ADMA BIOLOGICS, INC.
Form S-1/A
April 22, 2013

As filed with the Securities and Exchange Commission on April 22 , 2013
Registration No. 333-186579

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

amendment no. 2
to
Form S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

ADMA BIOLOGICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	8731	56-2590442
(State or other jurisdiction of incorporation or organization)	(Primary standard industrial classification code number)	(I.R.S. employer identification number)

65 Commerce Way
Hackensack, New Jersey 07601
(201) 478-5552
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Adam S. Grossman
Chief Executive Officer
ADMA Biologics, Inc.
65 Commerce Way
Hackensack, New Jersey 07601
(201) 478-5552
(Name, address, including zip code, and telephone number,
including area code, of agent for service)

Copies to:

Jeffrey A. Baumel, Esq. Roland S. Chase, Esq. Dentons US LLP	Michael D. Maline, Esq. Thomas S. Levato, Esq. Goodwin Procter LLP

1221 Avenue of the Americas
New York, New York 10020-1089
Tel. No.: 212-768-6700
Fax No.: 212-768-6800

The New York Times Building
620 Eighth Avenue
New York, New York 10018-1405
Tel. No.: 212-813-8800
Fax No.: 212-355-3333

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

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

Large Accelerated Filer	¨	Accelerated filer	¨
Non-accelerated filer	¨ (Do not check if a smaller reporting company)	Smaller reporting company	x

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

Subject to Completion, Dated April 22 , 2013

2,100,000 Shares

Common Stock
$ per share

ADMA Biologics, Inc. is offering 2,100,000 shares of common stock. We estimate that the offering price will be between $13.50 and $15.50 per share.

There is not currently, and there has never been, any public market for our common stock. Our common stock is not currently eligible for trading on any national securities exchange or any over-the-counter markets, including the OTC Bulletin Board. In connection with this offering, we have applied to have our common stock quoted on the OTC Bulletin Board under the symbol " ". We cannot assure you that our common stock will continue to be quoted on the OTC Bulletin Board after this offering.

We are an “emerging growth company” as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements for future filings. See “Prospectus Summary—Implications of Being an Emerging Growth Company.”

Investing in our common stock involves risks. See “Risk Factors” beginning on page 8.

	Per Share	Total
Public offering price	$	$
Underwriting discount and commission (1)	$	$
Proceeds to us, before expenses	$	$

(1) In addition, we have agreed to reimburse the underwriters for certain out-of-pocket expenses. See the section captioned “Underwriting” in this prospectus for additional information.

Certain of our existing stockholders, including Aisling Capital II, LP, Burrill Capital Fund IV, LP and certain other affiliates, have indicated an interest in purchasing an aggregate of up to approximately $5.0 million of our common stock in this offering at the initial public offering price. O f this amount, the underwriters have reserved $560,000 for purchase by our directors, executive officers, certain of their affiliates and others associated with us through a directed share program. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may sell more, less or no shares in this offering to any of these persons , or any of these persons may determine to purchase more, less or no shares in this offering. We will pay $ per share in underwriting discounts and commissions with respect to any shares of common stock that are sold to certain of our existing directors, principal stockholders or their affiliated entities in this offering, if any.

We have granted an over-allotment option to the underwriters. Under this option, the underwriters may elect to purchase a maximum of 315,000 additional shares from us within 30 days following the date of this prospectus to

cover over-allotments.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The shares will be ready for delivery on or about , 2013.

Joint Book-Running Managers

Oppenheimer & Co. BMO Capital Markets

Co-Manager

Ladenburg Thalmann & Co. Inc.

The date of this prospectus is , 2013

Table of Contents

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus we have prepared. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date.

Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus applicable to that jurisdiction.

We obtained statistical data and certain other industry forecasts used throughout this prospectus from market research, publicly available information and industry publications. Industry publications generally state that they obtain their information from sources that they believe to be reliable. While we believe that the statistical and industry data and forecasts and market research used herein are reliable, we have not independently verified such data. We have not sought the consent of the sources to refer to their reports in this prospectus.

