#### **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION WASHINGTON, DC 20549

#### **FORM 10-K**

(Mark One)  $\mathbf{X}$ 

#### ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) **OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2014

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 0-9314** 

# PLASMATECH BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

4848 Lemmon Avenue, Suite 517, Dallas, TX (Address of principal executive offices)

Registrant's telephone number, including area code: (214) 905-5100

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: Common Stock, \$0.01 par value

**Title of each Class** 

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.Yes 🗆 No X

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.Yes D No X

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  $\boxtimes$  No  $\square$ 

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 🖾 No 🗖

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. □

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 definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Act. (Check one):

83-0221517 (I.R.S. Employer Identification No.)

> 75219 (Zip Code)

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the average bid and asked price of such common equity, as of June 30, 2014, was approximately \$22,081,000.

The number of shares outstanding of the registrant's common stock as of March 30, 2015 was 19,988,801 shares.

#### DOCUMENTS INCORPORATED BY REFERENCE.

Portions of the registrant's definitive Proxy Statement relating to our 2015 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated.

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#### FORWARD-LOOKING STATEMENTS

This Form 10-K (including the information incorporated by reference) contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and that involve risks and uncertainties. These statements include, without limitation, statements relating to uncertainties associated with research and development activities, clinical trials, our ability to raise capital, the timing of and our ability to achieve regulatory approvals, dependence on others to market our licensed products, collaborations and our ability to attract licensing partners, future cash flow, the timing and receipt of licensing and milestone revenues, the future success of our marketed products and products in development, our sales projections, and the sales projections of our licensing partners, our ability to achieve licensing milestones, the size of the prospective markets in which we may offer products, anticipated product launches and our commercialization strategies, anticipated product approvals and timing thereof, product opportunities, clinical trials and U.S. Food and Drug Administration ("FDA") applications, as well as our drug development strategy, our clinical development organization expectations regarding our rate of technological developments and competition, our plan not to establish an internal marketing organization, our expectations regarding minimizing development risk and developing and introducing technology, the terms of future licensing arrangements, our ability to secure additional financing for our operations, our ability to establish new relationships and maintain current relationships, our ability to attract and retain key personnel, our belief that we will not pay any cash dividends in the foreseeable future, our belief that a failure to obtain necessary additional capital in the future will result in our operations being jeopardized, our belief that we will expend substantial funds to conduct research and development programs, preclinical studies and clinical trials of potential products, our belief that the market for a mucositis product is in excess of \$1 billion, our belief that we have a rich pipeline of products and product candidates, our belief that recently licensed technology will enable us to provide new therapeutic applications and expand market opportunities while enhancing margins, our belief that we will continue to evaluate the most cost-effective methods to advance our programs, and our expected cash burn rate. These statements relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "could," "anticipates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of such terms or other comparable terminology. We intend the forward-looking statements to be covered by the safe harbor for forward-looking statements in these sections. The forward-looking information is based on various factors and was derived using numerous assumptions.

Forward-looking statements necessarily involve risks and uncertainties, and our actual results could differ materially from those anticipated in the forward-looking statements due to a number of factors, including those set forth below in Item 1A. Risk Factors and elsewhere in this Form 10-K. The factors set forth under "Risk Factors" and other cautionary statements made in this Form 10-K should be read and understood as being applicable to all related forward-looking statements wherever they appear in this Form 10-K. The forward-looking statements contained in this Form 10-K represent our judgment only as of the date of this Annual Report on Form 10-K. We caution readers not to place undue reliance on such statements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

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#### PART I

### **ITEM 1. BUSINESS**

#### Business

PlasmaTech Biopharmaceuticals, Inc. (together with our subsidiaries, "we", "our", "PlasmaTech" or the "Company") is a Delaware corporation. We are an emerging biopharmaceutical company focused on developing a range of pharmaceutical products primarily based upon our nanopolymer chemistry technologies and salt diafiltration process ("SDF") technology recently licensed from Plasma Technologies LLC ("Licensor"). We currently have one marketed product licensed in the U.S., Europe, China, Australia, New Zealand and Korea. We also have additional products and platform technologies in various stages of development and/or to license the technology.

#### **Marketed Product**

MuGard® is our marketed product for the management of oral mucositis, a frequent side effect of cancer therapy for which there is no established treatment. The market for mucositis treatment is estimated to be in excess of \$1.0 billion worldwide. MuGard, a proprietary nanopolymer formulation, has received marketing clearance in the U.S. from the FDA. We launched MuGard in the U.S. in 2010.

On August 5, 2010, we entered into an exclusive license with RHEI Pharmaceuticals, N.V. ("RHEI") related to the commercialization of MuGard in China and other Southeast Asian countries. Our China partners have received an acceptance letter from the State Food and Drug Administration of the People's Republic of China, which provides marketing approval in China. MuGard has been manufactured in the U.S. and shipped to China for sale. RHEI has rights to sub-license MuGard sales in some Southeast Asia countries.

#### Recent Developments

On June 6, 2013 we entered into an exclusive license agreement with AMAG Pharmaceuticals, Inc. ("AMAG"), related to the commercialization of MuGard in the U.S. and its territories. Under the terms of the licensing agreement we received an upfront licensing fee of \$3.3 million and a tiered, double-digit royalty on net sales of MuGard in the licensed territory. We receive quarterly royalty payments from AMAG.

