ADMA BIOLOGICS, INC.
Form 10-Q
May 14, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2018

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)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No ¨

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

Large accelerated filer	¨	Accelerated filer ¨
Non-accelerated filer	¨	Smaller reporting company ý
(Do not check if a smaller reporting company)		Emerging growth company ý

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

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

As of May 14, 2018, there were 36,726,084 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 "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.

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Special Note Regarding Forward-Looking Statements

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

- our ability to successfully leverage the anticipated benefits and synergies from our June 6, 2017 acquisition of certain assets of Biotest Pharmaceuticals Corporation (the "Biotest Transaction"), including optimization of the combined businesses, operations and products and services, as well as the nature, strategy and focus of the combined company and the management and governance structure of the combined company;

- our ability to resume the manufacturing and commercialization of Bivigam once the deficiencies identified in a November 2014 warning letter (the "Warning Letter") with respect to the outstanding issues at the plasma fractionation facility in Boca Raton, FL acquired in the Biotest Transaction have been resolved by us to the satisfaction of the U.S. Food and Drug Administration (the "FDA"), as well as a positive review of the optimized manufacturing process under a Prior Approval Supplement by the FDA;

- our ability to successfully resubmit to the FDA our Biologics License Application (the "BLA") for our lead pipeline product candidate, RI-002 ("RI-002"), once the deficiencies identified in the Complete Response Letter we received in July 2016 reaffirming the issues set forth in the Warning Letter have been resolved by us and/or our third-party vendors to the satisfaction of the FDA, and other requests for information included therein have been provided by us;

- our plans to develop, manufacture, market, launch and expand our own commercial infrastructure and commercialize our current and future products and the success of such efforts;

- the safety, efficacy and expected timing of and our ability to obtain and maintain regulatory approvals for our current products and product candidates, including the timeframe within which we may receive approval from the FDA, if at all, of our BLA resubmission for RI-002 and the labeling or nature of any such approvals;

- the achievement of or expected timing, progress and results of clinical development, clinical trials and potential regulatory approvals;

- our dependence upon our third-party and related-party customers and vendors and their compliance with regulatory bodies;

- our ability to obtain adequate quantities of FDA-approved plasma with proper specifications;

- our plans to increase our supplies of plasma;

- the potential indications for our product candidates;

- potential investigational new product applications;

- the acceptability of any of our products, including RI-002, for any purpose by physicians, patients or payers;

- concurrence by the FDA with our conclusions and the satisfaction by us of its guidance;

- the comparability of results of our immune globulin products to other comparably run Intravenous Immune Globulin clinical trials;

- the potential of RI-002 and Bivigam to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease;

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- our ability to market and promote Nabi-HB in a highly competitive environment 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 RI-002 or other future pipeline product candidates;
- our manufacturing capabilities, third-party contractor capabilities and strategy;
- our plans relating to manufacturing, supply and other collaborative agreements;
- our estimates regarding expenses, capital requirements and the need for additional financing;
- possible or likely reimbursement levels for our currently marketed products and, if any, if and when RI-002 is approved for marketing;
- estimates regarding market size, projected growth and sales of our existing products as well as our expectations of market acceptance of RI-002;
- future economic conditions or performance; and
- expectations for future capital requirements.

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

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

publicly update any forward-looking statements or to publicly announce revisions to any of the forward-looking statements, whether as a result of new information, future events or otherwise.

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PART I
FINANCIAL INFORMATION

Item 1. Financial Statements.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2018 (Unaudited)	December 31, 2017 (Note 2)
ASSETS		
Current assets:		
Cash and cash equivalents	$26,119,837	$43,107,574
Accounts receivable, net	3,657,602	3,880,154
Inventories	12,438,802	12,628,181
Prepaid expenses and other current assets	2,703,214	2,050,740
Restricted cash	1,500,000	1,500,000
Total current assets	46,419,455	63,166,649
Property and equipment, net	30,615,530	30,466,858
Intangible assets, net	4,638,115	4,849,350
Goodwill	3,529,509	3,529,509
Assets to be transferred under purchase agreement	1,395,444	1,496,410
Restricted cash	4,000,000	4,000,000
Deposits and other assets	539,572	510,057
TOTAL ASSETS	$91,137,625	$108,018,833
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$5,718,121	$5,920,873
Accrued expenses	3,581,882	3,318,478
Current portion of deferred revenue	142,834	142,834
Other current liabilities	—	57,998
Total current liabilities	9,442,837	9,440,183
Notes payable, net of discount	25,616,653	25,368,458
End of term liability, notes payable	2,760,000	2,760,000
Deferred revenue, net of current portion	2,511,491	2,547,199
Note payable - related party, net of discount	14,850,048	14,842,396
Obligation to transfer assets under purchase agreement	12,621,844	12,621,844
Other non-current liabilities	309,353	105,996
TOTAL LIABILITIES	68,112,226	67,686,076
COMMITMENTS AND CONTINGENCIES	—	—