Table of Contents

Prospectus Summary

This summary highlights information contained in other parts of this prospectus. Because it is a summary, it does not contain all of the information that you should consider before investing in our securities. You should read the entire prospectus carefully.

As used in this prospectus, unless the context otherwise requires, "ADMA," "ADMA Biologics," the "Company," "we," "us" a "our" refer to ADMA Biologics, Inc., a Delaware corporation, as well as its subsidiary, ADMA Plasma Biologics, Inc., a Delaware corporation, taken as a whole, and also refer to the operations of ADMA Plasma Biologics, Inc. prior to the merger on February 13, 2012, as discussed in this prospectus, which resulted in ADMA Plasma Biologics, Inc. becoming our wholly-owned subsidiary. In each case, references to ADMA Plasma Biologics, Inc. also include its subsidiary ADMA BioCenters Georgia Inc., or ADMA BioCenters, a Delaware corporation. All shares and per share information included in this prospectus and relating to the shares of our common stock, par value $0.0001 per share, gives effect to a 1.27-for-1 stock split effected by means of a 0.27-for-1 stock dividend on April 4, 2013.

The Company

Overview

ADMA Biologics is a specialty immune globulin company that develops, manufactures and intends to market plasma-based biologics for the treatment and prevention of certain infectious diseases. Our targeted patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disease or who may be immune-suppressed for medical reasons. Our lead product candidate, RI-002, for which we have commenced a pivotal Phase III clinical trial, is intended for the treatment of primary immune deficiency disease, or PIDD. RI-002 is an injectable immune globulin derived from human plasma enriched with high levels of naturally occurring polyclonal antibodies (e.g. streptococcus pneumoniae, H. influenza type B, CMV, measles, tetanus, etc.) as well as high levels of antibodies targeted to respiratory syncytial virus, or RSV. RSV is a common virus that ordinarily leads to mild, cold-like symptoms in healthy adults and children. In high-risk groups, such as the immune-compromised, RSV can lead to a more serious infection and may even cause death. Our proprietary microneutralization assay allows us to effectively identify and isolate donor plasma with high-titer RSV antibodies, to standardize RI-002's potency and thereby potentially garner a premium price.

PIDD, a genetic disorder that causes a deficient or absent immune system, is caused by hereditary or genetic defects and can affect anyone regardless of age or gender. PIDD patients are more vulnerable to infections and more likely to suffer complications from these infections. Intravenous immune globulin, or IGIV, is a plasma derived product that is used to prevent serious infections in patients with PIDD. It is comprised of polyclonal antibodies, which are proteins produced by B-cells that are used by the body's immune system to neutralize foreign objects such as bacteria and viruses. RI-002, a specialty IGIV with standardized levels of high-titer RSV antibodies, is intended to prevent infections in PIDD patients. The polyclonal antibodies which are present in RI-002 are expected to prevent infections in immune-compromised patients. It is estimated that there are about 250,000 diagnosed PIDD patients in the United States approximately half of whom are treated with IGIV regularly. In the United States, sales of immune globulin products for all its uses were reported to be approximately $3.5 billion in 2011. Since the introduction of IGIV therapy, the incidence of infections in IGIV-treated patients has dropped significantly.

We commenced our pivotal Phase III clinical trial of RI-002 for the treatment of patients with PIDD in 2013. The trial is a single arm, open label study in which patients will be treated approximately once per month for a period of 12 months of treatment plus 90 days for follow up. We intend to treat an aggregate of between 60 and 70 patients in approximately 12 treatment centers in the United States. The pivotal Phase III primary endpoint follows the published Food and Drug Administration, or FDA, industry guidance, which provides for a reduction in the incidence of serious

infections to less than one per year in those receiving IGIV. The secondary endpoint is safety and includes other data collection points including antibody titers for certain agents, including RSV antibody levels at various time points after infusion. Following the FDA's guidance for our protocol should provide that a successful single Phase III trial and Biological License Application, or BLA, submission should lead to FDA approval. RI-001 was the subject of a Phase II randomized, double-blind, placebo-controlled human clinical trial in RSV-infected, immune-compromised patients. In that trial, RI-001 treated patients demonstrated a statistically significant rise in anti-RSV titers compared to patients receiving placebo. RI-002 is an improved formulation of our prior product candidate RI-001, which successfully completed a Phase II trial. RI-002 is manufactured using the same FDA-approved contract manufacturing facility as its predecessor. RI-002 has demonstrated improved production yields, an improved stability profile and comparable anti-RSV antibody titer potency relative to the prior formulation.

