UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2022

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
Preferred Share Purchase Right	-	Nasdaq Global Market

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

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

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

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

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

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

As of May 6, 2022, there were 196,351,925 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 and ASCENIV on a commercial scale and further commercialize these products as a result of their approval by the U.S. Food and Drug Administration (the "FDA") in 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 belief that we have addressed the delays experienced with final drug product Current Good Manufacturing Practices ("cGMP") release testing by our third-party vendors by adding additional release testing laboratories to our FDA-approved consortium listed in our drug approval documents;
- 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, our ability to obtain and maintain regulatory compliance and receive FDA approvals of new plasma collection centers and reliance on 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 BIVIGAM, ASCENIV and Nabi-HB, 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 ("IG") 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 and efficiencies of our manufacturing capacity, yield improvements, supply-chain robustness, in-house fill-finish capabilities, distribution and other collaborative agreements and the success of such endeavors;
- our estimates regarding revenues, expenses, capital requirements, timing to profitability and positive cash flows 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;
- 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; and
- future domestic and global economic conditions including, but not limited to, supply chain constraints, inflationary pressures or performance.

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, 2021 and in this Quarterly Report on Form 10-Q for the quarter ended March 31, 2022. 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, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 69,504,946	$ 51,089,118
Accounts receivable, net	25,629,625	28,576,857
Inventories	139,146,311	124,724,091
Prepaid expenses and other current assets	5,519,301	4,339,245
Total current assets	239,800,183	208,729,311
Property and equipment, net	53,220,480	50,935,074
Intangible assets, net	1,549,930	1,728,768
Goodwill	3,529,509	3,529,509
Right to use assets	7,106,642	7,262,658
Deposits and other assets	2,825,748	4,067,404
TOTAL ASSETS	$ 308,032,492	$ 276,252,724
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 14,115,135	$ 12,429,409
Accrued expenses and other current liabilities	16,654,540	17,214,988
Current portion of deferred revenue	142,834	142,834
Current portion of lease obligations	654,003	591,084
Total current liabilities	31,566,512	30,378,315
Senior notes payable, net of discount	138,423,052	94,866,239
Deferred revenue, net of current portion	1,940,156	1,975,865
End of term fee	1,500,000	-
Lease obligations, net of current portion	7,284,079	7,462,388
Other non-current liabilities	385,628	397,351
TOTAL LIABILITIES	181,099,427	135,080,158
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, 300,000,000 shares authorized, 196,347,529 and 195,813,817 shares issued and outstanding	19,635	19,581
Additional paid-in capital	564,034,008	553,265,706
Accumulated deficit	(437,120,578)	(412,112,721)
TOTAL STOCKHOLDERS' EQUITY	126,933,065	141,172,566
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 308,032,492	$ 276,252,724

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,	
	2022	**2021**
REVENUES:		
Product revenue	$ 29,067,385	$ 16,012,910
License revenue	35,708	35,708
Total revenues	29,103,093	16,048,618
Cost of product revenue	25,441,046	17,770,122
Gross profit (loss)	3,662,047	(1,721,504)
OPERATING EXPENSES:		
Research and development	624,111	987,649
Plasma center operating expenses	3,974,589	2,242,343
Amortization of intangible assets	178,838	178,838
Selling, general and administrative	13,699,575	10,033,915
Total operating expenses	18,477,113	13,442,745
LOSS FROM OPERATIONS	(14,815,066)	(15,164,249)
OTHER INCOME (EXPENSE):		
Interest income	33,068	22,059
Interest expense	(3,389,038)	(3,195,750)
Loss on extinguishment of debt	(6,669,941)	-
Other expense	(166,880)	(42,001)
Other expense, net	(10,192,791)	(3,215,692)
NET LOSS	$ (25,007,857)	$ (18,379,941)
BASIC AND DILUTED LOSS PER COMMON SHARE	$ (0.13)	$ (0.16)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:		
Basic and Diluted	195,871,932	115,661,937

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, 2022

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2021	195,813,817	$ 19,581	$ 553,265,706	$ (412,112,721)	$ 141,172,566
Stock-based compensation	-	-	1,641,388	-	1,641,388
Warrants issued in connection with notes payable	-	-	9,569,604	-	9,569,604
Vesting of Restricted Stock Units, net of shares withheld for taxes and retired	533,712	54	(442,690)	-	(442,636)
Net loss	-	-	-	(25,007,857)	(25,007,857)
Balance at March 31, 2022	196,347,529	$ 19,635	$ 564,034,008	$ (437,120,578)	$ 126,933,065

For the Three Months Ended March 31, 2021

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2020	104,902,888	$ 10,490	$ 428,704,039	$ (340,465,103)	$ 88,249,426
Stock-based compensation	-	-	781,397	-	781,397
Issuance of common stock, net of offering expenses	18,080,708	1,808	41,910,707	-	41,912,515
Vesting of Restricted Stock Units, net of shares withheld for taxes and retired	61,385	6	(59,317)	-	(59,311)
Net loss	-	-	-	(18,379,941)	(18,379,941)
Balance at March 31, 2021	123,044,981	$ 12,304	$ 471,336,826	$ (358,845,044)	$ 112,504,086

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,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (25,007,857)	$ (18,379,941)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,590,217	1,229,628
Loss on disposal of fixed assets	2,000	781
Stock-based compensation	1,641,388	781,397
Amortization of debt discount	584,842	443,794
Loss on extinguishment of debt	6,669,941	-
Amortization of license revenue	(35,708)	(35,708)
Changes in operating assets and liabilities:		
Accounts receivable	2,947,233	(2,124,740)
Inventories	(14,422,219)	(12,610,601)
Prepaid expenses and other current assets	(1,180,056)	(2,756,142)
Deposits and other assets	1,397,672	19,718
Accounts payable	1,685,724	1,079,144
Accrued expenses	(1,775,526)	(843,043)
Other current and non-current liabilities	(111,064)	(33,413)
Net cash used in operating activities	(26,013,413)	(33,229,126)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(2,842,085)	(2,571,161)
Net cash used in investing activities	(2,842,085)	(2,571,161)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Principal payments on notes payable	(100,000,000)	-
Proceeds from issuance of common stock, net of offering expenses	-	41,912,515
Payment of debt refinancing fees	(2,000,000)	-
Proceeds from issuance of note payable	151,750,000	-
Taxes paid on vested Restricted Stock Units	(91,367)	(59,311)
Payments on finance lease obligations	(8,941)	(8,360)
Payment of deferred financing fees	(2,378,366)	-
Net cash provided by financing activities	47,271,326	41,844,844
Net increase in cash and cash equivalents	18,415,828	6,044,557
Cash and cash equivalents - beginning of year	51,089,118	55,921,152
Cash and cash equivalents - end of period	$ 69,504,946	$ 61,965,709

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 BioCenters Georgia Inc. ("ADMA BioCenters"). 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") on June 6, 2017. The acquisition included certain assets of BTBU, including the U.S. Food and Drug Administration ("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"). BTBU had previously been the Company's third-party contract manufacturer. ADMA BioCenters is the Company's source plasma collection business with ten plasma collection facilities in various stages of approval and development located throughout the U.S., five of which hold an approved license with 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 the Company received FDA approval on May 9, 2019 and commenced commercial sales in August 2019; (ii) ASCENIV (Immune Globulin Intravenous, Human – slra 10% Liquid), an IVIG product indicated for the treatment of PI, for which the Company 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. In addition to its commercially available immunoglobulin products, the Company provides contract manufacturing and laboratory services for certain clients and generates revenues from the sale of intermediate by-products that result from the immunoglobulin production process. 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.

As of March 31, 2022, the Company had working capital of $208.2 million, including $69.5 million of cash and cash equivalents. Based upon the Company's current projected revenue and expenditures, including capital expenditures and continued implementation of the Company's commercialization and expansion activities, the Company's management currently believes that its cash, cash equivalents, projected revenue and accounts receivable, together with the remaining available funds under the distribution agreement entered into in September of 2021 (see Note 8) and the net proceeds received and expected to be received from the refinancing of the Company's senior debt on March 23, 2022 (see Note 7), will be sufficient to fund ADMA's operations, as currently conducted, into the first quarter of 2024, at which time the Company believes it will begin to generate positive cash flow from operations. These estimates may change based upon several factors, including the success of the Company's commercial efforts with respect to the sale of its products, whether or not the assumptions underlying the Company's projected revenues and expenses are correct and the acceptability of ADMA's immune globulin products by physicians, patients or payers. There can be no assurance that the Company's approved products will be commercially viable, or that plant capacity expansion, plasma center buildouts 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, inflationary pressures, supply chain constraints, protection of proprietary technology, and compliance with FDA and other governmental regulations and approval requirements. The Company is also continuing to evaluate a variety of strategic alternatives through its ongoing engagement with Morgan Stanley as a financial advisor.

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, 2021 included in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC") on March 24, 2022. The accompanying consolidated balance sheet as of December 31, 2021 was derived from the audited financial statements as of and for the year ended December 31, 2021. 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, 2022 and its results of operations, changes in stockholders' equity and cash flows for the three months ended March 31, 2022 and 2021.

During the three months ended March 31, 2022 and 2021, 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.

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 rebates and chargebacks deducted from gross revenues, 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 7) approximates fair value due to the variable interest rate on this debt.

Accounts Receivable

Accounts receivable is reported at realizable value, net of allowances for contractual credits and doubtful accounts in the amount of $0.1 million and $0.2 million at March 31, 2022 and December 31, 2021, respectively, 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 its credit risk is minimal. At March 31, 2022, four customers accounted for an aggregate of 92% of the Company's total accounts receivable, and at December 31, 2021, three customers accounted for approximately 94% of the Company's total accounts receivable.

Inventories

Raw materials inventory consists of various materials purchased from suppliers, including normal source plasma, used in the production of the Company's products. Work-in-process and finished goods inventories (see Note 3) reflect the cost of raw materials as well as costs for direct and indirect labor, primarily salaries, wages and benefits for applicable employees, as well as an allocation of overhead costs related to the Boca Facility including utilities, property taxes, general repairs and maintenance, consumable supplies and depreciation. The allocation of Boca Facility overhead to inventory is generally based upon the estimated square footage of the Boca Facility that is used in the production of the Company's products relative to the total square footage of the facility.

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. Net realizable value is generally determined based upon the consideration the Company expects to receive when the inventory is sold, less costs to deliver the inventory to the recipient. The estimates for net realizable value of inventory are based on contractual terms or upon historical experience and certain other assumptions, and the Company believes that such assumptions are reasonable. Inventory is periodically reviewed to ensure that its carrying value does not exceed its net realizable value, and adjustments are recorded to write down such inventory, with a corresponding charge to cost of product revenue, when the carrying value or historical cost exceeds its estimated net realizable value. In addition, costs associated with the production of conformance or engineering lots that would not qualify as immediately available for commercial sale are charged to cost of product revenue and not capitalized into inventory.

Goodwill

Goodwill represents the excess of purchase price over the fair value of net assets acquired by the Company. Goodwill at March 31, 2022 and December 31, 2021 was $3.5 million. All of the Company's goodwill is attributable to its ADMA BioManufacturing business segment and is related to the Biotest Transaction.

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, 2021 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, 2022 and 2021.

Impairment of Long-Lived Assets

The Company assesses the recoverability of its long-lived assets, which include property and equipment and finite-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, 2022 and 2021, the Company determined that there was no impairment of its long-lived assets.

Revenue Recognition

Revenues for the three months ended March 31, 2022 and 2021 are comprised of (i) revenues from the sale of the Company's immunoglobulin products, BIVIGAM, ASCENIV and Nabi-HB, (ii) product revenues from the sale of human plasma collected through the Company's Plasma Collection Centers business segment, (iii) contract manufacturing and laboratory services 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 amortized into income over the term of the Biotest license, representing a period of approximately 22 years.

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, 2022, three customers represented an aggregate of 83% of the Company's consolidated revenues. For the three months ended March 31, 2021, five customers represented an aggregate of 86% of the Company's consolidated revenues.

Cost of Product Revenue

Cost of product revenue includes costs associated with the manufacture of the Company's FDA approved products, intermediates and the sale of human source plasma, as well as expenses related to conformance batch production, process development and 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.