On March 11, 2014, we announced we had entered into an exclusive license agreement with Hanmi Pharmaceutical Co. Ltd. ("Hanmi") related to MuGard commercialization in South Korea. Under the terms of the agreement, we received an upfront licensing fee and will receive double digit royalties on sales of MuGard in the licensed territory.

On July 8, 2014, we announced we received notification from the Hong Kong Patent Office that a patent for MuGard had been granted.

On August 7, 2014, we entered into an exclusive license agreement with Norgine B.V. ("Norgine"), a leading independent European specialty pharmaceutical company, for the commercialization of MuGard in Europe. Under the terms of the license agreement, we could receive up to \$10 million in milestone payments and an escalating double digit royalty on the net sales of the oral mucositis product, MuGard, in the licensed territories. Norgine will develop, manufacture, and commercialize MuGard in the European Union, Switzerland, Norway, Iceland and Lichtenstein. Norgine anticipates launching MuGard in 2015.

On September 12, 2014, we announced we had received notification from the European Patent Office that an additional European patent for MuGard had been granted. The patent (EP1997478) protects a wide range of liquid formulations for the prevention and treatment of mucosal diseases and disorders.

On October 27, 2014, we entered into an exclusive license agreement with Norgine for the commercialization of MuGard in Australia and New Zealand. The terms of the agreement are congruent to our recent license with Norgine for MuGard in Europe. Norgine intends to develop, manufacture and commercialize MuGard in the new territories.

We are actively seeking partners to license MuGard in other territories.

#### **Product Candidates**

- ProctiGardTM received 510(K) marketing clearance from the FDA on July 22, 2014 for the treatment of symptomatic management of rectal mucositis. ProctiGard is our product for the treatment of radiation proctitis, a frequent side effect of radiation treatment to the pelvic region. Radiation proctitis, or RP, is the inflammation and damage to the lower portion of the colon after exposure to x-rays or ionizing radiation as part of radiation therapy. RP is most common after treatments for cancer, such as cervical, colon and prostate cancer. RP can be acute, occurring within weeks of initiation of therapy, or can occur months or years after treatment. We intend to commercialize ProctiGard in a manner similar to the commercialization of MuGard, which may include confirmatory clinical trials, with the objective of commercialization in collaboration with marketing partners globally.
- We are also developing additional products using our proprietary mucoadhesive hydrogel technology as a mucoprotectant and/or delivery vehicle, as well as our vitamin B-12 mediated delivery technology.

#### **PlasmaTech Portfolio Summary**

Compound	Originator Technology Indication		Indication	Clinical Stage <sup>(1)</sup>			
MuGard®	PlasmaTech	Mucoadhesive liquid	Mucositis	<ul> <li>Launched in U.S.</li> <li>Licensed to AMAG: U.S. rights</li> <li>Licensed to Norgine: European Union rights</li> <li>Licensed to RHEI: China rights and other SE Asian countries</li> <li>Licensed to Hanmi: South Korea rights</li> <li>Licensed to Norgine: Australia &amp;</li> </ul>			
				New Zealand rights			
Proctigard <sup>TM</sup>	PlasmaTech	Mucoadhesive hydrogel technology	Radiation proctitis	FDA clearance 7/22/14			
Alpha 1 Protease Inhibitor (A1PI)	Licensor	Proprietary biological processing	Various	Process validation			
Intravenous immune globulin (IVIG)	Licensor	Proprietary biological processing	Various	Process validation			

(1) For more information, see "Government Regulation" beginning on page <u>10</u> for description of clinical stages.

### **SDF Licensed Technology**

#### Background

On September 22, 2014, we entered into an exclusive, worldwide, licensing agreement with Licensor to obtain rights to utilize and to sub-license to other pharmaceuticals firms, its patented methods for the extraction of therapeutic biologics from human plasma.

Under the terms of the licensing agreement, as amended on January 23, 2015, we paid a license fee of \$1 million in cash, will pay \$4,000,000 in cash or 1,096,151 shares of our common stock in 2017, a regulatory approval milestone payment of 513,375 shares of our common stock upon the first FDA regulatory approval

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of a drug derived from the Licensor's proprietary SDF process, and a tiered royalty on annual net sales of plasma fractions produced with Licensor's proprietary SDF process.

Plasma biologics are bio-pharmaceutical proteins extracted, purified, and formulated from human blood plasma by the use of biotechnological processing techniques including precipitation, diafiltration, affinity chromatography, and ion-exchange chromatography. These products are rendered virus-safe by means of chemical treatment, nanofiltration, and pasteurization. FDA exercises rigorous control of plasma collection to assure its safety. Because plasma biologics are biosimilar, they are less likely than recombinant or transgenic proteins to cause toxic or other adverse reactions, or cause adverse immunological responses such as the stimulation of inhibitors in recipients.

Plasma biologics primarily address indications arising from genetic deficiencies which are increasingly being identified by means of newly available rapid and low cost diagnostic genetic tests. Examples of plasma biologics include Alpha 1 Protease Inhibitor ("A1PI"), Intravenous Immune Globulin ("IVIG"), Anti-Hemophilic Factor VIII ("AHF") and Albumin, to name a few.