Table of Contents

We have established, qualified and validated a proprietary microneutralization assay for plasma collection and donor screening as well as for determining the appropriate anti-RSV antibody potency for the manufacture of RI-002. Our assay provides for measurement of RSV antibody titer levels of RI-002 that are consistent and reproducible, which we believe is a competitive advantage and a barrier to the entry of competitive products. Our microneutralization assay could serve as a platform for identifying next generation virus-specific plasma-based therapeutics.

We have an FDA-licensed source plasma collection facility, ADMA BioCenters, which provides us with a portion of our blood plasma for the manufacture of RI-002. A typical plasma collection center, such as ADMA BioCenters, can collect 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 that is not used for making RI-002 is sold to customers under an existing supply agreement or in the open "spot" market. We have entered into long term manufacturing and licensing agreements with Biotest AG and their United States subsidiary, Biotest Pharmaceuticals, Inc., together referred to as Biotest, that provide for the exclusive manufacture of RI-002. At the same time, we granted Biotest an exclusive royalty-bearing license to market and sell RSV antibody-enriched IGIV in Europe and in other selected territories in North Africa and the Middle East.

The founders of ADMA have a combined 60 years of experience marketing and distributing blood plasma products and devices. With the appointment of the executive team and the board of directors, we added over 150 years of deep medical, technical and development experience in the biologics and pharmaceutical industry.

Our mission is to develop and commercialize plasma-derived, human immune globulins targeted to niche immune-compromised patient populations. We intend to accomplish our mission by achieving the following:

- Complete our pivotal Phase III trial and obtain FDA approval to manufacture and market RI-002 for the treatment of patients with PIDD.

- Establish a specialty sales force to commercialize RI-002.

- Explore other possible indications for RI-002.

- Develop additional plasma-derived products for the treatment of infectious diseases in immune-compromised patient populations.

- Expand our network of ADMA BioCenters facilities, both to maintain control of a portion of our raw material supply and to generate additional revenue through the collection and sale of source plasma to third party customers.

Risks Associated with Our Business

We are a clinical-stage company with no approved products and limited historical revenues, which makes it difficult to assess our future viability. As of December 31, 2012, we had an accumulated deficit of approximately $37.1 million. In addition to our history of operating losses, our business, financial condition, results of operations and prospects are subject to a number of risks and uncertainties. These risks and uncertainties are discussed more fully in the "Risk Factors" and "Special Note Regarding Forward-Looking Statements" sections of this prospectus. You should carefully consider all of the information set forth in this prospectus and, in particular, should evaluate the specific factors set forth under "Risk Factors" and "Special Note Regarding Forward-Looking Statements" in deciding whether to invest in our common stock. Among these important risks and uncertainties that could adversely affect our business, financial condition, results of operations and prospects are the following:

.

To date, we have generated limited product revenues. We are not currently profitable and may never become profitable. We have a limited operating history upon which to base an investment decision.

Table of Contents

- Our current product candidate, RI-002, requires extensive additional clinical testing. Clinical trials are very expensive, time-consuming and difficult to design and implement. If we are unsuccessful in obtaining regulatory approval for RI-002 or if our trials do not provide positive results, we will be required to delay or abandon development of such product, which would have a material adverse impact on our business.

- We depend on a third-party manufacturer for the production of RI-002, and such party is outside of our control.

- We do not own any issued patents and we do not have any patent applications in process relating to RI-002. If we are unable to protect our trade secrets or other proprietary rights, our competitiveness and business prospects may be materially damaged.

- We expect our securities will be quoted on the OTC Bulletin Board quotation system, which will limit the liquidity and price of our securities more than if we were quoted on a national securities exchange.