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 in the accompanying condensed consolidated financial statements as the Company reported a net loss for all periods presented. For the three months ended March 31, 2022 and 2021, 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,	
	2022	2021
Stock options	8,686,068	8,103,165
Restricted stock units	4,729,758	730,994
Warrants	13,631,207	4,528,160
	27,047,033	13,362,319

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 basis 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 2017 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 50% 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, 2022 and December 31, 2021, and during the three months ended March 31, 2022 and 2021, the Company recognized no adjustments for uncertain tax positions.

3. INVENTORIES

The following table provides the components of inventories:

	March 31, 2022	December 31, 2021
Raw materials	$ 46,034,969	$ 36,755,720
Work-in-process	45,139,511	58,968,535
Finished goods	47,971,831	28,999,836
Total inventories	$ 139,146,311	$ 124,724,091

Raw materials includes plasma and other materials expected to be used in the production of BIVIGAM, ASCENIV and Nabi-HB. These materials will be consumed in the production of goods expected to be available for sale or otherwise have alternative uses that provide a probable future benefit. 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 centers which is expected to be sold to third-party customers.

4. INTANGIBLE ASSETS

Intangible assets at March 31, 2022 and December 31, 2021 consist of the following:

	March 31, 2022			December 31, 2021		
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Trademark and other intangible rights related to Nabi-HB	$ 4,100,046	$ 2,830,985	$ 1,269,061	$ 4,100,046	$ 2,684,554	$ 1,415,492
Rights to intermediates	907,421	626,552	280,869	907,421	594,145	313,276
	$ 5,007,467	$ 3,457,537	$ 1,549,930	$ 5,007,467	$ 3,278,699	$ 1,728,768

All of the Company's intangible assets were acquired in the Biotest Transaction. Amortization expense related to these intangible assets was $0.2 million for the three months ended March 31, 2022 and 2021. Estimated aggregate future aggregate amortization expense is expected to be as follows:

Remainder of 2022	$ 536,514
2023	715,352
2024	298,064

5. PROPERTY AND EQUIPMENT

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

	March 31, 2022	December 31, 2021
Manufacturing and laboratory equipment	$ 17,100,261	$ 16,702,991
Office equipment and computer software	4,323,549	4,082,462
Furniture and fixtures	3,693,317	3,389,140
Construction in process	6,384,242	5,496,222
Leasehold improvements	12,966,337	11,129,639
Land	4,339,441	4,339,441
Buildings and building improvements	19,093,765	19,067,032
	67,900,912	64,206,927
Less: Accumulated depreciation	(14,680,432)	(13,271,853)
Total property, plant and equipment, net	$ 53,220,480	$ 50,935,074

Property and equipment 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, 2022 and 2021 of $1.4 million and $1.1 million, respectively.

6. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities at March 31, 2022 and December 31, 2021 are as follows:

	March 31, 2022	December 31, 2021
Accrued rebates	$ 6,324,746	$ 5,040,200
Accrued distribution fees	2,794,447	4,739,651
Accrued incentives	1,565,993	4,066,109
Accrued testing	674,191	1,189,970
Accrued payroll	2,206,409	1,167,072
Other	3,088,754	1,011,986
Total accrued expenses and other current liabilities	$ 16,654,540	$ 17,214,988

7. DEBT

A summary of outstanding senior notes payable is as follows:

	March 31, 2022	December 31, 2021
Notes payable	$ 151,750,000	$ 100,000,000
Less:		
Debt discount	(13,326,948)	(5,133,761)
Senior notes payable	$ 138,423,052	$ 94,866,239

On March 23, 2022, (the "Hayfin Closing Date") the Company and all of its subsidiaries entered into a Credit and Guaranty Agreement (the "Hayfin Credit Agreement") with Hayfin Services LLP ("Hayfin"). The Hayfin Credit Agreement provides for a senior secured term loan facility in a principal amount of up to $175.0 million (the "Hayfin Credit Facility"), composed of (i) a term loan made on the Hayfin Closing Date in the principal amount of $150.0 million (the "Hayfin Closing Date Loan"), and (ii) a delayed draw term loan in the principal amount of $25.0 million (the "Hayfin Delayed Draw Loan" and, together with the Hayfin Closing Date Loan, the "Hayfin Loans"). The obligation of the lenders to make the Hayfin Delayed Draw Loan expires on March 22, 2023 and is subject to the satisfaction of certain conditions, including, but not limited to, the Company's meeting certain 12-month revenue targets as set forth in the Hayfin Credit Agreement. The Hayfin Credit Facility has a maturity date of March 23, 2027 (the "Hayfin Maturity Date"), subject to acceleration pursuant to the Hayfin Credit Agreement, including upon an Event of Default (as defined in the Hayfin Credit Agreement).

On the Hayfin Closing Date, the Company used $100.0 million of the Hayfin Closing Date Loan to terminate and pay in full all of the outstanding obligations under the Company's previously existing credit facility (the "Perceptive Credit Facility") with Perceptive Credit Holdings II, LP ("Perceptive"). The Company also used $2.0 million of the Hayfin Closing Date Loan proceeds to pay a redemption premium to Perceptive and used approximately $0.6 million of the Hayfin Closing Date Loan proceeds to pay certain fees and expenses incurred in connection with this transaction. In addition, a $1.8 million upfront fee payable to Hayfin was paid "in kind" and was added to the outstanding principal balance in accordance with the terms of the Hayfin Credit Agreement. In connection with the retirement of the Perceptive Credit Facility and all of the obligations thereunder, the Company recorded a loss on extinguishment of debt in the amount of $6.7 million, consisting of the write-off of unamortized discount related to the Perceptive indebtedness and the redemption premium paid to Perceptive.

Borrowings under the Hayfin Credit Agreement will bear interest, at the Company's election, at either (a) a base rate (equal to the highest of (i) the rate of interest per annum last quoted by The Wall Street Journal as the "Prime Rate" in the United States, (ii) the federal funds rate in effect on such day plus 0.50% and (iii) adjusted Term Secured Overnight Financing Rate ("SOFR") for a one-month tenor in effect on such day plus 1.00%), plus an applicable margin of 8.5%, or (b) adjusted Term SOFR for either a one-month or three-month tenor, as elected by the Company, and subject to a floor of 1.25%, plus an applicable margin of 9.5% (the "Applicable Margin"); provided, however, that upon, and during the continuance of, an Event of Default, the Applicable Margin shall increase by an additional 3% per annum. On the last day of each calendar month or quarter during the term of the Hayfin Credit Facility, the Company will pay accrued interest to Hayfin. The rate of interest in effect as of the Hayfin Closing Date and at March 31, 2022 was 10.75%. The Company will also pay "in kind" a portion of the interest on the Hayfin Loans for each monthly or quarterly interest period in an amount equal to 2.5% per annum, which will be added to the principal amount of the outstanding debt under the Hayfin Credit Facility.

On the Hayfin Maturity Date, the Company will pay Hayfin the entire outstanding principal amount underlying the Hayfin Loans and any accrued and unpaid interest thereon, as well as an exit fee of 1.0% of the outstanding principal amount being paid. This exit fee is recorded separately as a non-current liability on the accompanying consolidated balance sheet as of March 31, 2022. Prior to the Hayfin Maturity Date, there are no scheduled principal payments on the Hayfin Loans. The Company may prepay outstanding principal on the Hayfin Loans at any time and from time to time upon five business days' prior written notice, subject to the payment to Hayfin of, (A) any accrued but unpaid interest on the prepaid principal amount plus (B) an early prepayment fee in the amount equal to (i) 7.0% of the prepaid principal amount, if prepaid on or prior to the first anniversary of the Hayfin Closing Date, (ii) 3.0% of the prepaid principal amount, if prepaid after the first anniversary of the Hayfin Closing Date and on or prior to the second anniversary of the Hayfin Closing Date, or (iii) 1.0% of the prepaid principal amount, if prepaid after the second anniversary of the Hayfin Closing Date and on or prior to the third anniversary of the Hayfin Closing Date. In addition, for any prepayments of principal or payment of principal on the Hayfin Maturity Date, the Company is required to pay an exit fee of 1.0% of the amount of principal being paid. This exit fee is classified as a separate non-current liability in the accompanying condensed consolidated balance sheet as of March 31, 2022.

All of the Company's obligations under the Hayfin 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 Hayfin 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 Hayfin 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 its subsidiaries' business activities; make certain Investments or Restricted Payments (each as defined in the Hayfin 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 Hayfin Credit Agreement. In addition, the Company is required (i) at all times prior to the Maturity Date to maintain a minimum cash balance of $6.0 million; and (ii) as of the last day of each fiscal quarter commencing with the fiscal quarter ending June 30, 2022, report IVIG product and related revenues for the trailing 12-month period that exceed the amounts set forth in the Hayfin Credit Agreement, which range from $75.0 million for the fiscal quarter ending June 30, 2022 to $250.0 million for the fiscal quarter ending December 31, 2026. As of March 31, 2022, the Company was in compliance with all of the covenants contained in the Hayfin Credit Agreement.

As consideration for the Hayfin Credit Agreement, the Company issued to various entities affiliated with Hayfin, on the Hayfin Closing Date, warrants to purchase an aggregate of 9,103,047 shares of the Company's common stock (the "Hayfin Warrants"). The Hayfin Warrants have an exercise price equal to $1.6478 per share, which is equal to the trailing 30-day Volume Weighted-average Price of the Company's common stock on the business day immediately prior to the Hayfin Closing Date. The Hayfin Warrants were valued by the Company at approximately $9.6 million as of the Hayfin Closing Date and have an expiration date of March 23, 2029.

As a result of the upfront fee and exit fee paid or payable to Hayfin, the expenses incurred by the Company in connection with this transaction and the value of the Hayfin Warrants, the Company recognized an aggregate discount on the Hayfin Loans in the amount of $13.4 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 Hayfin Warrants and the aggregate amount of fees and expenses associated with obtaining the Hayfin Credit Facility, the effective interest rate on the Hayfin Loans as of the Hayfin Closing Date and as of March 31, 2022 was approximately 13.0%.

8. 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, 2022 and December 31, 2021.

Common Stock

As of March 31, 2022 and December 31, 2021, the Company was authorized to issue 300,000,000 shares of its common stock, $0.0001 par value per share, and 196,347,529 and 195,813,817 shares of common stock were outstanding as of March 31, 2022 and December 31, 2021, respectively. After giving effect to the 32,811,653 shares reserved for outstanding warrants and awards issued or reserved for future issuance under the Company's equity incentive plans, as of March 31, 2022 there were 70,840,818 shares of common stock available for issuance.

On September 3, 2021, the Company entered into a distribution agreement with Raymond James & Associates, Inc., as agent ("Agent"), pursuant to which the Company may offer and sell, from time to time, at its option, through or to the Agent, up to an aggregate of $50 million of shares of the Company's common stock (the "Distribution Agreement"). The Company intends to use any net proceeds from the sale of common stock under the Distribution Agreement for general corporate purposes, including procurement of source plasma and other raw materials, supply chain initiatives and production expenditures, funding expansion of plasma collection centers, working capital, capital expenditures, expansion and resources for commercialization activities, and other potential research and development and business opportunities. The Company currently has approximately $42.8 million of shares available to sell under the Distribution Agreement.

On August 5, 2020, the Company entered into an open market sale agreement (as amended from time to time, the "Sale Agreement") with Jefferies LLC ("Jefferies"), pursuant to which the Company could offer and sell, from time to time, at its option, through or to Jefferies, up to an aggregate of $50 million of shares of the Company's common stock. On November 5, 2020 and February 3, 2021, the Company and Jefferies amended the Sale Agreement to provide for increases in the aggregate offering amount under the Sale Agreement such that the Company could sell shares having an aggregate offering price of up to $105.4 million under the Sale Agreement, as amended. During the three months ended March 31, 2021, the Company issued and sold 18,080,708 shares of common stock under the Sale Agreement and received net proceeds of $41.9 million.

Warrants

In connection with the Hayfin Credit Agreement that the Company entered into on March 23, 2022 (see Note 7), the Company issued the Hayfin Warrants to purchase 9,103,047 shares of the Company's common stock. The Hayfin Warrants were valued at $9.6 million using the Black-Scholes option-pricing model assuming an expected term of seven years, a volatility of 68.1%, a dividend yield of 0% and a risk-free rate of interest of 2.36%. At March 31, 2022, the Company had outstanding warrants to purchase an aggregate of 13,631,207 shares of common stock, with a weighted-average exercise price of $2.04 per share. At December 31, 2021, the Company had outstanding warrants to purchase an aggregate of 4,528,160 shares of common stock, with a weighted average exercise price of $2.82 per share and expiration dates ranging between June 2022 and December 2030.