STOCKHOLDERS' EQUITY		
Preferred Stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued and outstanding	—	—
Common Stock - voting, $0.0001 par value, 75,000,000 shares authorized, 36,726,084 and 36,725,499 shares issued and outstanding	3,673	3,673
Common Stock - non-voting, $0.0001 par value, 8,591,160 shares authorized, 8,591,160 shares issued and outstanding	859	859
Additional Paid-In Capital	191,536,802	191,022,018
Accumulated Deficit	(168,515,935)	(150,693,793)
TOTAL STOCKHOLDERS' EQUITY	23,025,399	40,332,757
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$91,137,625	$108,018,833

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

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2018	2017
REVENUES:		
Product revenue	$4,006,298	$2,593,163
License and other revenue	35,708	35,708
Total Revenues	4,042,006	2,628,871
OPERATING EXPENSES:		
Cost of product revenue (exclusive of amortization expense shown below)	12,242,748	1,616,287
Research and development	1,281,706	1,192,727
Plasma centers	1,833,774	1,479,476
Amortization of intangibles	211,235	—
Selling, general and administrative	5,005,046	4,277,384
TOTAL OPERATING EXPENSES	20,574,509	8,565,874
LOSS FROM OPERATIONS	(16,532,503)	(5,937,003)
OTHER INCOME (EXPENSE):		
Interest income	26,546	18,568
Interest expense	(1,323,152)	(618,528)
Other income	6,967	—
OTHER EXPENSE, NET	(1,289,639)	(599,960)
NET LOSS	$(17,822,142)	$(6,536,963)
BASIC AND DILUTED LOSS PER COMMON SHARE	$(0.39)	$(0.51)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:		
Basic and Diluted	45,317,042	12,886,741

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

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)

For the Three Months Ended March 31, 2018

	Common Stock Voting Shares	Amount	Non-Voting Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total
Balance - January 1, 2018	36,725,499	$3,673	8,591,160	$859	$191,022,018	$(150,693,793)	$40,332,757
Stock-based compensation	—	—	—	—	514,784	—	514,784
Stock options exercised	585	—	—	—	—	—	—
Net loss	—	—	—	—	—	(17,822,142)	(17,822,142)
Balance - March 31, 2018	36,726,084	$3,673	8,591,160	$859	$191,536,802	$(168,515,935)	$23,025,399

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

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Three Months Ended March 31,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(17,822,142)	$(6,536,963)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	829,541	118,062
Loss on disposal of fixed assets	—	4,155
Stock-based compensation	514,784	235,877
Amortization of debt discount	255,847	190,253
Amortization of license revenue	(35,708)	(35,708)
Changes in operating assets and liabilities, net of acquisition:		
Accounts receivable	222,552	178,089
Inventories	189,379	(288,346)
Prepaid expenses and other current assets	(652,474)	(432,932)
Other assets	(29,515)	(2,400)
Accounts payable	(202,754)	1,339,764
Accrued expenses	88,640	(160,637)
Other current and non-current liabilities	207,736	(7,640)
Net cash used in operating activities	(16,434,114)	(5,398,426)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Sales of short-term investments	—	5,145,184
Purchase of property and equipment	(549,246)	(3,584)
Net cash (used in) provided by investing activities	(549,246)	5,141,600
CASH FLOWS FROM FINANCING ACTIVITIES:		
Principal payments on notes payable	—	(1,111,111)
Payments of leasehold improvement loan	(4,377)	(4,002)
Net cash used in financing activities	(4,377)	(1,115,113)
Net decrease in cash and cash equivalents	(16,987,737)	(1,371,939)
Cash and cash equivalents, including restricted cash - beginning of period	48,607,574	9,914,867
Cash and cash equivalents, including restricted cash - end of period	$31,619,837	$8,542,928

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

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES

NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. ORGANIZATION AND BUSINESS

ADMA Biologics, Inc. ("ADMA" or the "Company") is a vertically integrated commercial biopharmaceutical company that manufactures, markets and develops specialty plasma-derived biologics for the treatment of Primary Immune Deficiency Disease ("PIDD") and the prevention and treatment of certain infectious diseases. The Company's targeted patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disorder or who may be immune-suppressed for medical reasons. ADMA operates through its wholly-owned subsidiaries ADMA BioManufacturing, LLC ("ADMA BioManufacturing") and ADMA Bio Centers Georgia Inc. ("ADMA BioCenters"). ADMA BioManufacturing was formed in January 2017 to facilitate the acquisition of the Biotest Therapy Business Unit ("BTBU") of Biotest Pharmaceuticals Corporation ("BPC" and, together with Biotest AG, "Biotest") as more fully described below. ADMA BioCenters is the Company's source plasma collection business, with facilities located in Norcross, GA, Marietta, GA and Kennesaw, GA. Both the Norcross and Marietta, GA facilities have approved licenses with the U.S. Food and Drug Administration (the "FDA") and certifications from the German Health Authority (the "GHA") and the Korean Ministry of Food and Drug Safety, and the Company filed a Biologics License Application ("BLA") with the FDA for its Kennesaw, GA facility in December 2017 and, pending FDA approval, this facility is expected to be approved during the second half of 2018. ADMA BioCenters supplies ADMA with a portion of its raw material plasma for the manufacture of RI-002, ADMA's lead pipeline product candidate, which the Company is currently developing for the treatment of PIDD.