Corporate History

ADMA Biologics, Inc. was incorporated in New Jersey on June 24, 2004 and re-incorporated in Delaware on July 16, 2007. On February 13, 2012, ADMA Biologics, Inc., merged into a subsidiary of R&R Acquisition VI, Inc., a Delaware "blank check" company, which had been incorporated in 2006 and which then changed its name to ADMA Biologics, Inc.

Corporate Information

Our primary executive offices are located at 65 Commerce Way, Hackensack, New Jersey, 07601, and our telephone number is (201) 478-5552. Our website address is http://www.admabiologics.com. The information contained in, or that can be accessed through, our website is not part of this prospectus.

Common Stock Market Data

We have been a public reporting company since February 13, 2012. However, there is not currently, and there has never been, any public market for our common stock. Our common stock is not currently eligible for trading on any national securities exchange or any over-the-counter markets, including the OTC Bulletin Board. In connection with this offering, we have applied to have our common stock quoted on the OTC Bulletin Board under the symbol " ". We cannot assure you that our common stock will continue to be quoted on the OTC Bulletin Board after this offering.

Implications of Being an Emerging Growth Company

As a company with less than $1 billion in revenue during our last fiscal year, we qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act, or JOBS Act, enacted in April 2012. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for qualifying public companies. As an “emerging growth company,” we may, under Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, delay adoption of new or revised accounting standards applicable to public companies until such standards would otherwise apply to private companies. We may take advantage of this extended transition period until the first to occur of the date that we (i) are no longer an “emerging growth company” or (ii) affirmatively and irrevocably opt out of this extended transition period.

We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until

the date that we are no longer an “emerging growth company” or affirmatively and irrevocably opt out of the exemption provided by Securities Act Section 7(a)(2)(B), upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard. As an emerging growth company, we are also exempt from the requirement to have our independent auditors provide an attestation report on our internal control over financial reporting.

We could be an emerging growth company for up to five years after the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act, which such fifth anniversary will occur in 2018. However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer,” our annual gross revenues exceed $1 billion or we issue more than $1 billion of non-convertible debt in any three-year period, we would cease to be an emerging growth company prior to the end of such five-year period.

Table of Contents

We are also a “smaller reporting company” as defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and have elected to take advantage of certain of the scaled disclosure available to smaller reporting companies.

Table of Contents

The Offering

Common stock offered by us	2,100,000 shares
Common stock to be outstanding after the offering	7,971,002 shares (or 8,286,002 shares if the underwriters exercise their overallotment option in full)
Option to purchase additional shares	The underwriters have a 30-day option to purchase up to an additional 315,000 shares of our common stock at the public offering price less the underwriting discount and commission.
Use of proceeds	We estimate that the net proceeds from this offering, after deducting the underwriting discount and commission and estimated offering expenses payable by us, will be approximately $27.3 million. We intend to use the proceeds of this offering to continue clinical development and testing of RI-002 and for working capital and other general corporate purposes.
Risk factors	See “Risk Factors” beginning on page 8 for a discussion of risks you should consider before purchasing shares of our common stock.
Proposed OTC Bulletin Board symbol	

Unless otherwise noted, the number of shares of our common stock to be outstanding after this offering is based on 5,871,002 shares outstanding as of March 31, 2013, and excludes:

- 774,798 shares of common stock issuable upon the exercise of options outstanding as of March 31, 2013 at a weighted average exercise price of $6.88 per share;
- 143,337 shares of common stock issuable upon the exercise of warrants outstanding as of March 31, 2013 at a weighted average exercise price of $7.56 per share; and
- 128,426 shares of common stock reserved for future issuance under our stock option plans.

Unless we specifically state otherwise, all information in this prospectus assumes no exercise of the underwriters’ option to purchase additional shares of common stock.