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, 2022 and 2021:

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

	Three Months Ended March 31,	
	2022	2021
Expected term	5.5 - 6.3 years	5.5 - 6.3 years
Volatility	68%	69%
Dividend yield	0.0	0.0
Risk-free interest rate	1.72-1.73%	0.80-1.04%

During the three months ended March 31, 2022 and 2021, the Company granted options to purchase an aggregate of 1,194,032 and 1,441,050 shares of common stock, respectively, to its directors and employees. The weighted average remaining contractual life of stock options outstanding and expected to vest at March 31, 2022 is 6.6 years. The weighted average remaining contractual life of stock options exercisable at March 31, 2022 is 5.3 years.

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

	Shares	Weighted Average Exercise Price
Options outstanding, vested and expected to vest at December 31, 2021	7,862,722	$ 3.93
Forfeited	(9,186)	$ 2.13
Expired	(361,500)	$ 6.48
Granted	1,194,032	$ 1.67
Options outstanding, vested and expected to vest at March 31, 2022	8,686,068	$ 3.51
Options exercisable	5,646,819	$ 4.25

As of March 31, 2022, the Company had $3.8 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 2.6 years.

During the three months ended March 31, 2022 and 2021, the Company granted Restricted Stock Units ("RSUs") representing an aggregate of 1,059,266 and 492,744 shares, respectively, to certain management employees of the Company and to members of its Board of Directors. These RSUs generally vest annually over a period of four years for employees and semi-annually over a period of one year for directors. During the three months ended March 31, 2022, there were 799,641 shares of common stock which vested in connection with grants of RSUs, including 254,745 milestone-based RSUs that vested in connection with the refinancing of the Company's senior credit facility (see Note 7) and 382,117 milestone-based RSUs that vested in connection with the Company achieving a targeted gross margin for its BIVIGAM product during the three months ended March 31, 2022. With respect to the vested RSUs, 265,929 shares valued at approximately $0.4 million were withheld by the Company to cover employees' tax liabilities. These shares have been retired by the Company and were no longer outstanding as of March 31, 2022. A summary of the Company's unvested RSU activity and related information is as follows:

	Shares	Weighted Average Grant Date Fair Value
Balance at December 31, 2021	4,485,133	$ 1.34
Granted	1,059,266	$ 1.67
Vested	(799,641)	$ 1.41
Forfeited	(15,000)	$ 1.22
Balance at March 31, 2022	4,729,758	$ 1.41

As of March 31, 2022, the Company had $5.7 million of unrecognized compensation expense related to unvested RSUs granted under the Company's equity incentive plans, which is expected to be recognized over a weighted-average period of 2.7 years.

Total stock-based compensation expense for all awards granted under the Company's equity incentive plans for the three months ended March 31, 2022 and 2021 is as follows:

	Three Months Ended March 31,	
	2022	2021
Research and development	$ 4,671	$ 105,227
Plasma center operating expenses	21,052	10,818
Selling, general and administrative	1,517,602	588,491
Cost of product revenue	98,063	76,861
Total stock-based compensation expense	$ 1,641,388	$ 781,397

9. 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. Rent expense for the three months ended March 31, 2022 and 2021 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 condensed consolidated financial statements for the three months ended March 31, 2022 and 2021.

During the three months ended March 31, 2022 and 2021, the Company purchased certain specialized medical equipment and services related to the Company's plasma collection centers, as well as personal protective equipment, from GenesisBPS and its affiliates ("Genesis"), which were not material to the consolidated financial statements. Genesis is owned by Dr. Grossman and Adam Grossman.

See Note 7 for a discussion of the Company's former credit facility and related transactions with Perceptive, a holder of more than 5% of the Company's common stock as of March 31, 2022.

10. 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 continues to monitor the ongoing developments related to the COVID-19 pandemic, including the emergence of the Delta and Omicron variants and other resistant strains of the coronavirus, and its impacts to the Company's commercial and manufacturing operations and plasma collection facilities, including collections of source plasma, 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. A substantial portion of such testing has historically been performed by contract laboratories outside the United States.

Due to a combination of previous state and local "shelter-in-place" orders, as well as government stimulus packages, persisting social distancing measures and varying roll-outs of vaccinations by state, the Company has experienced lower than normal donor collections at its FDA approved plasma collection centers. The Company was also subject to delays in shipments of source plasma from its contracted third-party suppliers, as well as delays in deliveries for personal protective equipment, reagents and other non-plasma raw materials and supplies used in the manufacture and distribution of its products. In addition, the Company is subject to supply chain delays as a result of certain of its suppliers diverting significant resources towards the rapid development and distribution of COVID-19 vaccines and, as a result, the Company has elected to carry more raw materials inventory than it has in the past. The COVID-19 pandemic has also impacted, to a certain degree, the Company's customer engagement initiatives, whereby ADMA's sales and medical affairs field personnel have faced difficulties communicating directly with physicians and other healthcare professionals, as well as the cancellation or postponement of a number of key scientific and medical meetings, further limiting the Company's ability to communicate with potential customers. The Company has implemented a comprehensive suite of virtual engagement initiatives; however, clinician engagement has been reduced due to rapidly evolving COVID-19 priorities at U.S. medical centers.

The pandemic could also impact the Company's ability to interact with the FDA or other regulatory authorities and may result in delays in the conduct of inspections or review of pending applications or submissions. Although the Company received several FDA approvals and two FDA inspections of the Boca Facility were completed during the year ended December 31, 2021, no assurances can be provided as to the timing for completion of any other regulatory submissions or applications that may be impacted by restrictions related to COVID-19.

During the three months ended March 31, 2022 and 2021, revenue attributable to international customers was approximately 6% and 15%, respectively, of the Company's total revenues. As the Company seeks to grow this aspect of its business, it may also be subject to the impacts of the COVID-19 pandemic in locations outside the United States.

Notwithstanding the foregoing, the COVID-19 pandemic to date 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 facilities have been significantly impacted by the COVID-19 pandemic. As a result, the Company does not anticipate and has not experienced 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 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 executes its commercialization plans for ASCENIV. 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. 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. 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 could 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). Effective January 1, 2022, RSV plasma purchased from these two plasma collection centers are subject to the pricing terms in effect for RSV plasma purchased from other plasma collection centers owned by Grifols.

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 normal source plasma 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 agreed 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.

Effective as of May 12, 2021, the Company and Grifols amended the foregoing 2017 Plasma Purchase Agreement whereby, among other things, the term of the agreement was extended through December 31, 2022, while certain historical provisions were deleted. In order to maintain a reliable supply of raw material plasma thereafter, the Company has executed additional agreements with multiple third-party suppliers of NSP to supplement the 2017 Plasma Purchase Agreement. The Company has also increased its number of planned plasma collection center buildouts such that the Company expects to have 10 FDA-approved plasma collection centers in operation by the end of 2023, while also continuing to increase its plasma collection capabilities at its ADMA BioCenters plasma collection centers business segment.

The Company purchases substantially all of its raw material plasma from Grifols. For the three months ended March 31, 2022, plasma purchases from Grifols totaled $15.5 million, or approximately 75% of the Company's total inventory purchases. For the three months ended March 31, 2021, plasma purchases from Grifols totaled approximately $12.7 million, representing approximately 72% 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. 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 to incur expenses of approximately $3.0 million to $4.0 million to complete these studies, with both studies to be completed by June of 2023.

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. The Company expects to incur expenses of approximately $2 million to complete this study, which is required to be completed by June of 2023.

Employment Contracts

The Company has entered into employment agreements with Mr. Grossman and with Brian Lenz, its Executive Vice President, Chief Financial Officer and General Manager, ADMA BioCenters.

Other Commitments

On September 28, 2021, following the approval of the Company's Board of Directors upon recommendation of the Compensation Committee of the Board of Directors, and in consultation with an independent compensation consultant, the Company implemented a retention incentive program, consisting of cash payments and awards of RSUs (see Note 8), to the Company's management, including Mr. Grossman and Mr. Lenz, and to certain other employees. The purpose of the retention program is to promote and ensure business continuity and provide an incentive to the Company's executive management and certain other employees considering the operational challenges presented by the ongoing COVID-19 pandemic and the competitive work environment in which the Company operates as an FDA regulated manufacturer of specialized biologic therapies. The retention awards were granted considering the nationwide labor shortages and the increased employee turnover rates that the Company, its pharmaceutical peers and other companies outside of the Company's industry have reported experiencing.

The cash portion of the retention program consists of two tranches. The first tranche was paid to employees on September 30, 2021 in the amount of $1.3 million, and the second tranche aggregating to approximately $1.3 million will be paid on June 15, 2022. Based on the terms of the retention agreements the Company entered into with each applicable executive and employee, $0.8 million of the first tranche is being recognized over the retention service period, which ends on December 31, 2022, with the remainder having been recognized as expense on September 30, 2021. The second tranche will be recognized as compensation expense over a 15-month period from October 1, 2021 through December 31, 2022.

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, 2022. The Company does not anticipate recognizing any significant losses relating to these arrangements.

11. 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 immunoglobulin manufacturing, commercial and development operations in Boca Raton, FL, acquired on June 6, 2017 (see Note 1). The Plasma Collection Centers segment as of March 31, 2022 consists of ten plasma collection facilities in various stages of approval and development located throughout the U.S., five of which hold an approved license with the FDA. The Corporate segment includes general and administrative overhead expenses. The Company defines its segments as those business units whose operating results are regularly reviewed by the chief operating decision maker ("CODM") to analyze performance and allocate resources. The Company's CODM is its President and Chief Executive Officer. Summarized financial information concerning reportable segments is shown in the following tables:

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

Three Months Ended March 31, 2022

	ADMA BioManufacturing	Plasma Collection Centers	Corporate	Consolidated
Revenues	$ 25,728,625	$ 3,338,760	$ 35,708	$ 29,103,093
Cost of product revenue	22,213,781	3,227,265	-	25,441,046
Loss from operations	(4,442,684)	(3,863,094)	(6,509,288)	(14,815,066)
Interest and other expense, net	(49,267)	(729)	(3,472,854)	(3,522,850)
Loss on extinguishment of debt	-	-	(6,669,941)	(6,669,941)
Net loss	(4,491,951)	(3,863,823)	(16,652,083)	(25,007,857)
Capital expenditures	1,310,379	1,531,706	-	2,842,085
Depreciation and amortization expense	1,111,951	477,503	763	1,590,217
Total assets	214,150,322	32,568,911	61,313,259	308,032,492

Three Months Ended March 31, 2021

	ADMA BioManufacturing	Plasma Collection Centers	Corporate	Consolidated
Revenues	$ 13,421,043	$ 2,591,867	$ 35,708	$ 16,048,618
Cost of product revenue	15,449,757	2,320,365	-	17,770,122
Loss from operations	(9,505,689)	(1,970,841)	(3,687,719)	(15,164,249)
Interest and other expense, net	(21,513)	(384)	(3,193,795)	(3,215,692)
Net loss	(9,527,202)	(1,971,225)	(6,881,514)	(18,379,941)
Capital expenditures	1,012,980	1,558,181	-	2,571,161
Depreciation and amortization expense	1,009,770	217,991	1,867	1,229,628
Total assets	156,535,177	17,397,612	61,734,239	235,667,028

Net revenues according to geographic area, based on the location of where the product is shipped, is as follows:

	Three Months Ended March 31,	
	2022	2021
United States	$ 27,316,151	$ 13,678,008
International	1,786,942	2,370,610
Total revenues	$ 29,103,093	$ 16,048,618

12. LEASE OBLIGATIONS

The Company leases certain properties and equipment for its ADMA BioCenters 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 2032. 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 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 for the Company's leases for the three months ended March 31, 2022 and 2021 was approximately $0.4 million and $0.3 million, respectively. Cash paid for the Company's leases for the three months ended March 31, 2022 and 2021 was approximately $0.4 million and $0.2 million, respectively.