Plasma biologics are currently obtained from human plasma by a fractionation process known as the Cohn Cold Ethanol Fractionation Process ("Cohn Process"), which was developed prior to World War II to provide a stable solution of human albumin for the rapid treatment of hemorrhagic shock on the battlefield. This process employs various concentrations of ethanol combined with adjustments of pH, ionic strength, and temperature to bring about the necessary separations by precipitation. This process has been used for over 70 years and is still currently considered an industry standard.

#### Licensor

Licensor was founded to develop superior high-yield technology to extract a wide range of therapeutically useful proteins from human blood plasma. Its founder, Eugene J. Zurlo, saw the opportunity to utilize new technology to replace the now 74-year-old Cohn Process in order to fundamentally change the economics of plasma fractionation, improve the quality of existing plasma biologics, and enable the extraction of additional useful plasma proteins.

Due to technology limitations in 1940, E.J. Cohn and his team at Harvard University were compelled to use ethanol combined with changes in pH, ionic strength, and temperature in a lengthy multi-step process to bring about the separation of albumin. In addition to the denaturing effects on plasma proteins by prolonged exposure to ethanol and pH changes from neutrality, commercial production facilities had to be explosion-proof and refrigerated, and were thus highly capital intensive.

Licensor's SDF Process uses salt as the precipitant at neutral pH, followed by salt removal by diafiltration, followed by the use of state-of-the-art chromatography for final separations and purification. The efficacy of the process has been confirmed in pilot scale batches in two independent laboratories. While several salts were found to work, Sodium Citrate was selected because of its "friendliness" to biologics, having been long used as an FDA approved protectant and preservative of whole blood and blood plasma.

The Licensor Process enables the production of unusually high yields of A1PI and IVIG compared with the Cohn process and comparable yields of Anti-Hemophilic Factor VIII, which separation occurs before either the Cohn or Licensor Process. Because the Licensor Process optimizes the yields of the more valuable A1PI and IVIG, its yields of less valuable albumin are somewhat lower than for Cohn fractionation.

Licensor's short, two-step salt precipitation process, in contrast to the highly denaturing Cohn process, may also enable the extraction of several additional plasma biologics by means of downstream affinity and/or ion-exchange chromatography, thus potentially further improving revenues and process economics derivable from the same starting plasma. Examples of these additional therapeutic proteins are C-1-Esterase Inhibitor, Protein C, Antithrombin III, Transferrin, and Haptoglobin, all of which are used as treatments for low-incidence genetic deficiencies which could qualify them as Orphan Drugs.

We believe that Licensor's proprietary fractionation process is expected to significantly enhance yields of key value blood proteins, including A1PI, expanding market opportunities, while greatly enhancing margins. The Company obtained rights to utilize and sub-license to other pharmaceutical firms the recently patented improved methods for the extraction of therapeutic biologics from human plasma. We believe that Licensor's



lead product, A1PI, offers a low-risk, high revenue, short time-to-market respiratory product for treatment of inherited COPD (pulmonary emphysema), among other genetic A1PI deficiencies. Additionally, the ability to extract several additional therapeutically useful and important proteins, due to the process being less destructive than historical fractionation processes, may enable us to seek new therapeutic applications and address high-value-added orphan indications.

#### Plasma Biologic Product Targets

### <u>A1PI</u>

A1PI is a protease inhibitor that protects tissues from enzymes produced by inflammatory cells, especially neutrophil elastase. Its normal concentration in human plasma is 1.8 to 3.5 grams per liter. The Licensor Process recovers at least 70% of the target A1PI, about 10 times that currently yielded from the Cohn process.

A1PI Deficiency is a genetic condition resulting in damage to lung, liver, and pancreatic tissues, with pulmonary emphysema being the most common indication. Approximately 1 in 3,000 Caucasians suffer from the genetic deficiency, with over 150,000 people in North America and Europe living with the deficiency. Treatment involves lifelong weekly injections of A1PI of at least 60 mg/Kg of body weight, or about 200 grams per year. Less than 5% of the treatable worldwide population receive A1PI therapy.

A1PI also exerts immunomodulatory as well as anti-viral and anti-bacterial effects independent of protease inhibition. Administration of A1PI in non-deficient individuals may interfere with disease progression in the following conditions: Diabetes (Type 1 and 2), acute myocardial infarction, inflammatory bowel disease, cystic fibrosis, graft vs. host disease, stroke, Alzheimer's disease, vasculitis, organ transplantation, and multiple sclerosis. The number of new potential therapeutic indications for A1PI could create supply problems due to the challenge of producing sufficient quantities using current plasma extraction methods to meet the demand created by the growing number of clinical indications. It is the view within the industry that the supply of A1PI (without new indications) is currently nearing capacity. The increase in demand, coupled with the limitations of plasma supply and the shortcomings of the Cohn Fractionation Process, combine to underscore the need for a high-yield process such as the Licensor Process.

### IVIG

IVIG is extracted from human plasma and contains a broad spectrum of Immunoglobulin G (IgG) antibodies. On-label indications of IVIG include Primary immune deficiencies of genetic origin (estimated 10 million potential patients worldwide; 60,000 currently treated with IVIG), Chronic lymphocytic leukemia, Idiopathic thrombocytopenia, Pediatric HIV, Allogeneic bone marrow transplantation, Kidney transplantation, and Kawasaki syndrome.