Certain of our existing stockholders, including Aisling Capital II, LP, Burrill Capital Fund IV, LP and certain other affiliates, have indicated an interest in purchasing an aggregate of up to approximately $5.0 million of our common stock in this offering at the initial public offering price . O f this amount, the underwriters have reserved $560,000 for purchase by our directors, executive officers, certain of their affiliates and others associated with us through a directed share program. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may sell more, less or no shares in this offering to any of these persons , or any of these persons may

determine to purchase more, less or no shares in this offering.

Table of Contents

Summary Consolidated Financial Information

This section presents our summary historical consolidated financial data. You should read carefully the consolidated financial statements included in this prospectus, including the notes to the consolidated financial statements. The summary consolidated data in this section are not intended to replace the consolidated financial statements.

We derived the statement of operations data for the years ended December 31, 2011 and 2012 and the balance sheet data as of December 31, 2011 and 2012 from the audited consolidated financial statements included in this prospectus.

	For the year ended December 31,	
	2011	2012
Statement of Operations Data:		
Revenues	$ 761,042	$ 1,118,118
Cost of sales	207,570	669,056
Gross profit	553,472	449,062
Operating expenses:		
Research and development	646,756	3,469,078
Loss on sale of inventory	1,934,630	-
Plasma center operating expenses	1,163,148	1,746,864
General and administrative	1,431,894	3,142,289
Total operating expenses	5,176,428	8,358,231
Loss from operations	(4,622,956)	(7,909,169)
Other income (expense), net	(1,601,269)	(9,759)
Loss before income taxes	(6,224,225)	(7,918,928)
State income tax benefit	320,765	617,615
Net loss	$ (5,903,460)	$ (7,301,313)
Basic and diluted net loss per common share	$ (13.16)	$ (1.39)
Weighted average common shares outstanding—basic and diluted	448,434	5,265,771

Table of Contents

	As of December 31, 2011	2012
Balance Sheet Data:		
Current assets	$ 1,294,360	$ 13,948,138
Total assets	$ 2,925,909	$ 15,555,419
Total liabilities	$ 2,540,093	$ 6,131,673
Total stockholders' equity	$ 385,816	$ 9,423,746
Total liabilities and stockholders' equity	$ 2,925,909	$ 15,555,419

Table of Contents

Risk Factors

There are numerous and varied risks that may prevent us from achieving our goals. We believe that the following are the material risks that we face. If any of the following risks actually occurs, our business, financial condition or results of operation may be materially adversely affected. In such case, the trading price of our common stock could decline and investors in our common stock could lose all or part of their investment.

Risks Relating to our Business

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

To date, we have generated limited revenues. All of our revenues to date have been derived from the sale of plasma collected by ADMA BioCenters, as well as our other plasma inventory sales. Unless and until we receive approval from the FDA and other regulatory authorities for our RI-002 product candidate, we will be unable to sell and generate revenues from that product. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from the revenues that may be generated by the sale of plasma collected by ADMA Biocenters, as well as cash on hand and potential future capital raises. While ADMA BioCenters is committed to maintain compliance with all applicable regulations, we cannot assure you that we will be able to retain the FDA license for our plasma collection center, which we need in order to sell plasma collected by ADMA BioCenters. We also cannot assure you that the net proceeds from this offering will be sufficient to enable us to complete the FDA approval process for our RI-002 product candidate.

If we are unable to successfully raise sufficient additional capital, we will likely not have sufficient cash flow and liquidity to fund our business operations, forcing us to curtail our activities and, ultimately, potentially cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, resulting in significant dilution of stockholders' interests and, in such event, the value and potential future market price of our common stock may decline.

We anticipate that, based upon our projected revenue and expenditures, our current cash and cash equivalents, along with (i) our option to borrow additional funds under the terms and conditions of our Loan Agreement, and (ii) a backstop financing agreement with the lead investors from the 2012 Financing will be sufficient to fund our operations into the second quarter of 2014. If we complete this offering, the expected net proceeds from the sale of the shares offered hereby, if added to our current cash and cash equivalents and our option to borrow additional funds under the terms and conditions of our loan agreement, is anticipated to be sufficient to fund our operations into the first half of 2016. If our assumptions underlying our estimated expenses prove to be wrong, we may have to raise additional capital sooner than anticipated, and we currently do not have arrangements to obtain additional financing. Any such financing could be difficult to obtain or only available on unattractive terms and could result in significant dilution of stockholders' interests. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business plan and financial performance and could delay, discontinue or prevent product development and clinical trial activities or the approval of any of our potential products. In addition, we could be forced to reduce or forego sales and marketing efforts and forego attractive business opportunities.