Including a finance lease the Company entered into in June 2018, the Company has aggregate lease liabilities of $7.9 million and $8.1 million as of March 31, 2022 and December 31, 2021, respectively, which are comprised primarily of the leases for the Company's plasma collection centers and an administrative office lease related to the Company's ADMA BioCenters subsidiary. The Company's operating leases have a weighted average remaining term of 8.9 years. Scheduled payments under the Company's lease obligations are as follows:

Remainder of 2022	$ 1,228,526
Year ended December 31, 2023	1,641,603
2024	1,517,229
2025	1,525,793
2026	1,260,391
2027	1,289,679
Thereafter	5,055,880
Total payments	13,519,101
Less: imputed interest	(5,581,019)
Current portion	(654,003)
Balance at March 31, 2022	$ 7,284,079

During the three months ended March 31, 2022, the Company entered into an additional property lease for its ninth plasma collection facility. The Company has not taken possession of this leased property and its lease commencement date has not been determined. With the exception of a security deposit and an initial months' rent totaling approximately $44,000, no payments have been made under this lease. The initial term of the lease is for 126 months with monthly rental payments varying between approximately $18,000 and $24,000, including common area maintenance charges.

13. SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

Supplemental cash flow information for the three months ended March 31, 2022 and 2021 is as follows:

	2022	2021
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	$ 2,525,987	$ 2,751,956
Noncash Financing and Investing Activities:		
Equipment acquired reflected in accounts payable and accrued liabilities	$ 1,940,425	$ 1,797,249
Right-to-use assets in exchange for lease obligations	$ -	$ 2,073,627
Warrants issued in connection with notes payable	$ 9,569,604	$ -

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, 2021, filed on March 24, 2022 (the "2021 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 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 and commenced commercial sales 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 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. pneumoniae*. 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.

We manufacture these products at our FDA-licensed, plasma fractionation and purification facility located in Boca Raton, Florida with a peak annual source plasma processing capability of up to 600,000 liters (the "Boca Facility"). Based on current production yields, our completed and ongoing supply chain enhancements and capacity expansion initiatives, we believe this facility has the potential to produce quantities of our immune globulin ("IG") products to generate more than $250 million in annual revenue beginning in 2024 and potentially in excess of $300 million of annual revenue thereafter, as well as achieving profitability during the first quarter of 2024, as we ramp-up production over the next two to four years. Based on our early 2022 revenue growth and gross margin trends, we have increased our total annual revenue target to $130 million or more for fiscal year 2022.

Through our ADMA BioCenters subsidiary, we currently operate FDA-licensed source plasma collection facilities in the U.S. This business unit, which we refer to as our Plasma Collection Centers business segment, provides us with a portion of our blood plasma for the manufacture of our products and product candidates, and also allows us to sell certain quantities of source plasma to customers for further manufacturing. As a part of our planned supply chain robustness initiative, we have opened five new plasma collection centers during the past 18 months, and we now have ten plasma collection centers in various stages of approval and development, including seven that are operational and collecting plasma. With respect to our operational plasma collection centers, five plasma collection centers currently hold FDA licenses. In addition, one of our FDA-approved plasma collection centers also has approvals from the Korean Ministry of Food and Drug Safety ("MFDS"), as well as FDA approval to operate a Hepatitis B immunization program. After giving effect to the progress we made in 2021 and thus far in 2022 with our plasma collection network expansion, we believe we remain on track to achieve our goal of having 10 plasma collection centers licensed by the FDA by the end of 2023. A typical plasma collection center, such as those operated by ADMA BioCenters, 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 BioCenters' 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 sell plasma-derived intermediate fractions to certain customers, which are generated as part of our FDA-approved manufacturing process for IG and 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 and testing services for certain third-party clients. We also provide laboratory contracting services to certain customers and anticipate providing contract filling, labeling and packaging services in light of the FDA approval of our in-house fill-finish capabilities.

On June 6, 2017, we completed the acquisition of certain assets (the "Biotest Assets") of the Therapy Business Unit ("BTBU") of Biotest Pharmaceuticals Corporation ("BPC" and, together with Biotest AG, "Biotest"), which included two FDA-licensed products, Nabi-HB and BIVIGAM, and 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.

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 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 for this product commenced in August of 2019.

On April 28, 2021, we announced that the FDA granted approval for our expanded plasma pool production scale process, allowing for a 4,400-liter plasma pool for the manufacture of our BIVIGAM IVIG product. We expect this increased IVIG plasma pool scale, which will allow us to produce BIVIGAM at an expanded capacity, will utilize the same equipment, release testing assays and labor force, and to have a favorable impact on our gross margins and operating results.

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. The Centers for Medicare and Medicaid Services ("CMS") has issued a permanent, product-specific-J-code for ASCENIV. Under the Healthcare Common Procedure Coding System ("HCPCS"), the J-code (J1554) became effective April 1, 2021. 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 antibody titers to respiratory syncytial virus ("RSV") using our proprietary microneutralization testing assay. We are able to identify the high titer or "hyperimmune" plasma that meets our internal and required specifications for ASCENIV with our patented testing methods and 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 Primary Immune Deficiency Disorder ("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 or potentially other respiratory viral pathogens. Due to the COVID-19 pandemic, our plans have been delayed. In the future however, we plan to work with the FDA and the immunology and infectious disease community to design an appropriate clinical trial to evaluate the use of ASCENIV in this patient population. 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. The FDA approved Nabi-HB on March 24, 1999. 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.

POTENTIAL IMPACT OF COVID-19

We continue to monitor the ongoing developments related to the COVID-19 pandemic, including the emergence of the Delta, Omicron and BA.2 variants and other resistant strains of the coronavirus, and its impacts to our commercial and manufacturing operations and plasma collection facilities, including collections of source plasma, 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. A substantial portion of such testing has historically been performed by contract laboratories outside the United States.

Due to a combination of previous state and local "shelter-in-place" orders, as well as government stimulus packages, persisting social distancing measures and varying roll-outs of vaccinations by state, we had experienced lower than normal donor collections at our FDA approved plasma collection centers. We were also subject to delays in shipments of source plasma from our contracted third-party suppliers, as well as delays in deliveries for personal protective equipment, reagents and other non-plasma raw materials and supplies used in the manufacture and distribution of our products. In addition, we are subject to supply chain delays as a result of certain of our suppliers diverting significant resources towards the rapid development and distribution of COVID-19 vaccines and, as a result, we have elected to carry more raw materials inventory than we have in the past. The COVID-19 pandemic has also impacted, to a certain degree, our customer engagement initiatives, whereby ADMA's sales and medical affairs field personnel have faced difficulties communicating directly with physicians and other healthcare professionals, as well as the cancellation or postponement of a number of key scientific and medical meetings, further limiting our ability to communicate with potential customers. We have implemented a comprehensive suite of virtual engagement initiatives; however, clinician engagement has been reduced due to rapidly evolving COVID-19 priorities at U.S. medical centers.

The pandemic could also impact our ability to interact with the FDA or other regulatory authorities and may result in delays in the conduct of inspections or review of pending applications or submissions. Although we received several FDA approvals and two FDA inspections of the Boca Facility were completed during the year ended December 31, 2021, no assurances can be provided as to the timing for completion of any other regulatory submissions or applications that may be impacted by restrictions related to COVID-19.

During the three months ended March 31, 2022 and 2021, our revenue attributable to international customers was approximately 6% and 15%, respectively, of our total revenues. As we seek to grow this aspect of our business, we may also be subject to the impacts of the COVID-19 pandemic in locations outside the United States.

Notwithstanding the foregoing, the COVID-19 pandemic to date has not had a material impact on our financial condition or results of operations, and we do not believe that our production operations at the Boca Facility, our contract fill/finishers or our plasma collection facilities have been significantly impacted by the COVID-19 pandemic. As a result, we do not anticipate and have not experienced 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, because we are 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 our workforce, customers or suppliers, at this time we are unable to predict whether COVID-19, or any known or future variant or government order, will have a material adverse impact on our business, financial condition, liquidity and results of operations.

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 condensed 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 rebates and certain other deductions from gross revenues, impairment of long-lived assets, 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 estimates and their application are considered to be critical to understanding our business operations, financial condition and results of operations. For a description of our significant accounting policies, see Note 2 to the Consolidated Financial Statements included in the 2021 10-K. Estimates and assumptions used in projecting future liquidity and capital requirements are described in Note 1 to the condensed Consolidated Financial Statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Revenues

Our gross product revenues are subject to a variety of deductions, which are estimated and recorded in the same period that the revenues are recognized. These deductions primarily consist of rebates, distribution fees, chargebacks and sales allowances. These deductions represent estimates of the related obligations, some of which are contractual in nature and do not require extensive judgment to be exercised by management, while other estimates require complex or subjective matters of knowledge and judgment when estimating the impact of these revenue deductions on net revenues for a reporting period.

Historically, adjustments to these estimates to reflect actual results or updated expectations have not been material to our overall business. However, two of our primary immunoglobulin products, ASCENIV and BIVIGAM, were only approved for commercial sale by the FDA in 2019, and as such our historical experience with rebates with respect to these products is limited. If any of our ratios, factors, assessments, experiences or judgments are not indicative or accurate estimates of our future experience, our results could be materially affected. Estimates that are most at risk for material adjustment are those associated with U.S. Medicaid rebates because of the extensive time delay between the recording of the accrual and its ultimate settlement, an interval that can generally take up to several years or more. While our results of operations to date have not required any material adjustment due to this risk, the lag time between when this obligation is initially recorded and ultimately settled could potentially materially impact our revenues and our results of operations in the future.

Stock-Based Compensation and Valuation of Warrants

All equity-based payments, including grants of stock options and restricted stock units ("RSUs") are recognized at their estimated fair value at the date of grant, and compensation expense is recognized on a straight-line basis over the grantee's requisite vesting period. For the purpose of valuing stock options granted to our employees, directors and officers, we use the Black-Scholes option pricing model. The Black-Scholes option valuation model was developed for use in estimating the fair value of publicly traded options, which have no vesting restrictions and are fully transferable. The Company's employee stock options have characteristics significantly different from those of traded options, and changes in the underlying Black-Scholes assumptions can materially affect the fair value estimate. To determine the risk-free interest rate, we utilize 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. Any changes in the foregoing Black-Scholes assumptions, or if we were to elect to utilize an alternative method for valuing stock options granted to employees, directors and officers, could potentially impact our stock-based compensation expense and our results of operations.

We also use the Black-Scholes option valuation model for the purpose of estimating the fair value of warrants we issue from time to time in connection with the issuance of notes payable. Changes in our Black-Scholes assumptions, or if we were to utilize an alternative method for valuing warrants issued to our lenders, could impact our interest expense and results of operations.

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, 2022 and 2021, we determined that there was no impairment of our long-lived assets. Examples of events or circumstances that may be indicative of impairment that would require the use of significant judgment by management include:

- A significant adverse change in legal factors or in the business climate that could affect the value of the asset.
- Significant and continued cash flow losses.
- A significant adverse change in the extent or manner in which an asset is used, such as a restriction imposed by the FDA or other regulatory authorities that could affect our ability to manufacture our products using a particular asset.
- An expectation of losses or reduced profits associated with an asset. This could result, for example, from the introduction of a competitor's product that impacts projected revenue growth, or a change in the acceptance of a product by patients, physicians and payers that results in an inability to sustain projected product revenues.

Goodwill is not amortized but is assessed for impairment on an annual basis or more frequently if impairment indicators exist. The testing of goodwill for impairment requires us to determine whether or not the fair value of the reporting unit associated with the goodwill is less than its carrying amount, including goodwill and other intangible assets. 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. In order to determine the fair value of the reporting unit, we utilize the fair value of the Company as a whole, as determined by its market capitalization. Determination of the fair value and carrying value of each reporting unit, relative to the fair value of the Company, requires management to employ certain estimates, assumptions and judgment, which we believe are reasonable. However, any changes to these estimates and assumptions could impact our determination of whether or not our goodwill is impaired. We did not recognize any impairment charges related to goodwill for the three months ended March 31, 2022 and 2021.