IVIG is currently the main driver for manufacturers utilizing the Cohn Process. Approximately 25 million liters of plasma are processed to produce approximately \$7 Billion of revenue. Licensor Process improves yields by at least 10% and is expected to extend half-life in circulation due to reduced denaturation. It also may eliminate thromboembolic events and other adverse events attributed to Cohn process.

### AHF

AHF is used to treat Hemophilia A, a genetic disease occurring in 1:6,000 male births. Because dose weight is miniscule, a recombinant form can be produced in cell culture to augment production from human plasma. Plasma-derived AHF is extracted from the cryoprecipitate formed during the thawing of Source Plasma before salt or ethanol precipitation. Its use is growing in developing markets; however an estimated 300,000 potential patients worldwide, or  $\sim$ 70%, of potential patients remain untreated.

#### Other Potential Products

Because Licensor's patented sodium citrate extraction process does not have the destructive effects associated with the Cohn Cold Ethanol Process, it becomes possible to extract additional valuable low-dosage biotherapeutic agents for genetic deficiencies through the use of state-of-the-art affinity chromatography now widely available. The following examples include, but not limited to, other biotherapeutics, potentially available through the use of the SDF process:

• C-1-esterase inhibitor treats hereditary angioma (HAE). Its genetic incidence: 1:10,000 – 1:50,000.

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- Protein C is used to treat venous thromboembolic events. Prevalence of Protein C deficiency is 0.2 0.5%.
- Antithrombin III inactivates thrombin and is used to treat thrombotic disorders. Its deficiency occurs in 1:2000 1:5000 in a normal population, but can also be acquired as a result of various diseases.

#### **Approved Product**

#### <u>MuGard®</u>

Mucositis is a debilitating condition involving extensive ulceration of the oral cavity that affects annually an estimated 400,000 cancer patients in the U.S. undergoing chemotherapy and radiation treatment. We believe that any treatment that would accelerate healing and/or diminish the rate of appearance of mucositis would have a significant beneficial impact on the quality of life of these patients and may allow for more aggressive chemotherapy. We believe the potential addressable market for a mucositis product could be over \$1.0 billion worldwide.

MuGard is a viscous hydrogel polymer solution that provides a protective coating for the oral cavity. MuGard is dispensed in a ready-to-use form. A multi-site, randomized clinical study was performed in the U.S. testing MuGard and MuGard containing an anti-inflammatory drug to determine the effect of these products on the prevention and treatment of mucositis. The data from this trial indicated that the patients using MuGard displayed a lower incidence of mucositis than is typically seen in the studied population with no additional benefit from the drug.

The data were retrospectively compared with two historical patient databases to evaluate the potential advantages MuGard may provide in the prevention, treatment and management of mucositis. The patient evaluation was conducted using the oral mucositis assessment scale (OMAS), which qualifies the disease severity on a scale of 0 to 5. Key highlights of the comparison with the historical patient databases are as follows:

- the average severity of the disease was reduced by approximately 40%;
- the maximum intensity of the mucositis was approximately 35% lower; and
- the median peak intensity was approximately 50% lower.

These data confirmed the fact that MuGard could represent an important advancement in the management of mucositis. On December 13, 2006, we announced our receipt of marketing clearance for MuGard from the FDA for the indication of the management of oral wounds including mucositis, aphthous ulcers and traumatic ulcers.

On July 29, 2009, we took control of the North American rights to MuGard from a previous partner which had not received required funding to launch the product in the U.S.

On September 11, 2009, we announced the appointment of Accupac, Inc. as our U.S. manufacturer for MuGard. We launched MuGard in the U.S. in the fourth quarter of 2010. MuGard had been launched in Germany, Italy, UK, Greece and the Nordic countries by our former European commercial partner, SpePharm. Our partners in China have received registration and marketing approvals.

On June 6, 2013 we entered into an exclusive license agreement with AMAG related to the commercialization of MuGard in the U.S. and its territories. Under the terms of the licensing agreement, we received an upfront licensing fee of \$3.3 million and a tiered, double-digit royalty on net sales of MuGard in the licensed territory. AMAG also purchased our existing MuGard inventory.

On March 11, 2014, we announced we had entered into an exclusive license agreement with Hanmi Pharmaceutical Co. Ltd. ("Hanmi") related to MuGard commercialization in South Korea. Under the terms of the agreement, we received an upfront licensing fee and will receive double digit royalties on sales of MuGard in the licensed territory.

On August 7, 2014, we entered into an exclusive license agreement with Norgine, an independent European specialty pharmaceutical company, for the commercialization of MuGard in Europe. Under the terms of the license agreement, we could receive up to \$10 million in milestone payments and an escalating double digit

royalty on the net sales of the oral mucositis product, MuGard, in the licensed territories. Norgine will develop, manufacture, and commercialize MuGard in the European Union, Switzerland, Norway, Iceland and Lichtenstein. Norgine anticipates launching MuGard in 2015.

On October 27, 2014, we entered into an exclusive license agreement with Norgine B.V., a European specialist pharmaceutical company, for the commercialization of MuGard in Australia and New Zealand. The terms of the agreement are congruent to our recent license with Norgine for MuGard in Europe. Norgine intends to develop, manufacture and commercialize MuGard in the new territories.