Our shares have never traded and even after the completion of this offering, trading volume in our shares could be limited.

We have been a public reporting company since February 13, 2012. However, we have fewer than ten stockholders and there is not currently, nor has there ever been, any public market for our common stock. We have applied to have

our common stock quoted on the OTC Bulletin Board after this offering. However, to the extent that we will not be eligible for listing on the NASDAQ or any other national securities exchange for 12 months, our trading volume and the liquidity of our shares could be limited. In addition, even after the completion of this Offering, we may not have a widespread retail distribution of our shares and our trading volume and liquidity could be limited. Accordingly, we cannot assure you that after the completion of the offering there will be significant trading in our shares, that there will be support for the trading thereof, that trading prices will not be volatile or that you will be able to dispose of your shares, if you so choose, at prices that are reflective of the value of the shares.

We are not currently profitable and may never become profitable.

We have a history of losses and expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we may never achieve or maintain profitability. For the years ended December 31, 2011 and December 31, 2012, we had a net loss of $5.9 million and $7.3 million, respectively, and from our inception in 2004 through December 31, 2012, we have incurred a net loss of $37.1 million. Even if we succeed in developing and commercializing one or more product candidates, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially in the foreseeable future as we:

· continue to undertake development and clinical trials for RI-002;

· seek regulatory approval(s);

Table of Contents

· implement additional internal systems, controls and infrastructure; and

· hire additional personnel.

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

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

We have not demonstrated an ability to perform the functions necessary for the successful commercialization of RI-002. The successful development and commercialization of any product candidate will require us or our collaborators to perform a variety of functions, including:

· undertaking product development and clinical trials;

· participating in regulatory approval processes;

· formulating and manufacturing products; and

· conducting sales and marketing activities once authorized.

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

Our current product candidate, RI-002, requires extensive additional clinical testing. Clinical trials are very expensive, time-consuming and difficult to design and implement. If we are unsuccessful in obtaining regulatory approval for RI-002 or any of our product candidates don't provide positive results, we may be required to delay or abandon development of such product, which would have a material adverse impact on our business.

Continuing product development requires additional and extensive clinical testing. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time consuming. We cannot provide any assurance or certainty regarding when we might complete the clinical trial process or submit a Biological License Application, or BLA, for regulatory approval for RI-002 or whether any such BLA will be accepted or approved. We estimate that clinical trials of our product candidate will take at least 18 months to several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

· unforeseen safety issues;

· determination of dosing issues;

· lack of effectiveness during clinical trials;

· slower than expected rates of patient recruitment;

· inability to monitor patients adequately during or after treatment; and

· inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, we or the FDA or an Institutional Review Board, or IRB, may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our Investigational New Drug Application, or IND, submissions or the conduct of these trials. Therefore, we cannot provide any assurance or predict with certainty the schedule for future clinical trials. No assurance can be given that we will be able to enroll sufficient patients to complete a successful Phase III clinical trial.

Table of Contents

In the event we do not ultimately receive regulatory approval for RI-002, we may be required to terminate development of our only product candidate. Unless we acquire or develop other product candidates that are saleable, our business will be limited to plasma collection and sales.

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.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate 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 the filing of a BLA with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. In addition, our clinical trials involve a relatively small patient population. Because of the small sample size, the results of these clinical trials may not be indicative of future results. In addition, certain portions of the clinical trial for RI-002 were performed outside the United States, and therefore, may not have been performed in accordance with standards normally required by the FDA and other regulatory agencies.

Currently, our only viable product candidate is RI-002. If we do not obtain the necessary U.S. or worldwide regulatory approvals to commercialize RI-002, or any other product candidate, we will not be able to sell RI-002.