Deferred Tax Assets

We maintain a full valuation allowance against all of our net deferred tax assets, and as a result have recorded no income tax benefit in the accompanying consolidated financial statements. This valuation allowance reflects our assessment of whether it is more likely than not that we will generate sufficient taxable income in the future to be able to utilize our deferred tax assets. In determining whether a valuation allowance is warranted, we evaluate factors such as prior earnings history, expected future earnings, carryback and carryforward periods and tax strategies. We consider all positive and negative evidence to estimate if sufficient future taxable income will be generated to realize our deferred tax assets. We consider cumulative losses in recent years to be a significant type of negative evidence. Based on our history of losses, at this time we have not included future projected taxable income as a source of income to recognize our deferred tax assets.

Three Months Ended March 31, 2022 Compared to Three Months Ended March 31, 2021

The following table presents a summary of the changes in our results of operations for the three months ended March 31, 2022, our first fiscal quarter, compared to the three months ended March 31, 2021:

	Three Months Ended March 31,		
	2022	2021	Increase (Decrease)
Revenues	$ 29,103,093	$ 16,048,618	$ 13,054,475
Cost of product revenue	25,441,046	17,770,122	7,670,924
Gross profit (loss)	3,662,047	(1,721,504)	5,383,551
Research and development expenses	624,111	987,649	(363,538)
Plasma center operating expenses	3,974,589	2,242,343	1,732,246
Amortization of intangibles	178,838	178,838	-
Selling, general and administrative expenses	13,699,575	10,033,915	3,665,660
Loss from operations	(14,815,066)	(15,164,249)	349,183
Interest expense	(3,389,038)	(3,195,750)	(193,288)
Loss on extinguishment of debt	(6,669,941)	-	(6,669,941)
Other expense, net	(133,812)	(19,942)	(113,870)
Net loss	$ (25,007,857)	$ (18,379,941)	$ (6,627,916)

Revenues

We recorded total revenues of $29.1 million during the three months ended March 31, 2022, as compared to $16.0 million during the three months ended March 31, 2021, an increase of $13.1 million, or approximately 81%. The increase is due to increased sales of immunoglobulin products generated by our Boca Facility manufacturing operations in 2022, primarily ASCENIV and BIVIGAM, of $12.3 million, as we continue to expand our customer base for BIVIGAM and experience increased physician, payer and patient acceptance of ASCENIV. We also benefitted from an increased sales of normal source plasma through ADMA BioCenters of $0.7 million.

Cost of Product Revenue and Gross Profit

Cost of product revenue was $25.4 million for the three months ended March 31, 2022, as compared to $17.8 million for the three months ended March 31, 2021. This increase is primarily attributable to increased product revenue costs related to the sale of our immunoglobulin products of $5.2 million and increased product revenue costs related to our ADMA BioCenters business segment in the amount of $0.9 million. The increase also reflects additional costs related to the otherwise routine shutdown of the Boca Facility for a portion of the first quarter of 2022, which we elected to extend in order to complete certain projects that had been forecasted for completion later in fiscal 2022.

For the three months ended March 31, 2022, we had gross profit of $3.7 million, as compared to a gross loss of $1.7 million for the same period of a year ago. This gross profit improvement of $5.4 million was primarily due to a more favorable mix of our higher margin products, notably ASCENIV, as well as the benefits we have begun to realize from our expanded plasma pool production scale process, allowing for a 4,400-liter plasma pool for the manufacture of our BIVIGAM IVIG product, as compared to a 2,200-liter plasma pool we were utilizing with BIVIGAM prior to receiving FDA approval in 2021 for the expanded production scale.

Research and Development Expenses

R&D expenses totaled $0.6 million for the three months ended March 31, 2022, as compared to $1.0 million for the three months ended March 31, 2021. The decrease is primarily due to reduced compensation costs, including stock-based compensation, associated with R&D activities due to the resignation of our former Chief Medical and Scientific Officer in the second quarter of 2021.

Plasma Center Operating Expenses

During the first quarter of 2022, we had six plasma collection centers in operation, excluding our seventh plasma collection center that opened on March 29, 2022, as compared to three plasma collection centers in operation during the first quarter of 2021. As a result, plasma center operating expenses increased by $1.7 million in the first quarter of 2022 as compared to the same period of a year ago. The increase is mainly comprised of higher donor fees in the amount $2.1 million, employee compensation and benefits of $1.3 million, softgoods and supplies of $0.7 million, donor testing expenses of $0.4 million, depreciation expense of $0.2 million, advertising expenses of $0.1 million and rent of $0.1 million, partially offset by increased donor collections which had the impact of reducing our operating expenses by $3.4 million, as such expenses were charged to inventory for future manufacturing or sales. As we continue our planned expansion with the goal of having ten plasma collection centers licensed by the FDA by the end of 2023, we expect our plasma center operating expenses to continue to increase.

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, 2022 and 2021.

Selling, General and Administrative Expenses

Selling, general and administrative ("SG&A") expenses were $13.7 million for the three months ended March 31, 2022, an increase of $3.7 million from the three months ended March 31, 2021. The increase reflects $1.3 million of professional fees incurred in connection with our strategic alternatives process in 2022 with no comparable amount in 2021. In addition, we had an increase in employee compensation and related expenses, including travel, relocating and recruiting, in the amount of $2.4 million due to increased headcount associated with the overall size and scope of the organization and the stepped-up commercialization efforts for BIVIGAM and ASCENIV, increased insurance expense of $0.3 million and increased software maintenance fees of $0.2 million. These costs were partially offset by $0.5 million of third-party market intelligence fees for a one-time project related to ASCENIV that concluded in the first quarter of 2021.

Loss from Operations

Our operating loss was $14.8 million for the first quarter of 2022, as compared to $15.2 million for the first quarter of 2021. The $0.4 million decrease in operating loss was mainly due to the improved gross profit of $5.4 million and lower R&D expenses, largely offset by the increases in plasma center operating expenses and SG&A.

Interest Expense

The increase in interest expense of $0.2 million for the three months ended March 31, 2022 as compared to the same period of a year ago was mainly due to higher amortization of debt discount related to our new senior credit facility. (see "Liquidity and Capital Resources").

Loss on Extinguishment of Debt

On March 23, 2022, we refinanced our senior credit facility (see "Liquidity and Capital Resources"). In connection with this transaction, we incurred a loss on the extinguishment of debt in the amount of $6.7 million as a result of the redemption premium we paid to retire our previously existing credit facility in the amount of $2.0 million, and the write-off of unamortized debt discount of $4.7 million related to that facility.

Net Loss

Our net loss was $25.0 million for the three months ended March 31, 2022, as compared to $18.4 million for the three months ended March 31, 2021. The $6.6 million increase in net loss was primarily due to the loss on extinguishment of debt in 2022 of $6.7 million, with no comparable amount in 2021.

LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2022, we had working capital of $208.2 million, primarily consisting of $139.1 million of inventory, cash and cash equivalents of $69.5 million and accounts receivable of $25.6 million, partially offset by accounts payable and accrued expenses of $30.8 million, as compared to working capital of $178.4 million, primarily consisting of $124.7 million of inventory, cash and cash equivalents of $51.1 million and accounts receivable of $28.6 million, partially offset by $29.6 million of accounts payable and accrued expenses, as of December 31, 2021. We have incurred an accumulated deficit of $437.1 million since inception, had negative cash flows from operations of $26.0 million and $33.2 million for the three months ended March 31, 2022 and 2021, respectively, and had negative cash flows from operations of $112.4 million and $102.0 million for the years ended December 31, 2021 and 2020, respectively. We have funded our operations over the past few years primarily from the sale of our equity and debt securities. Our material cash requirements are primarily comprised of:

- The procurement of raw material plasma and other raw materials necessary to maintain and scale up our manufacturing operations;
- Employee compensation and benefits;
- Capital expenditures for the building of additional plasma collection facilities and for equipment upgrades and capacity expansion at the Boca Facility;
- Plasma donor fees and plasma center supplies;
- Interest on our debt;
- Marketing programs and continued commercialization efforts;
- Boca Facility maintenance, repairs and supplies; and
- Conducting required post-marketing clinical trials for our FDA-approved products.

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 or potentially longer, 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 until the beginning of 2024. We currently anticipate, based upon our projected revenue and expenditures, that our current cash, cash equivalents and accounts receivable, including the proceeds received and expected to be received from the refinancing of our senior credit facility as discussed below, along with the remaining amounts available under the distribution agreement for the sale of our common stock also discussed below, will be sufficient to fund our operations, as currently conducted, into the first quarter of 2024, at which time we believe we will begin to generate positive cash flow from operations. This time frame may change based several factors, including the success of our commercial efforts with respect to the sale of our products and the acceptability of our immune globulin products by physicians, patients or payers, and whether or not the assumptions underlying our projected revenues and expenses are correct. If we are unable to raise additional capital if needed, including due to widespread liquidity constraints or significant market instability that could result from the COVID-19 pandemic, inflationary pressures or other factors beyond our control, we may have to delay, curtail or eliminate some of our commercialization efforts or product development activities. We are also continuing to evaluate a variety of strategic alternatives through our ongoing engagement with Morgan Stanley as a financial advisor.

On March 23, 2022, (the "Hayfin Closing Date") we and all of our subsidiaries entered into a Credit and Guaranty Agreement (the "Hayfin Credit Agreement") with Hayfin Services LLP ("Hayfin"). The Hayfin Credit Agreement provides for a senior secured term loan facility in a principal amount of up to $175.0 million (the "Hayfin Credit Facility"), composed of (i) a term loan made on the Hayfin Closing Date in the principal amount of $150.0 million (the "Hayfin Closing Date Loan"), and (ii) a delayed draw term loan in the principal amount of $25.0 million (the "Hayfin Delayed Draw Loan" and, together with the Hayfin Closing Date Loan, the "Hayfin Loans"). The obligation of the lenders to make the Hayfin Delayed Draw Loan expires on March 22, 2023, and is subject to the satisfaction of certain conditions, including, but not limited to, our meeting certain 12-month revenue targets as set forth in the Hayfin Credit Agreement. The Hayfin Credit Facility has a maturity date of March 23, 2027 (the "Hayfin Maturity Date"), subject to acceleration pursuant to the Hayfin Credit Agreement, including upon an Event of Default (as defined in the Hayfin Credit Agreement).

On the Hayfin Closing Date, we used $100.0 million of the Hayfin Closing Date Loan to terminate and pay in full all of the outstanding obligations under our previous senior credit facility with Perceptive (see Note 7 to the Consolidated Financial Statements). We also used $2.0 million of the Hayfin Closing Date Loan proceeds to pay a redemption premium to Perceptive and used approximately $0.6 million of the Hayfin Closing Date Loan proceeds to pay certain fees and expenses incurred in connection with this transaction. In addition, a $1.8 million upfront fee payable to Hayfin was paid "in kind" and was added to the outstanding principal balance in accordance with the terms of the Hayfin Credit Agreement. The remainder of the proceeds received or to be received from the Hayfin Loans will be used for working capital and other general corporate purposes.

Borrowings under the Hayfin Credit Agreement bear interest at our election, at either (a) a base rate (equal to the highest of (i) the rate of interest per annum last quoted by The Wall Street Journal as the "Prime Rate" in the United States, (ii) the federal funds rate in effect on such day plus 0.50% and (iii) the adjusted Term SOFR for a one-month tenor in effect on such day plus 1.00%), plus an applicable margin of 8.50% or (b) adjusted Term SOFR for either a one-month or three-month tenor, as elected by us, and subject to a floor of 1.25%, plus an applicable margin of 9.5% (the "Applicable Margin"); provided, however, that upon, and during the continuance of, an Event of Default, the Applicable Margin shall increase by an additional 3% per annum. We will also pay "in kind" a portion of the interest on the Hayfin Loans for each monthly or quarterly interest period in an amount equal to 2.5% per annum. Such interest paid "in kind" will reduce our quarterly cash interest obligation by approximately $1.0 million and will be added to the principal amount of the outstanding debt under the Hayfin Credit Facility. On the Hayfin Closing Date, our interest rate was 10.75%. On the last day of each calendar month or quarter during the term of the Hayfin Credit Facility, we are required to pay accrued interest to Hayfin of approximately $1.1 million per month or $3.2 million per quarter, after giving effect to the "in kind" interest of 2.5% per annum, but without giving effect to the Hayfin Delayed Draw Loan.