On March 5, 2015, we announced that enrollment has begun in a clinical trial at UCLA's Jonsson Comprehensive Cancer Center that is evaluating MuGard in the prevention and treatment of stomatitis in breast cancer patients using everolimus (marketed by Novartis Oncology under the tradename Afinitor®). The title of the trial is "Phase II Randomized Trial of MuGard Compared With Best Supportive Care for Prevention and Treatment of Stomatitus in Women With Hormone Receptor Poistive Breast Cancer Initiating Treatment With Everolimus-based Endocrine Therapy".

We initiated a new clinical study of the safety and effectiveness of MuGard in the first quarter of 2011. The study was a controlled, randomized, double-blinded trial of MuGard with a standard treatment for mucositis as a comparator in patients receiving chemoradiation for head and neck cancer. On February 18, 2014, we announced the online publication of the final results of our post-approval marketing study of MuGard in Cancer, the journal of the American Cancer Society. The publication, entitled "Multi-Institutional, Randomized, Double-Blind, Placebo-Controlled Trial to Assess the Efficacy of a Mucoadhesive Hydrogel (MuGard) in Mitigating Oral Mucositis Symptoms in Patients Being Treated With Chemoradiation Therapy for Cancers of the Head and Neck" is available at *http://onlinelibrary.wiley.com/doi/10.1002/cncr.28553/full*. The publication discusses the results of this post-marketing clinical trial, providing further evidence of the efficacy of MuGard in controlling symptoms caused by oral mucositis in 120 patients receiving chemoradiation therapy for the treatment of cancers of the head and neck.

#### **Other Products in Development**

### ProctiGard<sup>TM</sup>

ProctiGard is our product being developed for the management of radiation proctitis ("RP"), a frequent side effect of radiation treatment to the pelvic region. RP is the inflammation and damage to the lower portion of the colon after exposure to x-rays or ionizing radiation as part of radiation therapy. RP is most common after treatments for cancer, such as cervical, colon and prostate cancer. RP can be acute, occurring within weeks of initiation of therapy, or can occur months or years after treatment. We intend to develop ProctiGard in a manner similar to the development of MuGard, which may include confirmatory clinical trials, with the objective of commercialization in collaboration with marketing partners globally. On July 22, 2014, we received 510(k) marketing clearance from the FDA for ProctiGard.

#### Drug Development Strategy

We have a rich potential pipeline of products and product candidates ranging from preclinical development candidates to one approved product. To maximize return on this portfolio, we plan to develop in-house or with collaborators the following products and technologies: MuGard, Mucoadhesive hydrogel technology and CobOral/CobaCyte.

A part of our integrated drug development strategy is to form alliances with centers of excellence in order to obtain alternative lead compounds while minimizing the overall cost of research. We do not spend significant resources on fundamental biological research but rather focus on our chemistry expertise and clinical development.

We will continue to evaluate the most cost-effective methods to advance our programs. We plan to contract with certain research and development, manufacturing and manufacturing scaleup, preclinical testing and product production to research organizations, contract manufactures and strategic partners as appropriate to achieve cost savings and accelerate our development programs. We also plan to expand our internal core capabilities and infrastructure in the areas of chemistry, formulation, analytical methods development, clinical development, biology and project management to maximize product opportunities in a timely manner.



#### Process

We generally begin the product development effort by screening and formulating potential product candidates, selecting an optimal active component, developing a formulation, and developing the processes and analytical methods. Pilot stability, toxicity and efficacy testing are conducted prior to advancing the product candidate into formal preclinical development. Specialized skills are required to produce these product candidates utilizing our technology. We have a limited core internal development capability with significant experience in developing these formulations, but also depend upon the skills and expertise of our contractors.

Once the product candidate has been successfully screened in pilot testing, our scientists, together with external consultants, assist in designing and performing the necessary preclinical efficacy, pharmacokinetic and toxicology studies required to obtain regulatory approval to conduct clinical trials. External investigators and scaleup manufacturing facilities are selected in conjunction with our consultants. The initial Phase 1 and Phase 2 studies are conducted by institutions and investigators supervised and monitored by our employees and contract research organizations. We do not plan to have an extensive clinical development organization as we plan to have the advanced phases of this process conducted by a development partner. We expect to engage a contract research organization to perform Phase 3 clinical studies to the extent they are conducted.

We contract with third party contract research organizations to complete our large clinical trials and for data management of all of our clinical trials.

With all of our product development candidates, we cannot be certain that the results of the in vitro or animal studies are or will be indicative of the results that will be obtained if and when these product candidates are tested in humans. We cannot be certain that any of these projects will be successfully completed or that regulatory approval of any product will be obtained.

We expended approximately \$333,000 and \$884,000 on research and development during the years ended December 31, 2014 and 2013, respectively.

#### **Other Technology Platforms**

Our other drug delivery technology platforms are:

- Mucoadhesive Hydrogel Technology;
- CobOral® Mediated Oral Delivery Technology; and
- CobaCyte® Mediated Targeted Delivery Technology.