At the present time, our entire focus is obtaining regulatory approval for RI-002, our only product candidate. If we cannot obtain regulatory approval for RI-002, our only source of revenue will be plasma collection and sales. We cannot assure you that we will receive the approvals necessary to commercialize RI-002 or any other product candidate we may acquire or develop in the future. In order to obtain FDA approval of RI-002 or any other 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 submit a BLA. To attain required FDA approval of any other 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. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive product revenues from, our product candidate;
- impose costly procedures on us; and
- diminish any competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately reject our BLA. We may never obtain regulatory approval for RI-002 or any other potential product candidate. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by leaving us without a saleable product beyond the plasma collected by ADMA BioCenters, and therefore without any source of additional revenues if and until another product candidate

can be developed and commercialized. There is no guarantee that we will ever be able to develop or acquire another product candidate.

Table of Contents

In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize any products. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. We cannot assure you that we will receive the approvals necessary to commercialize any product candidate for sale outside the United States.

We depend on third-party researchers and developers to develop RI-002, and such parties are, to some extent, outside of our control.

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

Relying exclusively on third parties to manufacture our product candidates exposes us to risks that may delay testing, development, regulatory approval and commercialization of our product candidates.

We have limited experience in manufacturing and do not intend to establish our own manufacturing facilities. We lack the resources to manufacture RI-002. Although we have agreements pertaining to the manufacture, supply, storage and distribution of product supplies of RI-002, upon commercialization, it is possible that our manufacturing requirements may exceed the available supply allotments under our existing agreements. We will rely on one or more third-party contractors to manufacture our products. Our anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.

- Third-party manufacturers might be unable to manufacture our products in the volume and of the quality required to meet our clinical and commercial needs, if any.

- Contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.

- Product manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration, and corresponding state agencies to ensure strict compliance with good manufacturing practice and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

- If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation. We may be required to pay fees or other costs for access to such improvements.

Table of Contents

Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenues.

If physicians and patients do not accept and use our product, our ability to generate revenue from sales will be materially impaired.

Even if the FDA approves RI-002, physicians and patients may not accept and use it. Acceptance and use of our product will depend on a number of factors including:

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

Because we expect sales of RI-002, if approved, to generate substantially all of our product revenues other than the revenue attainable from the sale of plasma collected by ADMA BioCenters, the failure of this product 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 RI-002 product candidate through new product development or the in-license or acquisition of other new products, and if our business development efforts are not successful, our ability to achieve profitability may be negatively impacted.

Our current product development portfolio consists primarily of RI-002. We intend to seek to expand our current portfolio through new product development efforts or to in-license or acquire additional products. If we are not successful in developing or acquiring additional products, we will have to depend on our ability to raise capital for, and the successful development and commercialization of, RI-002 and the revenue we may generate from the sale of plasma attributable to the operations of ADMA BioCenters.

Our loan and security agreement with Hercules is subject to acceleration in specified circumstances, which may result in Hercules taking possession and disposing of any collateral.

On December 21, 2012, we entered into a Loan and Security Agreement, or the Loan Agreement, with Hercules Technology Growth Capital, Inc., or Hercules. Under the Loan Agreement, we may borrow up to a maximum of $6 million. We borrowed $4 million on the closing date, have recently borrowed an additional $1 million upon reaching our first milestone under the agreement and have the option to borrow an additional $1 million upon the satisfaction of a second milestone. Our obligations under the Loan Agreement are secured by a security interest in all of our assets, except for our intellectual property (which is subject to a negative pledge). The Loan Agreement contains customary representations, warranties and covenants, including limitations on acquisitions, dispositions, incurrence of indebtedness and the granting of security interests. Upon the occurrence and during the continuance of any event of default, including upon the occurrence of any event deemed to result in a material adverse event, Hercules may, and at the written request of the requisite lenders shall, terminate the commitments under the facilities and declare any or all of the obligations to be immediately due and payable, without demand or notice to us. However, any event of default relating to timely payment of debts, insolvency, liquidation, bankruptcy or similar events will result in automatic acceleration. Among the remedies available to Hercules in case of an event of default are the taking possession and

disposition of any collateral under the Loan Agreement.