On the Hayfin Maturity Date, we will pay Hayfin the entire outstanding principal amount underlying the Hayfin Loans and any accrued and unpaid interest thereon, as well as an exit fee of 1.0% of the outstanding principal amount being paid. Prior to the Hayfin Maturity Date, there are no scheduled principal payments on the Hayfin Loans. We may prepay outstanding principal on the Hayfin Loans at any time and from time to time upon five business days' prior written notice, subject to the payment to Hayfin of, (A) any accrued but unpaid interest on the prepaid principal amount plus (B) an early prepayment fee in the amount equal to (i) 7.0% of the prepaid principal amount, if prepaid on or prior to the first anniversary of the Hayfin Closing Date, (ii) 3.0% of the prepaid principal amount, if prepaid after the first anniversary of the Hayfin Closing Date and on or prior to the second anniversary of the Hayfin Closing Date, or (iii) 1.0% of the prepaid principal amount, if prepaid after the second anniversary of the Hayfin Closing Date and on or prior to the third anniversary of the Hayfin Closing Date. In addition, for any prepayments of principal, we are required to pay an exit fee of 1.0% of the amount of principal being paid.

All of our obligations under the Hayfin Credit Agreement are secured by a first-priority lien and security interest in substantially all of our tangible and intangible assets, including intellectual property and all of the equity interests in our subsidiaries. The Hayfin Credit Agreement contains certain representations and warranties, affirmative covenants, negative covenants and conditions that are customarily required for similar financings. The negative covenants restrict or limit our ability and the ability of our subsidiaries to, among other things and subject to certain exceptions contained in the Hayfin Credit Agreement, incur new indebtedness; create liens on assets; engage in certain fundamental corporate changes, such as mergers or acquisitions, or changes to our or our subsidiaries' business activities; make certain Investments or Restricted Payments (each as defined in the Hayfin Credit Agreement); change our fiscal year; pay dividends; repay other certain indebtedness; engage in certain affiliate transactions; or enter into, amend or terminate any other agreements that have the impact of restricting our ability to make loan repayments under the Hayfin Credit Agreement. In addition, we are required (i) at all times prior to the Maturity Date to maintain a minimum cash balance of $6.0 million; and (ii) as of the last day of each fiscal quarter commencing with the fiscal quarter ending June 30, 2022, report IVIG product and related revenues for the trailing 12-month period that exceed the amounts set forth in the Hayfin Credit Agreement, which range from $75.0 million for the fiscal quarter ending June 30, 2022 to $250.0 million for the fiscal quarter ending December 31, 2026 and each fiscal quarter thereafter.

On October 25, 2021, we completed an underwritten public offering whereby we issued 57.5 million shares of our common stock and received gross proceeds of $57.5 million. Net proceeds, after underwriting discounts and expenses associated with the offering, were approximately $53.8 million, and are being used (i) to advance the commercial sales of our FDA approved products through the procurement of raw materials for the manufacturing of BIVIGAM and ASCENIV; (ii) to expand our plasma collection facility network; (iii) to scale up the manufacturing capacity of the Boca Facility and make continuous improvements in order to adhere to cGMP compliance; (iv) to explore business development opportunities; and (v) for general corporate purposes and other capital expenditures.

On September 3, 2021, we entered into a distribution agreement with Raymond James & Associates, Inc., as agent ("Agent"), pursuant to which we may offer and sell, from time to time, at our option, through or to the Agent, up to an aggregate of $50 million of shares of our common stock (the "Distribution Agreement"). We currently intend to use any net proceeds from the sale of our common stock under the Distribution Agreement for general corporate purposes, including procurement of source plasma and other raw materials, supply chain initiatives and production expenditures, funding expansion of plasma collection centers, working capital, capital expenditures, expansion and resources for commercialization activities, and other potential research and development and business opportunities. We currently have approximately $42.8 million of shares available to sell under the Distribution Agreement.

Cash Flows

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

	Three Months Ended March 31,	
	2022	2021
Net cash used in operating activities	$ (26,013,413)	$ (33,229,126)
Net cash used in investing activities	(2,842,085)	(2,571,161)
Net cash provided by financing activities	47,271,326	41,844,844
Net change in cash and cash equivalents	18,415,828	6,044,557
Cash and cash equivalents - beginning of year	51,089,118	55,921,152
Cash and cash equivalents - end of period	$ 69,504,946	$ 61,965,709

Net Cash Used in Operating Activities

Cash used in operations for the three months ended March 31, 2022 was $26.0 million, a decrease of $7.2 million from the same period of a year ago, mainly due to reductions in accounts receivable and prepaid expenses and other current assets. The following table illustrates the primary components of our cash flows from operations:

	Three Months Ended March 31,	
	2022	2021
Net loss	$ (25,007,857)	$ (18,379,941)
Non-cash expenses, gains and losses	10,452,680	2,419,892
Changes in accounts receivable	2,947,233	(2,124,740)
Changes in inventories	(14,422,219)	(12,610,601)
Changes in prepaid expenses and other current assets	(1,180,056)	(2,756,142)
Changes in accounts payable and accrued expenses	(89,802)	236,101
Other	1,286,608	(13,695)
Cash used in operations	$ (26,013,413)	$ (33,229,126)

Net Cash Used in Investing Activities

Net cash used in investing activities for the three months ended March 31, 2022 and 2021 was $2.8 million and $2.6 million, respectively, consisting of capital expenditures for the construction and buildout of new plasma collection centers and related equipment and capital expenditures at the Boca Facility. We expect our total capital expenditures will be between $8.0 million and $12.0 million for the remainder of fiscal 2022, mainly for continued plasma collection center expansion.

Net Cash Provided by Financing Activities

Cash provided by financing activities of $47.3 million for the three months ended March 31, 2022 and primarily consisted of proceeds received from the Hayfin Credit Facility, net of payments to retire our previously existing credit facility with Perceptive. Cash provided by financing activities of $41.8 million for the three months ended March 31, 2021 was mainly comprised of net proceeds received from the issuance of our common stock (see Note 8 to the Consolidated Financial Statements).

Effect of Inflation

Although inflation or changing prices did not have a significant impact on our revenues or net loss for the year ended December 31, 2020 or the three months ended March 31, 2021, inflation did impact a number of facets of our business during the year ended December 31, 2021 and the first three months of 2022 at both of our business segments. We experienced price increases for, among other items, certain raw materials, consumable supplies, services for repairs and maintenance of our facilities, shipping and freight charges and labor costs. We expect this trend to continue at least into the second half of 2022, which could have a significant impact on our future results of operations. In addition, some of our plasma purchase agreements provide for annual price increases that are tied to various consumer price indices, which have resulted in higher than historical price increases and has resulted in and is expected to continue to result in higher source plasma costs in 2022 and future periods.

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, 2022. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures as of March 31, 2022 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, 2022 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

Summary of Risk Factors

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Form 10-K and our other filings with the SEC, before making an investment decision regarding our common stock.

- We have a history of losses and we may, in the future, need to raise additional capital to operate our business, which may not be available on favorable terms, if at all.
- We are currently not profitable and may never become profitable.
- 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, as well as a change to the overall market size and potential for our products.
- 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.
- 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.
- Both of our business segments and our facilities are subject to periodic inspections by the FDA, which, depending on the outcome of such inspections, could result in certain FDA actions, including the issuance of observations, notices, citations or warning letters.
- Business interruptions could adversely affect our business.
- 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.
- 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 and FDA could require clinical trials beyond what we may deem to be reasonable. Unless additional clinical trials are successfully conducted and the FDA approves a BLA or other required submission for review, we may not be authorized to market ASCENIV for any other indication.
- With the approval to market ASCENIV, BIVIGAM and Nabi-HB, there can be no assurance that we will be successful in further developing and expanding commercial operations or balancing our research and development activities with our commercialization activities.
- We depend on third-party researchers, developers and vendors to develop, manufacture, supply materials for or test our products and product candidates, and such parties are outside of our control.

- 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 requisite approval from the FDA.

- 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.

- 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.

- 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.

- 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.

- 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 ADMA BioCenters 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.

- Our senior credit facility with Hayfin Services LLP (“Hayfin”) is subject to acceleration in specified circumstances, which may result in Hayfin taking possession and disposing of any collateral.

- 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.

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

- 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.

- 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.

- We require additional funding and may be unable to raise capital in the future, which would force us to delay, curtail or eliminate one or more of our research and development programs or potentially modify our ongoing operations, commercialization efforts and expansion plans, as well as impact the overall business plan for the organization.

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

Risk Factors

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

Risks Relating to our Business

To date, we have a history of losses and have historically needed to raise, and in the future may be required to raise, additional capital to operate our business.

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, continue to build out our commercial infrastructure and meet our ongoing obligations. 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 or potentially longer, requiring substantial investments in raw material plasma and other manufacturing materials.

We currently anticipate, based upon our projected revenue and expenditures, that our current cash, cash equivalents and accounts receivable, including the proceeds received and expected to be received from the refinancing of our senior credit facility and the amount of remaining funds available under the distribution agreement for the sale of our common stock (see "Liquidity and Capital Resources"), will be sufficient to fund our operations, as currently conducted, into the first quarter of 2024, at which time we believe we will begin to generate positive cash flow from operations. This time frame may change based upon how quickly we are able to execute on our commercialization efforts and operational initiatives and whether or not the assumptions underlying our projected revenues and expenses are correct. We are also continuing to evaluate a variety of strategic alternatives through our ongoing engagement with Morgan Stanley as a financial advisor. We anticipate that we will not be able to generate a sufficient amount of product revenue to achieve profitability until the beginning of 2024. If we are unable to raise additional capital if needed, we may 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 equity or debt 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.

Historically, the major source of our cash has been from proceeds from various public and private offerings of our common stock. The actual amount of cash that we will need is subject to many factors. There can be no assurances that additional financing will be available if needed or that management will be able to obtain financing on terms acceptable to us or that we will become profitable and generate positive operating cash flow.

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 flows into fiscal 2023, and we may never achieve or maintain profitability. For the three months ended March 31, 2022 and 2021, we incurred net losses of $25.0 million and $18.4 million, respectively, and for the years ended December 31, 2021 and 2020, we incurred net losses of $71.6 million and $75.7 million, respectively. From our inception in 2004 through December 31, 2021, we have incurred an accumulated deficit of $437.1 million. We expect that we will not be able to generate a sufficient amount of product revenue to achieve profitability until the beginning of 2024 and, as a result, we may need to continue 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.

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

The COVID-19 pandemic, including the Delta and Omicron variants and other resistant strains of the coronavirus, has the potential to adversely impact several aspects of each of our business segments, our commercial manufacturing operations and plasma collection facilities, 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 historically been performed by contract laboratories outside the United States. While we do not believe that the COVID-19 pandemic has significantly affected operations and immunoglobulin production at our Boca Facility or our ADMA BioCenters plasma collection operations at this time, we may experience adverse effects in the future. For example, our employees becoming ill, the imposition of additional mandatory remote working environments and federal, state and local responses to the pandemic could materially affect the efficiency and pace of our operations and manufacturing at our Boca Facility. Employee or donor illness, if not properly managed, could also impact the availability of and quality of our products. Further, in certain instances and geographic regions, we may experience decreased customer engagement (for example, as a result of a temporary shutdown of a customer's facilities resulting from the COVID-19 pandemic or the continuation of no in-person meetings) could impact our results of operations. In addition, travel and other restrictions that have been implemented in the United States could impact our commercial 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 are subject to limitations, rescheduling virtual attendance or outright cancellation in response to the pandemic. Also, due to a combination of previous state and local "shelter-in-place" orders, as well as government stimulus packages, amongst other initiatives, we have experienced, and may experience in the future, lower than expected donor collections at our FDA-licensed plasma collection centers. We were also subject to delays in shipments of source plasma from our contracted third-party suppliers, as well as delays in deliveries for personal protective equipment, reagents and other non-plasma raw materials and supplies used in the manufacture, testing and distribution of our products. We have also experienced supply chain delays as a result of significant resources being diverted towards the rapid development and distribution of COVID-19 vaccines, which could result in our need to carry more inventory than we have in the past, which would put an additional strain on our cash resources.