As discussed in Note 3, on June 6, 2017, ADMA completed the acquisition of certain assets (the "Biotest Assets") of BTBU, which include two FDA-licensed products, Nabi-HB (Hepatitis B Immune Globulin, Human) and Bivigam (Immune Globulin Intravenous, Human), and a plasma fractionation facility located in Boca Raton, FL (the "Boca Facility") (the "Biotest Transaction"). In addition to Nabi-HB and Bivigam, BTBU also provides contract manufacturing services for certain clients, including the sale of intermediate by-products. The Boca Facility is FDA-licensed and certified by the GHA. Immediately following the closing of the Biotest Transaction, the Biotest Assets were contributed into ADMA BioManufacturing.

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

Bivigam is indicated for the treatment of primary humoral immunodeficiency. FDA approval for Bivigam was received on December 19, 2012, and sales commenced in the first quarter of 2013. In December 2016, Biotest temporarily suspended the commercial production of Bivigam in order to focus on the completion of planned improvements to the manufacturing process. ADMA resumed production of Bivigam during the fourth quarter of 2017. The Bivigam inventory currently being produced will be used in conjunction with a Prior Approval Supplement (the "PAS"), which is expected to be filed with the FDA during the first half of 2018. Upon approval of the PAS by the FDA, the Company intends to relaunch Bivigam. This relaunch is expected to take place no earlier than the second half of 2018.

Prior to the closing of the Biotest Transaction, BTBU was the Company's third-party manufacturer for RI-002. In the third quarter of 2015, the FDA accepted for review the Company's BLA for RI-002 (the "RI-002 BLA") for the treatment of PIDD. In July 2016, the FDA issued a Complete Response Letter (the "CRL") to the Company for the RI-002 BLA. Although the CRL did not cite any concerns with the clinical safety or efficacy data for RI-002 submitted in the RI-002 BLA, nor did the FDA request any additional clinical studies be completed prior to FDA approval of RI-002, the CRL reaffirmed the issues set forth in the November 2014 warning letter (the "Warning Letter") that had been issued by the FDA to Biotest related to certain compliance issues identified at the Boca Facility, and also identified certain outstanding inspection issues and deficiencies at the Boca Facility and certain of the Company's third-party vendors, and requested documentation of corrections for a number of these issues. The FDA indicated in the CRL that it cannot grant final approval of the BLA until, among other things, these deficiencies are resolved. Upon the completion of the Biotest Transaction, ADMA gained control over the regulatory, quality, general operations and drug substance manufacturing process at the Boca Facility, and the Company's highest priority has been the remediation of the outstanding compliance issues that were identified at the Boca Facility in the Warning Letter. The Company has been working with a consulting firm consisting of quality management systems and biologics production subject matter experts in order to improve the FDA inspection classification relative to the Warning Letter compliance issues as indicated in the CRL. The Company anticipates that it will be in a position to refile the RI-002 BLA in the second half of 2018 and, pending FDA approval, ADMA anticipates initial commercial sales of RI-002 to occur no earlier than the first half of 2019.

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES

NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

As of March 31, 2018, the Company had working capital of $37.0 million, including $26.1 million of cash and cash equivalents. Based upon the Company's current projected revenue and expenditures for 2018, including capital expenditures and regulatory and consulting fees for the remediation of the Warning Letter and ongoing discussions with the FDA, as well as continuing implementation of the Company's commercialization and expansion activities and certain other assumptions, the Company's management currently believes that its cash, cash equivalents, projected revenue and accounts receivable, along with the $10.0 million it expects to be able to access under its senior credit facility, will be sufficient to fund ADMA's operations, as currently conducted, into the fourth quarter of 2018. In order to have sufficient cash to fund its operations thereafter and to continue as a going concern, the Company will need to raise capital prior to the end of 2018. These estimates may change based upon how quickly the Company is able to execute on its quality management systems' remediation plans for the ADMA BioManufacturing operations, timing of receipt of communications, determinations and feedback from the FDA regarding inspectional outcomes and remediation activities undertaken to date, commercial manufacturing ramp-up activities and the various financing options available to the Company. The Company currently has no firm commitments for additional financing, and there can be no assurances that the Company will be able to secure additional financing on terms that are acceptable to the Company, or at all. Furthermore, if the Company's assumptions underlying its estimated expenses and revenues are incorrect, it may have to raise additional capital sooner than currently anticipated.