#### Mucoadhesive Hydrogel Technology

MuGard® is the first product to be developed using our Mucoadhesive Hydrogel Technology. MuGard is an innovative mucoadhesive hydrogel product that has been studied clinically in patients with head and neck cancer that are undergoing radiation treatment. Approximately 90% of patients undergoing radiation treatment for head and neck cancer, and 20 - 50% of patients receiving cytotoxic chemotherapy for various cancers experience a condition known as mucositis, a very painful and debilitating ulceration and infection of the oral cavity, which can be severe enough that the patient may forego proper treatment for the underlying cancer. In clinical trials, MuGard was shown to lessen the severity and duration of the mucositis in patients, when compared to no treatment or standard of care practices. The protective coating provided by our Mucoadhesive Hydrogel Technology has the potential to treat other ulcerative conditions of the oral cavity such as oral lichen planus and aphthous ulcers. The Mucoadhesive Hydrogel Technology has the potential to provide the basis for additional products which protect other mucosal surfaces, particularly those which are accessible via an external orifice, such as the throat, esophagus, vagina, and rectum.

The Mucoadhesive Hydrogel Technology was originally developed as a drug-delivery vehicle, and the muco-protectant properties described above were discovered subsequently from clinical and preclinical studies of formulations of the Mucoadhesive Hydrogel Technology. PlasmaTech continues to explore new opportunities from the drug-delivery aspects of the Mucoadhesive Hydrogel Technology. Compounds such as drugs, nutritional supplements and medicinal foods normally diffuse rapidly from aqueous formulations. During the original development of the Mucoadhesive Hydrogel Technology, in vitro studies showed that PlasmaTech's hydrogel formulations slowed the release of the drug amlexanox from the aqueous hydrogel



formulation to a simulated mucosal surface. Prolonged drug exposure (compared with almost instant release) of the mucosa can be beneficial in treating a number of conditions. Slowed drug release can also provide benefit when the drug is required systemically, as evidenced by the large number of 'CR' solid-dose oral formulations that have been developed and brought to the market following initial development and approval of instant release tablet and capsule formulations. We are now applying its Mucoadhesive Hydrogel Technology to the development of products which benefit from both the mucosal protectant and drug delivery aspects of the technology.

# ProctiGard<sup>TM</sup>

ProctiGard is our product being developed for the management of RP, a frequent side effect of radiation treatment to the pelvic region. RP is the inflammation and damage to the lower portion of the colon after exposure to x-rays or ionizing radiation as part of radiation therapy. RP is most common after treatments for cancer, such as cervical, colon and prostate cancer. RP can be acute, occurring within weeks of initiation of therapy, or can occur months or years after treatment. We intend to develop ProctiGard in a manner similar to the development of MuGard, which may include confirmatory clinical trials, with the objective of commercialization in collaboration with marketing partners globally. On July 22, 2014, we received 510(k) marketing clearance from the FDA for ProctiGard.

## <u>CobOral<sup>TM</sup></u> — Mediated Oral Delivery Technology

Oral delivery is the preferred method of administration of drugs where either long-term or daily use (or both) is required. Many therapeutics, including peptide and protein drugs, are poorly absorbed when given orally. With more peptide and protein based biopharmaceuticals entering the market, there is an increasing need to develop an effective oral delivery system for them, as well as for long-standing injected drugs such as insulin.

The difficulty in administering proteins orally is their susceptibility to degradation by digestive enzymes, their inability to cross the intestinal wall and their rapid excretion by the body. Over the years, many different methodologies for making protein drugs available orally have been attempted. Most of the oral protein delivery technologies involve protecting the protein degradation in the intestine. More recently, strategies have been developed that involve co-administering the protein or peptide with permeation enhancers, which assist in passive transit through the gut wall or by attaching the protein or peptide to a molecule that transports the protein across the gut wall. However, the field of oral drug delivery of proteins and peptides has yet to achieve successful commercialization of a product (although positive results have been achieved in early clinical trials for some products under development).

Many pharmaceutically active compounds such as proteins, peptides and cytotoxic agents cannot be administered orally due to their instability in the gastrointestinal tract or their inability to be absorbed and transferred to the bloodstream. A technology that would allow many of these actives to be taken orally would greatly enhance their acceptance and value. Several technologies for the protection of sensitive actives in the gastro-intestinal tract and/or enhancement of gastro-intestinal absorption have been explored and many have failed.

Our proprietary technology for oral drug delivery utilizes the body's natural vitamin B12 ("VB12") transport system in the gut. The absorption of VB12 in the intestine occurs by way of a receptor-mediated endocytosis. Initially, VB12 binds to naturally-produced intrinsic factor ("IF") in the small intestine, and the VB12-IF complex then binds to the IF receptor on the surface of the intestine. Receptor-mediated endocytosis then allows the transport of VB12 across the gut wall. After binding to another VB12-binding protein, transcobalamin II, VB12 is transferred to the bloodstream.

Our scientists discovered that VB12 will still be transported by this process even when drugs, macromolecules, or nanoparticles are coupled to the VB12. Thus CobOral (VB12 conjugatges of drugs, macromolecules, or nanoparticles) serves as a carrier to transfer these materials from the intestinal lumen to the bloodstream. For drugs and macromolecules that are stable in the gastro-intestinal tract, the drug or macromolecule can be coupled directly (or via a linker) to CobOral. If the capacity of the CobOral transport system is inadequate to provide an effective blood concentration of the active, transport can be amplified by attaching many molecules of the drug to a polymer, to which CobOral is also attached. A further option, especially for drugs and macromolecules that are unstable in the intestine, is to formulate the drug in a nanoparticle which is then coated with CobOral. Once in the bloodstream, the active is released by diffusion



and/or erosion of the nanoparticle. Utilization of nanoparticles also serves to "amplify" delivery by transporting many molecules at one time due to the inherently large nanoparticle volume compared with the size of the drug.

