain additional financing and are otherwise unable to become profitable and generate cash from operations in the amounts necessary to repay our outstanding debt obligations when due, including as a result of the impact of the COVID-19 pandemic, our creditors would be able to accelerate all of the amounts due and, in the case of the Perceptive Credit Facility, seek to enforce their security interests, which could lead to our creditors taking immediate possession of and selling substantially all of our assets with no return provided to our stockholders.

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 and cash equivalents could be adversely affected if the financial institutions in which we hold our cash and cash equivalents 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 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, 2019, we had federal and state NOLs of $175.1 million and $116.2 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 of 1986, as amended (the "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 Code 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 a 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.

The TCJA, among other things, reduced the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limited the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limited the deduction for net operating losses generated after December 31, 2017 to 80% of current year taxable income and eliminated net operating loss carrybacks, provided immediate deductions for certain new investments instead of deductions for depreciation expense over time and modified or repealed 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 BIVIGAM and ASCENIV;
- 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.

Sales of a substantial number of shares of our common stock, or the perception that such sales may occur, may adversely affect the market price of our common stock.

As of May 4, 2020, most of our 86,345,313 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 under the Securities Act, or under effective registration statements. Sales of a substantial number of shares of our common stock, or the perception that such sales may occur, could cause the market price of our common stock to decline or adversely affect demand for our common stock.

Our affiliates control a substantial amount of our shares of common stock. Provisions in our Second 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 March 31, 2020, Perceptive, our directors and executive officers and their affiliates beneficially owned approximately 27% 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 the Biotest Transfer Agreement, 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. This 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. For example, the Perceptive Credit Agreement prohibits 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 Global 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 the Nasdaq Global Market 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 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.

Consequently, we have, and will continue to, incur increased costs related to our compliance with Section 404 of the Sarbanes-Oxley Act. For example, in 2018, our Audit Committee retained the services of BDO, 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 150,000,000 shares of common stock. As of March 31, 2020, there were 54,429,673 shares remaining available for issuance, after giving effect to 9,225,014 shares of our common stock that were subject to outstanding stock options, RSUs, warrants or other convertible securities as of March 31, 2020 that may be issued by us without stockholder approval.

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 6, 2020

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

Date: May 6, 2020

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

EXHIBIT INDEX

Exhibit Number	Description
4.1	Note, dated March 20, 2020, 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 March 20, 2020).
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, 2020, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets as of March 31, 2020 (Unaudited) and December 31, 2019, (ii) Condensed Consolidated Statements of Operations (Unaudited) for the three months ended March 31, 2020 and 2019, (iii) Condensed Consolidated Statements of Changes in Stockholders' Equity (Unaudited) for the three months ended March 31, 2020 and 2019, (iv) Condensed Consolidated Statements of Cash Flows (Unaudited) for the three months ended March 31, 2020 and 2019, 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.

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 6, 2020

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 6, 2020

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, 2020, 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 6, 2020

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, 2020, 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 6, 2020

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