Due to numerous risks and uncertainties associated with ongoing remediation efforts, the research and development and potential future commercialization of its products and product candidates, the Company is unable to estimate with certainty the amounts of increased capital outlays and operating expenditures associated with its development activities. The Company's current estimates may be subject to change as circumstances regarding its business requirements evolve. The Company may decide to raise capital through public or private equity offerings or debt financings, or obtain a bank credit facility or corporate collaboration and licensing arrangements. The sale of additional equity or debt securities, if convertible, could result in dilution to the Company's stockholders and, in such event, the value and potential future market price of its common stock may decline. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict the Company's operations or other financing alternatives. Failure to secure any necessary financing in a timely manner and on commercially reasonable terms could have a material adverse effect on the Company's business plan and financial performance and it could be forced to delay or discontinue its product development, clinical trial or commercialization activities, delay or discontinue the approval efforts for any of the Company's potential products or potentially cease operations. The Company has reported losses since inception in June 2004 through March 31, 2018 of $168.5 million. Management believes that the Company will continue to incur net losses and negative net cash flows from operating activities to fund its research and development, commercial programs and meet its obligations on a timely basis through the foreseeable future. As such, these factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying condensed consolidated financial statements do not include any adjustments related to the recoverability and classification of asset carrying amounts and the classification of liabilities that might be necessary from the outcome of this uncertainty.

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

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES

NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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 related notes thereto as of and for the year ended December 31, 2017 included in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC") on March 29, 2018. These condensed consolidated interim financial statements have been prepared in accordance with the instructions to Form 10-Q and Article 8 of Regulation S-X, and therefore omit or condense certain footnotes and other information normally included in consolidated interim financial statements prepared in accordance with U.S. GAAP. All intercompany balances and transactions have been eliminated in consolidation. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's financial position as of March 31, 2018 and its results of operations for the three and ended March 31, 2018 and 2017 and cash flows for the three months ended March 31, 2018 and 2017.

During the three months ended March 31, 2018 and 2017, comprehensive loss was equal to the net loss amounts presented for the respective periods in the accompanying condensed consolidated interim statements of operations. In addition, certain prior year balances have been reclassified to conform to the current presentation. Specifically, the change in the Company's deferred rent liability in the accompanying statement of cash flows for the three months ended March 31, 2017 has been reclassified to changes in other current and non-current liabilities. Operating results for the three months ended March 31, 2018 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2018.

Use of estimates

The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include the fair value of assets acquired and liabilities assumed in a business combination, the valuation of inventory and assumptions used in the fair value determination of stock-based compensation and the allowance for the valuation of future tax benefits.

Business Combinations

The Company accounts for business combinations using the acquisition method of accounting in accordance with FASB ASC 805, *Business Combinations*. Identifiable assets acquired, liabilities assumed, and contingent consideration are recorded at their acquisition date fair values. Any change in the fair value of the acquisition-related contingent consideration subsequent to the acquisition date, including changes from events after the acquisition date, will be recognized in the period of the estimated fair value change. Goodwill represents the excess of the purchase price over the fair value of identifiable assets acquired and liabilities assumed as a result of the business combination. Identifiable assets with finite lives are amortized over their useful lives. Acquisition related costs are expensed as incurred.

Fair value of financial instruments

The carrying amounts of certain of the Company’s financial instruments, including cash and cash equivalents and accounts payable, are shown at cost which approximates fair value due to the short-term nature of these instruments. The debt outstanding under the Company’s senior secured term loan (see Note 4) approximates fair value due to the variable interest rate on this debt. With respect to the related party note payable in the amount of $15.0 million as of March 31, 2018 (see Note 4), which is held by a principal stockholder of the Company and was issued concurrent with an acquisition transaction with such stockholder, the Company has concluded that an estimation of fair value for this note is not practicable.

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES

NOTES TO (UNAUDITED) CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Accounts receivable

Accounts receivable are reported at realizable value, net of allowances for contractual credits and doubtful accounts, which are recognized in the period the related revenue is recorded. At March 31, 2018, three customers accounted for approximately 84% of the Company’s total accounts receivable, and at December 31, 2017, two customers accounted for approximately 79% of the Company’s total accounts receivable.

Inventories

Inventories, including plasma intended for resale and plasma intended for internal use in the Company's research and development and future anticipated commercialization activities, are carried at the lower of cost or net realizable value determined by the first-in, first-out method. Research and development plasma used in clinical trials is processed to a finished product and subsequently expensed to research and development.