Our proprietary position in this technology involves the conjugation of CobOral or its analogs to a polymer to which the drug to be delivered is also attached, or to a nanoparticle in which the drug is incorporated. Since many molecules of the drug are attached to a single polymer strand, or are incorporated in a single nanoparticle, oral uptake is amplified compared to simpler conjugates involving one molecule of the vitamin with one drug molecule. However, in situations when such a simple conjugate might be preferred, our patents also encompass these vitamin-drug conjugates.

# <u>CobaCyte<sup>TM</sup></u> — Mediated Targeted Delivery Technology

Most drugs are effective only when they reach a certain minimum concentration in the region of disease, yet are well distributed throughout the body following delivery to the bloodstream contributing to undesirable side effects. It is therefore advantageous to alter the natural biodistribution of a drug to have it more localized where it is needed. Our CobaCyte-mediated targeted delivery technology utilizes the fact that in many diseases where there is rapid growth and/or cell division, the demand for certain vitamins increases. By coupling the drug to a vitamin analog, the analog serves as a carrier to increase the amount of drug at the disease site relative to its normal distribution.

One application of this technology is in tumor targeting. The use of cytotoxic drugs is one of the most common methods for treating a variety of malignancies including solid and non-solid tumors. The drawbacks of chemotherapeutic treatments, which include tumor resistance, cancer relapse and toxicity from severe damage to healthy tissues, has fuelled a scientific quest for novel treatments that are specifically targeted to malignant cells thus reducing damage to collateral tissues.

The design of targeted therapies involves exploitation of the difference between the structure and function of normal cells compared with malignant cells. Differences include the increased levels of surface receptors on cancer cells, which makes them more sensitive to treatment regimes that target these cell surface receptors and differences in blood supply within and around tumor cells compared with normal cells.

Two basic types of targeting approaches are utilized — passive tumor targeting and active tumor targeting:

- passive tumor targeting involves transporting anti-cancer agents through the bloodstream to tumor cells using a "carrier" molecule. Many different carrier molecules, which can take a variety of forms (micelles, nanoparticles, liposomes and polymers), are being investigated as each provides advantages such as specificity and protection of the anti-cancer drug from degradation due to their structure, size (molecular weights) and particular interactions with tumor cells. Our ProLindac program uses a passive tumor targeting technology; and
- active tumor targeting involves attaching an additional fragment to the anticancer drug and the carrier molecule to create a
  new "targeted" agent that will actively seek a complementary surface receptor to which it binds (preferentially located on
  the exterior of the tumor cells). The theory is that the targeting of the anti-cancer agent through active binding to the
  affected cells should allow more of the anti-cancer drug to enter the tumor cell, thus amplifying the response to the
  treatment and reducing the toxic effect on bystander, normal tissue.

Examples of active targeting fragments include antibodies, growth factors and vitamins. Our scientists have specifically focused on using CobaCyte compounds (analogs of vitamin B12), but we have also used and have certain intellectual property protection for the use of folate and biotin in combination with vitamin B12 which may more effectively target anti-cancer drugs to certain solid tumors.

It has been known for some time that vitamin B12 and folic acid are essential for tumor growth, and as a result, receptors for these vitamins are up-regulated in certain tumors. Vitamin B12 receptor over-expression occurs in breast, lung, leukemic cells, lymphoma cells, bone, thyroid, colon, prostate and brain cancers and some other tumor lines, while folate receptor over-expression occurs in breast, lung, ovarian, endometrial, renal, colon, brain and cancers of myeloid hemotopoietic cells and methotrexate-sensitive tumors.



#### **Intellectual Property**

We believe that the value of technology both to us and to our potential corporate partners is established and enhanced by our broad intellectual property positions. Consequently, we have already been issued and seek to obtain additional U.S. and foreign patent protection for our products, including those under development and for new discoveries. Patent applications are filed with the U.S. Patent and Trademark Office and, when appropriate, with the Paris Convention's Patent Cooperation Treaty (PCT) Countries (most major countries in Western Europe and the Far East) for our inventions and prospective products.

We licensed our SDF patents from Licensor issued U.S. Patents #7,879,331, #7,879,332, and #8,293,242, the last of which expires in September 2025. We have also licensed issued patents in Europe, China and Australia and pending applications in Canada and India.

For our mucoadhesive liquid technology, used in MuGard, two U.S. patents have been issued and two European patents have been granted. One European patent has been issued in 19 European countries the other patent is in nationalization process. Patents have also been granted, or are under review, in several other major territories worldwide. Our mucoadhesive liquid technology patents and applications cover a range of products for a variety of diseases and conditions affecting the oral cavity, including the management of the various phases of mucositis.

We have two patented CobaCyte/CobOral-mediated targeted therapeutic technologies:

- two U.S. patents and several U.S. and worldwide patent applications for the use of vitamin B12 to target the transcobalamin II receptor which is upregulated in numerous diseases including cancer, rheumatoid arthritis, certain neurological and autoimmune disorders; and
- six U.S. patents and two European patents and several U.S. and worldwide patent applications for oral delivery of a wide variety of molecules which cannot otherwise be orally administered, utilizing the active transport mechanism which transports vitamin B12 into the systemic circulation.