Table of Contents

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. Should we obtain regulatory approval for RI-002 or any future product we may develop, we will have to compete with existing 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 United States and abroad. In addition, companies pursuing different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater capital 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.

We do not own any issued patents and we do not have any patent applications currently pending relating to our primary product candidate. If we are unable to protect our trade secrets or other proprietary rights, our competitiveness and business prospects may be materially damaged.

We do not own any issued patents and we do not have any patent applications currently pending relating to our primary product candidate. Rather, we rely exclusively on a combination of 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 trade secret policies and practices or other agreements will adequately protect our intellectual property. 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.

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

We may not be able to operate our business without infringing third-party patents. Numerous U.S. and foreign patents and pending patent applications owned by third parties exist in fields that relate to the development and commercialization of immune globulins. In addition, many companies have employed intellectual property litigation as a way to gain a competitive advantage. It is possible that infringement claims may occur as the number of products and competitors in our market increases. In addition, to the extent that we gain greater visibility and market exposure as a public company, we face a greater risk of being the subject of intellectual property infringement claims. We cannot be certain that the conduct of our business does not and will not infringe intellectual property or other proprietary rights of others in the United States and in foreign jurisdictions. If our products, methods, processes and other technologies are found to infringe third party patent rights, we could be prohibited from manufacturing and commercializing the infringing technology, process or product unless we obtain a license under the applicable third party patent and pay royalties or are able to design around such patent. We may be unable to obtain a license on terms acceptable to us, or at all, and we may not be able to redesign our products or processes to avoid infringement. Even if we are able to redesign our products or processes to avoid an infringement claim, our efforts to design around the

patent could require significant time, effort and expense and ultimately may lead to an inferior or more costly product and/or process. Any claim of infringement by a third party, even those without merit, could cause us to incur substantial costs defending against the claim and could distract our management from our business. Furthermore, if any such claim is successful, a court could order us to pay substantial damages, including compensatory damages for any infringement, plus prejudgment interest and could, in certain circumstances, treble the compensatory damages and award attorney fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. A court also could enter orders that temporarily, preliminarily or permanently prohibit us, our licensees, if any, and our customers from making, using, selling, offering to sell or importing one or more of our products or practicing our proprietary technologies or processes, or could enter an order mandating that we undertake certain remedial activities. Any of these events could seriously harm our business, operating results and financial condition.

Table of Contents

Continued instability in the credit and financial markets may negatively impact our business, results of operations, and financial condition.

Financial markets in the United States, Canada, Europe and Asia continue to experience disruption, including, among other things, significant volatility in security prices, declining valuations of certain investments, as well as severely diminished liquidity and credit availability. Business activity across a wide range of industries and regions continues to be greatly reduced and local governments and many businesses are still suffering from the lack of consumer spending and the lack of liquidity in the credit markets. As a clinical-stage biotechnology company, we rely on third parties for several important aspects of our business, including contract manufacturing of drug product, plasma collection supplies, transportation and storage of plasma, and conduct of our clinical trials. These third parties may be unable to satisfy their commitments to us due to tightening of global credit from time to time, which would adversely affect our business. The continued instability in the credit and financial market conditions may also negatively impact our ability to access capital and credit markets and our ability to manage our cash balance. While we are unable to predict the continued duration and severity of the adverse conditions in the United States and other countries, any of the circumstances mentioned above could adversely affect our business, financial condition, operating results and cash flow or cash position.

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

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

If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.

We will need to hire additional qualified personnel with expertise in finance and accounting, clinical research and testing, government regulation, formulation and manufacturing and sales and marketing. In particular, over the next 12 months, we expect to hire up to 10 new employees devoted to medical and scientific affairs, regulatory affairs, quality control, financial services, and general and operational management. We expect that the hiring of such additional personnel will increase our annual expenditures by approximately $1.5 million or more. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot assure you that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success, and any failure to do so successfully may have a material adverse effect on us.

Table of Contents

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

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

Many of our business practices are subject to scrutiny by 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.