Although the Company expects that the Bivigam inventory produced during 2017 and 2018 will ultimately be available for commercial sale, due to uncertainties surrounding the timing and outcome of any FDA determinations concerning the Warning Letter and the PAS related to improvements in the manufacturing process that must be filed with and approved by the FDA prior to this inventory being available for commercial sale, all costs related to the production of Bivigam during the three months ended March 31, 2018 in the amount of $1.1 million have been charged to cost of product revenue in the accompanying consolidated statement of operations. In addition, the costs related to the manufacture of conformance lots of RI-002 during the three months ended March 31, 2018 in the amount of $2.5 million were also charged to cost of product revenue.

Goodwill

Goodwill represents the excess of purchase price over the fair value of net assets acquired by the Company. Goodwill at March 31, 2018 and December 31, 2017 was $3.5 million. All of the Company’s goodwill is attributable to its ADMA BioManufacturing business segment.

Goodwill is not amortized, but is assessed for impairment on an annual basis or more frequently if impairment indicators exist. The Company has the option to perform a qualitative assessment of goodwill to determine whether it is more likely than not that the fair value of its reporting unit is less than its carrying amount, including goodwill and other intangible assets. If the Company concludes that this is the case, then it must perform a goodwill impairment test by comparing the fair value of the reporting unit to its carrying value. An impairment charge is recorded to the extent the reporting unit's carrying value exceeds its fair value, however the impairment loss recognized would not 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.

Impairment of long-lived assets

The Company assesses the recoverability of its long-lived assets, which include property and equipment and definite-lived intangible assets, whenever significant events or changes in circumstances indicate impairment may have occurred. If indicators of impairment exist, projected future undiscounted cash flows associated with the asset are compared to its carrying amount to determine whether the asset's 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, 2018 and 2017, the Company determined that there was no impairment of its long-lived assets.

Revenue recognition

Revenue from the sale of Nabi-HB is recognized when the product reaches the customer's destination. Nabi-HB revenue is recorded net of estimated customer prompt pay discounts and contractual allowances in accordance with managed care agreements, including wholesaler chargebacks, rebates, customer returns and other wholesaler fees. For sales of intermediates, title typically transfers when the product is delivered to a third party warehouse. With all other contract manufacturing, the title transfers to the customer when they take possession of the product from the Boca Facility. As the Company maintains a significant risk of loss throughout the contract manufacturing process, contract manufacturing revenue is not recognized until the product is released and title transfers to the customer.

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Product revenues from the sale of human plasma collected at the Company's plasma collection centers are recognized at the time of transfer of title and risk of loss to the customer, which generally occurs at the time of delivery.

License and other revenues are primarily attributable to the out-licensing of RI-002 to Biotest to market and sell in Europe and selected countries in North Africa and the Middle East. Biotest has provided the Company with certain services and financial payments in accordance with the related Biotest license agreement and is obligated to pay the Company certain amounts in the future if certain milestones are achieved. Deferred revenue is recognized over the term of the Biotest license. Deferred revenue is amortized into income for a period of approximately 20 years, the term of the Biotest license agreement.

For the three months ended March 31, 2018, three customers represented 90% of the Company's consolidated revenues, with BPC representing 58% of the Company's consolidated revenues and the other two customers representing 32% of the Company's consolidated revenues. For the three months ended March 31, 2017, sales to BPC represented 81% of the Company's consolidated revenues, and another customer represented 17% of the Company's consolidated revenues.

Cost of product revenue

Cost of product revenue includes expenses related to process development as well as scientific and technical operations when these operations are attributable to marketed products. When the activities of these operations are attributable to new products in development, the expenses are classified as research and development expenses. Expenses associated with remediating the issues identified in the Warning Letter for the three months ended March 31, 2018 in the approximate amount of $0.7 million are expensed as incurred and are reflected in cost of product revenue in the accompanying consolidated statements of operations. In addition, for the three months ended March 31, 2018, all operating expenses associated with the Boca Facility, other than the Nabi-HB production that was capitalized into inventory, have been expensed as incurred.

Loss per common share

Basic net loss per 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. For purposes of computing basic and diluted loss per share, the non-voting class of common stock (see Notes 3 and 5) is included in the common stock outstanding as the characteristics of the non-voting class are substantially the same as the voting class of common stock.

Diluted net loss per 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, including the non-voting class 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 in the diluted net loss per share computation is excluded to the extent that it would be anti-dilutive. No potentially dilutive securities are included in the computation of any diluted per share amounts as the Company reported a net loss for all periods presented. For the three months ended March 31, 2018 and 2017, the following securities were excluded from the calculation of diluted loss per common share because of their anti-dilutive effects:

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	For the Three Months Ended March 31,	
	2018	2017
Stock options	4,127,950	1,691,123
Warrants	528,160	188,859
	4,656,110	1,879,982

Stock-based compensation

The Company follows recognized accounting guidance which requires all equity-based payments, including grants of stock options, to be recognized in the statements of operations as compensation expense based on their fair values at the date of grant. The Company uses the Black-Scholes option pricing model to determine the fair value of options granted. Compensation expense related to awards to employees and directors with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term (see Note 5).