In the future we may continue to experience pandemic-related challenges with respect to obtaining and manufacturing a sufficient amount of supplies, raw materials, and finished product to meet our need for commercial and clinical product supply. If we or any of our suppliers or manufacturers are adversely impacted by the pandemic or the restrictions resulting from the outbreak, if they or we cannot obtain the necessary supplies, or if third parties need to prioritize other products or customers over us, including under the Defense Production Act, we may experience future delays or disruptions in our supply chain, which could have a material and adverse impact on our business. Moreover, we, our suppliers, and any third-party manufacturers may also need to implement measures and changes, or deviate from typical requirements, because of the pandemic that may otherwise adversely impact our supply chains or the quality of the resulting products or supplies. Depending on the change, we may need to obtain FDA pre-approval or otherwise provide the FDA with a notification of the change.

To the extent that we or our partners are conducting clinical trials, the pandemic could cause delays or disruptions in these or future development programs. By example, the pandemic may result in slower enrollment, the need to suspend enrollment into studies, patient withdrawals, postponement of planned clinical or preclinical studies, redirection of site resources from studies, study modification, suspension, or termination, the introduction of remote study procedures and modified informed consent procedures, study site changes, direct delivery of investigational products to patient homes requiring state licensing, study deviations or noncompliance, and changes or delays in site monitoring. The foregoing may require that we consult with relevant review and ethics committees, IRBs, and the FDA. The foregoing may also impact the integrity of our study data. The effects of the COVID-19 pandemic may also increase the need for clinical trial patient monitoring and regulatory reporting of adverse effects. The pandemic could further impact our ability to interact with the FDA or other regulatory authorities and may result in delays in the conduct of inspections or review of pending applications or submissions. No assurances can be provided as to the timing for completion of any regulatory submissions or applications that may be impacted by restrictions related to COVID-19 or other circumstances unknown to us presently or that are out of our direct control. Due to the potential impact of the COVID-19 outbreak on clinical trials, drug development, and manufacturing, the FDA issued a number of guidances specifically concerning COVID-19, including guidances with respect to blood and blood components. The FDA's guidance is continually evolving.

The COVID-19 pandemic may also result in changes in laws and regulations. By example, in March 2020, the U.S. Congress passed the CARES Act, which includes various provisions regarding FDA drug shortage reporting requirements, as well as provisions regarding supply chain security, such as risk management plan requirements, and the promotion of supply chain redundancy and domestic manufacturing. The CARES Act further included reporting requirements related to the volume of products produced over the course of the year. FDA recently issued guidance regarding this requirement. This and any future changes in law may require that we change our internal processes and procedures to ensure continued compliance. Additionally, the previous guidelines that were issued by public health authorities or any new or changing recommendations or guidelines may still impact the demand for or usage as well as the prescriptions of our IVIG products.

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 a portion of 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 and results from operations.

Although we have received FDA approval for the fill/finish suite we built at the Boca Facility, we also intend to continue to utilize third parties to supplement our fill/finish process for final drug substance. 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;

- the COVID-19 pandemic could adversely affect our contracted fill/finishers' operations, supply chain or workforce;
- 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;
- contract manufacturers may fail to comply with applicable regulatory requirements, placing them and us at risk of regulatory enforcement actions, recalls and other adverse consequences, which may negatively impact our business and their ability to supply products to meet our development, clinical and commercial needs;
- 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 us or the FDA, which could result in higher costs or adversely impact the commercialization of our products. These risks could also result in the delay in obtaining clinical supplies, which would delay our development programs. 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, international conflicts, trade and sanction requirements and limits, 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.

Both of our business segments and our facilities, as well as our suppliers and contractors, are subject to periodic inspections by the FDA, which, depending on the outcome of such inspections, could result in certain FDA actions, including the issuance of observations, notices, citations or warning letters.

We and our suppliers and contractors may be unable to comply with our specifications, cGMP requirements and with other FDA, state, and foreign regulatory requirements for commercial and clinical supply. The FDA is authorized to perform inspections of our and our suppliers' facilities, including the Boca Facility. The FDA also may inspect and approve our and our third-parties' facilities before they may be used for commercial production. At the end of such an inspection, the FDA could issue a Form 483 Notice of Inspectional Observations, which could cause FDA to not approve the use of the facility and cause us to modify certain activities identified during the inspection. Following such inspections, the FDA may issue an untitled letter as an initial correspondence that cites violations that do not meet the threshold of regulatory significance of a warning letter. FDA guidelines also provide for the issuance of warning letters for violations of "regulatory significance" for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action. FDA also may issue warning letters and untitled letters in connection with events or circumstances unrelated to an FDA inspection. Depending on the seriousness of any findings, we or our suppliers may be subject to additional significant enforcement actions which could have a material impact on our business.

We may not be able to timely resolve concerns raised by the FDA as a result of an inspection or without expending significant resources. We are unable to control the timing of FDA inspections, communications and actions, and will be required to respond to the FDA and make certain submissions within certain timeframes. We also do not know 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 a 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.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our commercial manufacturing and any research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized internally and by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our commercial manufacturing, research and development, or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties, or other sanctions.

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, cyberattacks on our operations and information technology systems and breakdown, human error, employee issues, global health occurrences such as the COVID-19 pandemic, war geopolitical conditions 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 BLAs, 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 could be adversely affected.

In addition, the FDA or an IRB may not permit us to commence a clinical trial, may require amendments to our clinical trial protocols, or may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA or IRB finds deficiencies in our IND submissions or the conduct of these trials. Regulatory authorities may also not accept data from clinical trials if the trials are not conducted in accordance with the applicable regulatory requirements. Failure to comply with the applicable regulatory requirements may also result in enforcement actions. 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.

Other issues that may impact our clinical trials and that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, include:

- Delays in reaching, or failure to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and our CROs;
- Regulators requiring us to perform additional or unanticipated clinical trials to obtain approval or becoming subject to additional post-marketing testing, surveillance, or REMS requirements to maintain regulatory approval;
- Failure by our third-party contractors to comply with regulatory requirements or the clinical trial protocol, or meet their contractual obligations to us in a timely manner, or at all, or our being required to engage in additional clinical trial site monitoring;
- The cost of clinical trials of our product candidates being greater than we anticipate or our having insufficient funds for a clinical trial or to pay the substantial user fees required by FDA upon the filing of a marketing application;
- Insufficient supply or inadequate quality of our product candidates or other materials necessary to conduct clinical trials;
- Inability to achieve sufficient study enrollment, subjects dropping out or withdrawing from our studies, delays in adding new investigators or clinical trial sites or a withdrawal of clinical trial sites;
- Flaws in our clinical trial design that are not discoverable until the clinical trial has progressed;
- Disagreement by the FDA or comparable foreign regulatory authorities with our intended indications or study design, including endpoints, or our interpretation of data from preclinical studies and clinical trials, finding that a product candidate's benefits do not outweigh its safety risks or requiring that we conduct additional development or study work;
- The need to make changes to our product candidates that require additional testing or that cause our product candidates to perform differently than expected;
- Global trade policies that may impact our ability to obtain raw materials and/or finished product for commercialization;

- FDA or comparable regulatory authorities taking longer than we anticipate to make decisions on our products or product candidates; and
- Potential inability to demonstrate that a product or product candidate provides an advantage over current standards of care or current or future competitive therapies in development.

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 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. 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 revenues from, our product candidates;
- 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 review, inspection and 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 and other governmental authorities strictly regulate and monitor marketing, labeling and the 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 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. 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, require payment of civil fines or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, among other consequences, 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 further developing and expanding commercial operations or balancing our research and development activities with our commercialization activities.

Since receiving FDA approval for ASCENIV, we have been commercializing 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 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. As a result, we may experience an insufficient supply of this plasma.

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 or test products and product candidates, as well as for other pre-and-post approval services, 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, CROs, contract manufacturers, contract fill/finishers and consultants to conduct our preclinical activities, 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, our trials may be repeated, extended, delayed, or terminated, the approval of our FDA application(s), if any, and our introduction of new products, if any, will be delayed. We or they may also be subject to regulatory enforcement actions and we may not be able to meet commercial demand. 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 requisite approval 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 our fill-finish machine at our Boca Facility. Following the expansion of any of our manufacturing processes or the addition of new equipment, such as our 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 and 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, discovery that the product is less effective than previously thought, 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;

- clinical holds or termination of clinical trials;
- requirements to conduct further post-marketing studies or clinical trials, implement risk mitigation strategies, or to issue corrective information;
- 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;
- FDA debarment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from healthcare programs, consent decrees, or corporate integrity agreements;
- product seizure or detention; 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, 2022, three customers, BioCARE, Inc. ("BioCare"), Biolife Plasma Services, L.P. ("Biolife"), and Priority Healthcare Distribution, Inc. ("Curascript"), represented an aggregate of 83% of our consolidated revenues. For the year ended December 31, 2021, four customers, BioCare, Reliance Life Sciences Pvt Limited ("Reliance"), Curascript and AmerisourceBergen Corporation, represented an aggregate of 81% of our consolidated revenues.

As of March 31, 2022, four customers, BioCare, Biolife, Curascript and Reliance represented an aggregate of 92% of our consolidated accounts receivable. As of December 31, 2021, three customers, Curascript, BioCare and Reliance, represented a total of 94% 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. Moreover, we anticipate deriving increased revenue from some of these customers 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 any of our key customers 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 or 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.

In addition, as a manufacturer of biological products, we are subject to the risks inherent in biological production, which could include normal course losses and failures inherent in the manufacturing process. As our biologics production levels increase, there may be normal course inventory losses or write-downs as we ensure product quality and compliance with cGMP, FDA, state and local regulations, or due to testing results not meeting specifications. As a result, our operating results are subject to potentially significant variability from one reporting period to the next should such normal course losses occur in any given period. However, because our products and product candidates are plasma-based products, not only are we subject to FDA's drug and biologic cGMP requirements, but we are also subject to special requirements for the collection, testing, handling, storage, and use of blood products. This adds an extra level of compliance and complexity to our operations, which we may not be able to successfully meet. Failure to meet any regulatory quality standards could have an adverse impact on our business.

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, but not limited to:

- 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, as well as expanding our IP estate with patents issued for *S. Pneumoniae* hyperimmune IG. 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 successfully commercialize ASCENIV, as well as our ability to generate revenue from Nabi-HB, BIVIGAM, contract manufacturing, intermediate fractions and plasma attributable to the operations of ADMA BioCenters, to support our operations.

Our ADMA BioCenters 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, and will be amended by the California Privacy Rights Act, effective January 1, 2023. 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.

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

On March 23, 2022 (the "Hayfin Closing Date"), we entered into the Hayfin Credit Agreement with Hayfin (see "Liquidity and Capital Resources"). The Hayfin Credit Agreement provides for a senior secured term loan facility in the principal amount of up to $175.0 million (the "Hayfin Credit Facility"), composed of (i) a term loan made on the Hayfin Closing Date in the principal amount of $150.0 million (the "Hayfin Closing Date Loan"), (ii) a delayed draw term loan in the principal amount of $25.0 million (the "Hayfin Delayed Draw Loan" and, together with the Hayfin Closing Date Loan, the "Hayfin Loans"). The obligation of the lenders to make the Hayfin Delayed Draw Loan expires on March 22, 2023 is subject to the satisfaction of certain conditions, including but not limited to, our meeting certain 12-month revenue targets as set forth in the Hayfin Credit Agreement. The Hayfin Credit Facility has a maturity date of March 23, 2027 (the "Hayfin Maturity Date"). The Hayfin 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 Hayfin Loans of 3% per annum, the occurrence of an Event of Default could result in, among other things, the termination of commitments under the Hayfin Credit Facility, the declaration that all outstanding Loans are immediately due and payable in whole or in part, and Hayfin taking immediate possession of, and selling, any collateral securing the Hayfin 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 patents, 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 or biosimilar 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, or 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.

Our success depends in part on our ability to attract, motivate, and retain a sufficient number of qualified employees across various areas of our operations, such as research and development, manufacturing operations, and sales, who understand and appreciate our strategy and culture and are able to contribute to our mission. 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. Qualified individuals of the requisite caliber and number needed to fill these positions may be in short supply in some areas. 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, including but not limited to overall increases in the cost of labor or travel restrictions related to COVID-19, prevent us from being able to hire qualified personnel. If we are unable to hire and retain personnel capable of consistently performing at a high level, our business and operations could be materially adversely affected. Additionally, any material increases in existing employee turnover rates or increases in labor costs could have a material adverse effect on our business, financial condition or operating results.