During the three months ended March 31, 2018 and 2017, the Company granted stock options to purchase 848,700 and 182,000 shares of common stock, respectively, to its directors and employees, and during the three months ended March 31, 2018, the Company granted stock options to purchase 20,000 shares of common stock to a third party service provider.

Recent Accounting Pronouncements

In May 2017, the FASB issued ASU No. 2017-09, *Modification Accounting for Share-Based Payment Arrangements*, which amends the scope of modification accounting for share-based payment arrangements. The ASU provides guidance on the types of changes to the terms or conditions of share-based payment awards to which an entity would be required to apply modification accounting under ASC 718. Specifically, an entity would not apply modification accounting if the fair value, vesting conditions, and classification of the awards are the same immediately before and after the modification. The ASU is effective for annual reporting periods, including interim periods within those annual reporting periods, beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period. Adoption of this new guidance in 2018 did not have a material impact on the Company’s condensed consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842),* which requires lessees to recognize assets and liabilities for the rights and obligations created by most leases on their balance sheet. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. ASU 2016-02 requires modified retrospective adoption for all leases existing at, or entered into after, the date of initial application, with an option to use certain transition relief. The Company is currently evaluating the impact the standard may have on its condensed consolidated financial statements and related disclosures.

In May 2014, the FASB issued new guidance related to revenue recognition, ASU 2014-09, *Revenue from Contracts with Customers* ("ASC 606"), which outlines a comprehensive revenue recognition model and supersedes most current revenue recognition guidance. The new guidance requires a company to recognize revenue upon transfer of goods or services to a customer at an amount that reflects the expected consideration to be received in exchange for those goods or services. ASC 606 defines a five-step approach for recognizing revenue, which may require a company to use more judgment and make more estimates than under the current guidance. The new guidance became effective in calendar year 2018. Two methods of adoption are permitted: (a) full retrospective adoption, meaning the standard is applied to all periods presented; or (b) modified retrospective adoption, meaning the cumulative effect of applying the new guidance is recognized at the date of initial application as an adjustment to the opening retained earnings balance.

In March 2016, April 2016 and December 2016, the FASB issued ASU No. 2016-08, *Revenue From Contracts with Customers (ASC 606): Principal Versus Agent Considerations*, ASU No. 2016-10, *Revenue From Contracts with Customers (ASC 606): Identifying Performance Obligations and Licensing*, and ASU No. 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue From Contracts with Customers*, respectively, which further clarify the implementation guidance on principal versus agent considerations contained in ASU No. 2014-09. In May 2016, the FASB issued ASU 2016-12, *Revenue from Contracts with Customers*, narrow-scope improvements and practical expedients which provides clarification on assessing the collectability criterion, presentation of sales taxes, measurement date for non-cash consideration and completed contracts at transition. These standards became effective for the Company beginning in the first quarter of 2018.

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ADMA adopted the new standard and related updates effective January 1, 2018, using the modified retrospective method of adoption. Adoption of the new revenue recognition guidance did not have a material impact on the Company's consolidated financial statements.

3. ACQUISITION

On June 6, 2017, ADMA completed the acquisition of the Biotest Assets from BPC. As a result of this transaction, the Company acquired Nabi-HB, Bivigam, the Boca Facility and certain other assets of BTBU. The acquisition of the Biotest Assets expands the Company's product offering with two FDA-approved products and provides direct control over the manufacturing and regulatory processes impacting the Company's RI-002 product candidate, including remediation of the Warning Letter as well as certain other remediation items affecting the Boca Facility. Pursuant to the acquisition, the Company issued to Biotest 4,295,580 voting shares of its common stock and 8,591,160 non-voting shares of common stock. The Company will also transfer ownership of two of its plasma centers to Biotest on January 1, 2019 as additional consideration, which are reflected as non-current assets in the accompanying consolidated balance sheets at March 31, 2018 and December 31, 2017 in the amount of $1.4 million and $1.5 million, respectively.

As a result of the foregoing transaction, BPC became a principal stockholder and Biotest became a related party of the Company. Therefore, all transactions with Biotest subsequent to June 6, 2017, including product and license revenues attributable to Biotest (see Note 2), are related party transactions. The results from BTBU's operations are included in the Company's consolidated financial statements from the date of acquisition.

The following unaudited pro forma summary presents consolidated information of the Company as if the business combination had occurred on January 1, 2017. The pro forma information is presented for informational purposes only and is not necessarily indicative of the results of operations that would have been achieved had the acquisition been consummated as of that time or that may result in the future.

	Three Months Ended March 31, 2017
Revenues:	
As reported	$ 2,628,871

Proforma	$ 13,722,649
Net loss	
As reported	$ (6,536,963)
Proforma	$ (12,773,860)
Basic and diluted net loss per share:	
As reported	$ (0.51)
Proforma	$ (0.50)

4. DEBT

Senior Notes Payable

A summary of outstanding senior notes payable is as follows:

	March 31, 2018	December 31, 2017
Notes payable:	$ 30,000,000	$ 30,000,000
Less:		
Debt discount	(4,383,347)	(4,631,542)
Senior notes payable	$ 25,616,653	$ 25,368,458

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On October 10, 2017 (the "Marathon Closing Date"), the Company entered into a Credit Agreement (the "Credit Agreement") with Marathon Healthcare Finance Fund, L.P. ("Marathon" or the "Lender") and Wilmington Trust, National Association, as the administrative agent for the Lender (the "Administrative Agent"). The Credit Agreement provides for a senior secured term loan facility in an aggregate amount of up to $40.0 million (collectively, the "Credit Facility"), comprised of (i) a term loan made on the Marathon Closing Date in the principal amount of $30.0 million evidenced by a secured promissory note (the "Tranche One Note"), and (ii) an additional term loan evidenced by a secured promissory note to be made in the maximum principal amount not to exceed $10.0 million (the "Tranche Two Note" and, together with the Tranche One Note, the "Notes"), which Tranche Two Note availability is subject to the satisfaction of certain conditions, including, but not limited to, those described below. The Notes each have a maturity date of April 10, 2022 (the "Maturity Date"), subject to acceleration pursuant to the Credit Agreement, including upon an Event of Default (as defined in the Credit Agreement).

Borrowings under the Credit Agreement bear interest at a rate per annum equal to LIBOR plus 9.50% with a 1% LIBOR floor; provided, however, that in the event that the Company achieves sales of not less than $61.7 million for the 2018 calendar year and the Tranche Two Loan has been funded, then the interest rate on the borrowings under the Credit Agreement will decrease to LIBOR plus 7.75% with a 1% LIBOR floor. During an Event of Default under the Credit Agreement, the outstanding amount of indebtedness under the Credit Agreement will bear interest at a rate per annum equal to the interest rate then applicable to the borrowings under the Credit Agreement plus 5% per annum. Quarterly cash interest payments are due the first business day of each March, June, September and December, beginning on December 1, 2017. During the three months ended March 31, 2018, the interest rate on the Tranche One Note ranged from 10.99% to 11.51%.

The Company will pay Marathon a facility fee in an amount equal to 9.20% of the amount of the Tranche One Note, payment of which is deferred until the Maturity Date pursuant to the terms of the Credit Agreement. Commencing on October 10, 2020, and on the first business day of each month, the Company is required to make principal payments on the Tranche One Note (and Tranche Two Note in the event it shall have been funded) in equal monthly installments over 18 months, subject to certain conditions in the Credit Agreement. The outstanding principal amount of the Notes, together with all accrued interest thereon, is due on the Maturity Date.

The Credit Agreement contains market representations and warranties, affirmative covenants, negative covenants, financial covenants, and conditions that are customarily required for similar financings. The affirmative covenants, among other things, require the Company to undertake various reporting requirements. The negative covenants restrict or limit the ability of the Company and its subsidiaries to, among other things, incur new indebtedness; create liens on assets; engage in certain fundamental corporate changes or changes to the Company's business activities; sell or otherwise dispose of assets; repurchase stock, pay dividends; repay certain other indebtedness; engage in certain

affiliate transactions; or enter into any other agreements that restrict the Company's ability to make loan repayments. In addition, the Company is required to maintain a minimum liquidity, defined in the Credit Agreement as cash held in the debt service reserve account and any other deposit account subject to a control agreement with the Administrative Agent, of not less than $5.5 million at all times. The Credit Agreement also required the establishment of the debt service reserve account. The Company is currently required to maintain a minimum balance in this account of $5.5 million, and this amount is reflected as restricted cash in the accompanying consolidated balance sheets as of March 31, 2018 and December 31, 2017. Upon the satisfaction of certain conditions related to some of the Company's leased properties, the minimum required balance in the debt service reserve account, as well as the minimum liquidity requirement, will be reduced to $4.0 million. At March 31, 2018 and December 31, 2017, the Company was in compliance with all of the covenants contained in its senior lending agreements.

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The Credit Agreement also contains customary Events of Default which 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. The occurrence of an Event of Default could result in, among other things, the termination of commitments under the Credit Facility and the declaration that all outstanding Loans are immediately due and payable in whole or in part.