We currently collect human blood plasma at our ADMA BioCenters facilities, and if we cannot maintain FDA approval for these facilities 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 BioCenters collection facilities for the collection of human blood plasma and we may seek other governmental and regulatory approvals for these facilities. We also plan to grow through the building and licensing of additional ADMA BioCenters 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 and blood standards and FDA and other governmental approvals, as applicable. Failure to comply with applicable governmental regulations or to receive applicable approvals for our current or future facilities may result in enforcement actions, such as adverse inspection reports, warning or untitled 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 material adverse effect on our ability to manufacture our products or offer for sale plasma collected at the affected sites.

We 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.

There are no assurances we will be able to maintain compliance with all FDA or other regulations. Moreover, to the extent that we use third-party vendors to fulfill our regulatory or contractual requirements, these 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. If we are not able to maintain manufacturing compliance at our facilities or our vendors' facilities for our products and product candidates, we may not be able to successfully develop and commercialize our products and product candidates and we may face potential contractual or regulatory actions, which would have an adverse impact on our business.

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. Product liability claims may also result in recalls and/or regulatory enforcement actions. Even successful defense, however, could impair our results of operations. 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 civil and criminal Federal False Claims Act, the civil monetary penalty statute, requirements regarding the reporting and repayment of overpayments, other fraud and abuse laws 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 states, including the State of Florida with respect to the manufacture and marketing 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 recently promulgated a regulation that is effective in two phases. First, the regulation excludes from the definition of "remuneration" limited categories of (a) PBM rebates or other reductions in price to a plan sponsor under Medicare Part D or a Medicaid Managed Care Organization plan reflected in point-of sale reductions in price and (b) PBM service fees. Second, effective January 1, 2023, the regulation expressly provides that rebates to plan sponsors under Medicare Part D either directly to the plan sponsor under Medicare Part D, or indirectly through a pharmacy benefit manager will not be protected under the anti-kickback discount safe harbor.

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 of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to or at the request of covered recipients, such as, but limited to, physicians, physician assistants, nurse practitioners, clinical nurse specialists and certified registered nurse anesthetists and teaching hospitals, must be tracked and reported to CMS, and are publicly disclosed. Such "applicable manufacturers" are also required to report certain ownership interests held by physicians and their immediate family members. 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 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, operations, facilities, suppliers and CROs 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, CRLs, 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 approvals. Any failure to receive the marketing approvals necessary to commercialize our product or product candidates could harm our business.

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 the 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 or product components 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. Product or component quality issues may also result in regulatory enforcement actions, liability, corrective actions and recalls, among other actions, as described elsewhere in this annual report.

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 generally 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 current plasma collection facilities, an unsatisfactory inspection could prevent a new center from being licensed or risk the suspension or revocation of an existing license, among other enforcement actions. 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, including the supply of plasma. 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 and other applicable regulatory requirements, 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 BioCenters plasma collection facilities. This strategy is dependent upon our ability to maintain a cGMP compliant environment at our plasma collection facilities and to expand production and attract donors to our facilities. There is no assurance that the FDA will inspect and license any of our current or future unlicensed plasma collection facilities 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 facilities to more efficient production levels may be affected by changes in the economic environment and population in selected regions where ADMA BioCenters operates its current or future plasma facilities, by the entry of competitive plasma centers into regions where ADMA BioCenters operates such centers, by misjudging the demographic potential of individual regions where ADMA BioCenters 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.

Additionally, our supply contract with Grifols for the purchase of normal source plasma ("NSP") expires December 31, 2022. There can be no assurances that we will be able to obtain NSP from other third-party suppliers or be able to collect NSP in the same quantities, or at all, through our ADMA BioCenters plasma collection facilities at a cost that is comparable to the price we currently pay to Grifols for NSP. If our costs to obtain NSP through collections at our ADMA BioCenters plasma collection facilities or from other third-party suppliers are higher than what we currently pay to Grifols, our liquidity and results of operations could be adversely impacted.

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 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. Moreover, in an effort to increase competition in the biologic product marketplace, Congress, the executive branch, and the FDA have taken certain legislative and regulatory steps. For example, in 2020 the FDA finalized a guidance to facilitate biologic product importation. The 2020 Further Consolidated Appropriations Act included provisions requiring that sponsors of approved biologic products provide samples of the approved products to persons developing biosimilar products within specified timeframes, in sufficient quantities, and on commercially reasonable market-based terms. 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. This reform establishes significant cost-saving measures 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, plus the inflation penalty if applicable. 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, plus the inflation penalty if applicable. For non-innovator multiple source (generic) products, the rebate percentage was increased from a minimum of 11.0% to a minimum of 13.0% of AMP, and the Bipartisan Budget Act of 2015 established a new inflation penalty for these drugs. In 2010, the Healthcare Reform Law also newly extended the Medicaid drug 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, and recent regulations have established a civil monetary penalty for failure to refund these overcharges.

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 also created 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 now equal to 70% 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 legal challenges and attempts by Congress to repeal or change the Healthcare Reform Law and the possibility of future challenges or legislative changes contribute to the uncertainty of the ongoing implementation and impact of the law and also underscores the potential for additional reform going forward. We cannot assure that the law, as currently enacted or as amended in the future, will not adversely affect our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business. Certain provisions of enacted or proposed legislative changes may negatively impact coverage and reimbursement of, or rebates paid by manufacturers for, healthcare items and services. We will continue to evaluate the effect that the Healthcare Reform Law and any potential changes may have on our business.

Corporate responsibility, specifically related to environmental, social and governance ("ESG") matters, may impose additional costs and expose us to new risks.

Public ESG and sustainability reporting is becoming more broadly expected by investors, stockholders and other third parties. Certain organizations that provide corporate governance and other corporate risk information to investors and stockholders have developed, and others may in the future develop, scores and ratings to evaluate companies and investment funds based upon ESG or "sustainability" metrics. Many investment funds focus on positive ESG business practices and sustainability scores when making investments and may consider a company's ESG or sustainability scores as a reputational or other factor in making an investment decision. In addition, investors, particularly institutional investors, use these scores to benchmark companies against their peers and if a company is perceived as lagging, these investors may engage with such company to improve ESG disclosure or performance and may also make voting decisions, or take other actions, to hold these companies and their boards of directors accountable. Board diversity is an ESG topic that is, in particular, receiving heightened attention by investors, stockholders, lawmakers and listing exchanges. Certain states have passed laws requiring companies to meet certain gender and ethnic diversity requirements on their boards of directors. We may face reputational damage in the event our corporate responsibility initiatives or objectives, including with respect to board diversity, do not meet the standards set by our investors, stockholders, lawmakers, listing exchanges or other constituencies, or if we are unable to achieve an acceptable ESG or sustainability rating from third-party rating services. A low ESG or sustainability rating by a third-party rating service could also result in the exclusion of our common stock from consideration by certain investors who may elect to invest with our competition instead. Ongoing focus on corporate responsibility matters by investors and other parties as described above may impose additional costs or expose us to new risks.

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 adversely affect our operations and could force us to delay, curtail or eliminate some of our commercialization efforts or one or more of our research and development programs.

Our operations have consumed substantial amounts of cash since inception. For the three months ended March 31, 2022 and 2021, we had negative cash flows from operations of $26.0 million and $33.2 million, and for the years ended December 31, 2021 and 2020, we had negative cash flows from operations of approximately $112.4 million and $102.0 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 and building additional plasma collection facilities. 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 or potentially longer, 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 until the beginning of 2024 and, as a result, we may need to continue 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, that our current cash, cash equivalents and accounts receivable, including the proceeds received and expected to be received from the refinancing of our senior credit facility, along with the remaining funds available under the distribution agreement for the sale of our common stock (see "Liquidity and Capital Resources"), will be sufficient to fund our operations, as currently conducted, into the first quarter of 2024, at which time we believe we will begin to generate positive cash flow from operations. This time frame may change based upon how quickly we are able to execute on our commercialization efforts and operational initiatives and whether or not the assumptions underlying our projected revenues and expenses are correct. If we are unable to raise additional capital if 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 Hayfin Credit Facility provides for a senior secured term loan facility in an aggregate principal amount of up to $175.0 million, of which $150.0 million has been drawn down and is currently outstanding. Borrowings under the Hayfin Credit Facility bear interest at a rate per annum equal to 9.5% plus the greater of (i) one- or three-month SOFR as we elect and (ii) 1.25%, as more fully described in "Liquidity and Capital Resources"; provided, however, that upon, and during the continuance of, an Event of Default, the interest rate will automatically increase by an additional 300 basis points. We are currently required to make monthly payments of interest during the term of the Hayfin Credit Facility of approximately $1.1 million, with all principal and unpaid interest due at maturity. The Hayfin Credit Facility has a maturity date of March 23, 2027, subject to acceleration pursuant to the Hayfin Credit Agreement, including upon an Event of Default. All of our obligations under the Hayfin 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.

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 Hayfin 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.

Consequently, we have incurred increased costs related to our compliance with Section 404 of the Sarbanes-Oxley Act and will continue to do so. Our Audit Committee has retained the services of BDO, a Sarbanes-Oxley advisor, to assist with our internal control 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 ability to use our net operating loss carryforwards ("NOLs") may be limited.

We have incurred substantial losses during our history. As of December 31, 2021, we had federal and state NOLs of $299.9 million and $185.0 million, respectively. Federal and State NOLs of approximately $55.2 million and $77.8 million, respectively, 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. On October 25, 2021, we completed a public offering of our common stock whereby we issued 57,500,000 shares of our common stock resulting in another change of ownership for ADMA under section 382 of the Code, resulting in an additional write-off of $3.0 million of federal NOLs, $28.1 million of state NOLs and $1.0 million of research and development credits. 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.

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;
- uncertainties in the equity markets related to the effects of the COVID-19 pandemic;
- 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;
- overall market volatility;
- 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 6, 2022, most of our 196,351,925 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, 2021, Perceptive, Stonepine Capital Management, LLC, Caligan LP, NWQ Investment Management Company, LLC and our directors and executive officers and their affiliates owned approximately 26% of the outstanding 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;
- 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.

Our Board also recently adopted a short-term stockholder rights agreement with an expiration date of June 15, 2022 and an ownership trigger threshold of 10%. This stockholder rights agreement could render more difficult or discourage a merger, tender offer or assumption of control of the Company that is not approved by our Board. The rights agreement, however, should not interfere with any merger, tender or exchange offer or other business combination approved by our Board. In addition, the rights agreement does not prevent our Board from considering any offer that it considers to be in the best interest of the Company's stockholders.

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 Hayfin 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, 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.

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 300,000,000 shares of common stock. As of March 31, 2022, there were 70,840,818 shares remaining available for issuance, after giving effect to 27,047,033 shares of our common stock that were subject to outstanding stock options, RSUs and warrants as of March 31, 2022 that may be issued by us without stockholder approval, as well as an additional 5,764,620 shares reserved for the future issuance of awards under our equity compensation plans.

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.

None.

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 11, 2022

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

Date: May 11, 2022

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

EXHIBIT INDEX

Exhibit Number	Description
4.1	Form of Warrant to Purchase Stock, in the form issued by the Company to various entities affiliated with Hayfin Services LLP, dated as of March 23, 2022 (incorporated by reference to Exhibit 4.13 to the Company's Annual Report on Form 10-K, filed with the SEC on March 24, 2022.
10.1	Credit Agreement and Guaranty, dated as of March 23, 2022, by and among the Company, Hayfin Services LLP and the lenders party thereto (incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K, filed with the SEC on March 24, 2022).
10.2	Security Agreement, dated as of March 23, 2022, by and among the Company, certain subsidiaries of the Company and Hayfin Services LLP (incorporated by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K, filed with the SEC on March 24, 2022).
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, 2022, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets as of March 31, 2022 (Unaudited) and December 31, 2021, (ii) Condensed Consolidated Statements of Operations (Unaudited) for the three months ended March 31, 2022 and 2021, (iii) Condensed Consolidated Statements of Changes in Stockholders' Equity (Unaudited) for the three months ended March 31, 2022 and 2021, (iv) Condensed Consolidated Statements of Cash Flows (Unaudited) for the three months ended March 31, 2022 and 2021, and (v) Notes to (Unaudited) Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* 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 11, 2022

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 11, 2022

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, 2022, 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 11, 2022

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, 2022, 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 11, 2022

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