Related Party Note Payable

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

	March 31, 2018	December 31, 2017
Biotest - Gross proceeds	$ 15,000,000	$ 15,000,000
Less:		
Debt discount	(149,952)	(157,604)
Note payable - related party	$ 14,850,048	$ 14,842,396

In connection with the acquisition of the Biotest Assets (see Note 3), ADMA BioManufacturing issued a subordinated note payable to BPC and in connection therewith received cash proceeds of $15.0 million. The note bears interest at a rate of 6.0% per annum and matures on June 6, 2022. The Company is obligated to make semi-annual interest payments, with all principal and unpaid interest due at maturity. The note is subordinate to all amounts outstanding under the Credit Agreement. In the event of default, all principal and unpaid interest is due on demand. The subordinated note also contains several non-financial covenants with which the Company was in compliance as of March 31, 2018. The Company incurred $0.2 million of debt issuance costs in connection with the issuance of this note, which were recorded as a debt discount. The debt discount is being amortized as interest expense over the term of the note.

5. 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, 2018 and December 31, 2017.

Common Stock

As of March 31, 2018 and December 31, 2017, the Company was authorized to issue 75,000,000 shares of its common stock, and 36,726,084 and 36,725,499 shares of common stock, respectively, were outstanding. After giving effect to shares reserved for the issuance of warrants and stock options, 33,617,806 shares of common stock were available for issuance as of March 31, 2018. As of March 31, 2018 and December 31, 2017, 8,591,160 shares of the Company's non-voting common stock were authorized, issued and outstanding.

Equity Incentive Plan

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, 2018 and 2017:

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	Three Months Ended March 31,	
	2018	2017
Expected term	6.3 years	5.8 - 6.3 years
Volatility	57%	64%
Dividend yield	0.0	0.0
Risk-free interest rate	2.59%	2.29%

The weighted average remaining contractual life of stock options outstanding and expected to vest at March 31, 2018 is 8.1 years. The weighted average remaining contractual life of stock options exercisable at March 31, 2018 is 5.8 years.

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

	Three Months Ended March 31, 2018	
	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	3,276,043	$ 5.52
Forfeited	(12,500)	$ 3.58
Expired	(2,334)	$ 2.68
Granted	868,700	$ 3.72
Exercised	(1,959)	$ 2.68
Outstanding at end of period and expected to vest	4,127,950	$ 5.15
Options exercisable	1,452,273	$ 7.51

During the three months ended March 31, 2018, an aggregate of 1,959 option shares were exercised in cashless exercise transactions resulting in the issuance of an aggregate of 585 shares of common stock. Stock-based compensation expense for the three months ended March 31, 2018 and 2017 is as follows:

	Three Months Ended March 31,	
	2018	2017
Research and development	$78,305	$52,983
Plasma centers	7,086	12,751
Selling, general and administrative	394,858	170,143
Cost of product revenue	34,535	—
Total stock-based compensation expense	$514,784	$235,877

As of March 31, 2018, the Company had $5.3 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 3.0 years.

6. INVENTORIES

The following table provides the components of inventories:

	March 31, 2018	December 31, 2017
Raw materials	$8,962,207	$10,395,433
Work-in-progress	1,265,586	1,265,339
Finished goods	2,211,009	967,409
Total inventories	$12,438,802	$12,628,181

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Inventories are stated at the lower of cost or net realizable value with cost being determined on the first-in, first-out method. Finished goods inventories as of March 31, 2018 is comprised of Nabi-HB, a portion of which is recorded at fair value as part of the purchase price allocation of the Biotest Assets acquired. Raw materials includes materials expected to be used in the production of Nabi-HB, Bivigam and RI-002. All other activities and materials associated with the production of inventories used in research and development activities are expensed as incurred.

7. INTANGIBLE ASSETS

Intangible assets at March 31, 2018 and December 31, 2017 consist of the following:

	March 31, 2018			December 31, 2017		
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Trademark and other intangible rights related to Nabi-HB	$4,100,046	$488,101	$3,611,945	$4,100,046	$341,670	$3,758,376
Rights to intermediates	907,421	108,026	799,395	907,421	75,618	831,803
Customer contract	1,076,557	849,782	226,775	1,076,557	817,386	259,171
	$6,084,024	$1,445,909	$4,638,115	$6,084,024	$1,234,674	4,849,350

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

Remainder of 2018	$633,704
2019	715,352
2020	715,352
2021	715,352
2022	715,352

8. PROPERTY AND EQUIPMENT

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

	March 31, 2018	December 31, 2017
Manufacturing and laboratory equipment	$ 7,148,405	$ 7,148,405
Office equipment and computer software	1,660,926	1,086,756
Furniture and fixtures	843,123	1,136,623
Construction in process	1,116,309	738,093
Leasehold improvements	1,650,029	1,642,903
Land	4,339,441	4,339,441
Buildings	15,660,559	15,660,559
	32,418,792	31,752,780
Less: Accumulated depreciation and amortization	(1,803,262)	(1,285,922)
	$ 30,615,530	$ 30,466,858