Enhanced tumor delivery is achieved by targeting folate receptors, which are upregulated in certain tumor types.

Our patents for the following technologies expire in the years and during the date ranges indicated below:

- MuGard mucoadhesive technology in 2022, and
- CobaCyte/CobOral mediated technology between 2016 and 2019.

In addition to issued patents, we have a number of pending patent applications. If issued, the patents underlying these applications could extend the patent life of our technologies beyond the dates listed above.

We have a strategy of maintaining an ongoing line of patent continuation applications for each major category of patentable carrier and delivery technology. By this approach, we are extending the intellectual property protection of our basic targeting technology and initial agents to cover additional specific carriers and agents, some of which are anticipated to carry the priority dates of the original applications.

#### **Government Regulation**

We are subject to extensive regulation by the federal government, principally by the FDA, and, to a lesser extent, by other federal and state agencies as well as comparable agencies in foreign countries where registration of products will be pursued. Although a number of our formulations incorporate extensively tested drug substances, because the resulting formulations make claims of enhanced efficacy and/or improved side effect profiles, they are expected to be classified as new drugs by the FDA.

The Federal Food, Drug and Cosmetic Act and other federal, state and foreign statutes and regulations govern the testing, manufacturing, safety, labeling, storage, shipping and record keeping of our products. The FDA has the authority to approve or not approve new drug applications and inspect research, clinical and manufacturing records and facilities.

Among the requirements for drug approval and testing is that the prospective manufacturer's facilities and methods conform to the FDA's Code of Good Manufacturing Practices regulations, which establishes the



minimum requirements for methods to be used in, and the facilities or controls to be used during, the production process. Such facilities are subject to ongoing FDA inspection to insure compliance.

The steps required before a pharmaceutical product may be produced and marketed in the U.S. include preclinical tests, the filing of an Investigational New Drug ("IND") application with the FDA, which must become effective pursuant to FDA regulations before human clinical trials may commence, numerous phases of clinical testing and the FDA approval of a New Drug Application (NDA) prior to commercial sale.

Preclinical tests are conducted in the laboratory, usually involving animals, to evaluate the safety and efficacy of the potential product. The results of preclinical tests are submitted as part of the IND application and are fully reviewed by the FDA prior to granting the sponsor permission to commence clinical trials in humans. All trials are conducted under International Conference on Harmonization, good clinical practice guidelines. All investigator sites and sponsor facilities are subject to FDA inspection to insure compliance. Clinical trials typically involve a three-phase process. Phase 1 the initial clinical evaluations, consists of administering the drug and testing for safety and tolerated dosages and in some indications such as cancer and HIV, as preliminary evidence of efficacy in humans. Phase 2 involves a study to evaluate the effectiveness of the drug for a particular indication and to determine optimal dosage and dose interval and to identify possible adverse side effects and risks in a larger patient group. When a product is found safe, and initial efficacy is established in Phase 2, it is then evaluated in Phase 3 clinical trials. Phase 3 trials consist of expanded multi-location testing for efficacy and safety to evaluate the overall benefit-to-risk index of the investigational drug in relationship to the disease treated. The results of preclinical and human clinical testing are submitted to the FDA in the form of an NDA for approval to commence commercial sales.

The process of forming the requisite testing, data collection, analysis and compilation of an IND and an NDA is labor intensive and costly and may take a protracted time period. In some cases, tests may have to be redone or new tests instituted to comply with FDA requests. Review by the FDA may also take considerable time and there is no guarantee that an NDA will be approved. Therefore, we cannot estimate with any certainty the length of the approval cycle.

We are also governed by other federal, state and local laws of general applicability, such as laws regulating working conditions, employment practices, as well as environmental protection.

#### License Agreements

On September 22, 2014, we entered into an exclusive, worldwide, licensing agreement with Licensor to obtain rights to utilize and to sub-license to other pharmaceuticals firms, its patented methods for the extraction of therapeutic biologics from human plasma.

Under the terms of the licensing agreement, as amended on January 23, 2015, we paid a license fee of \$1 million in cash, will pay \$4,000,000 in cash or 1,096,151 shares of our common stock in 2017, a regulatory approval milestone payment of 513,375 shares of our common stock upon the first FDA regulatory approval of a drug derived from the Licensor's proprietary SDF process, and a tiered royalty on annual net sales of plasma fractions produced with Licensor's proprietary SDF process.

We believe that Licensor's proprietary fractionation process is expected to significantly enhance yields of key value blood proteins, including A1PI, expanding market opportunities, while greatly enhancing margins. The Company obtained rights to utilize and sub-license to other pharmaceutical firms the recently patented improved methods for the extraction of therapeutic biologics from human plasma. We believe that Licensor's lead product, A1PI, offers a low-risk, high revenue, short time to market respiratory product for treatment of inherited COPD (pulmonary emphysema), among other genetic A1PI deficiencies. Additionally, the ability to extract several additional therapeutically useful and important proteins, due to the process being less destructive than historical fractionation processes, may enable us to seek new therapeutic applications and address high-value-added orphan indications.

On June 6, 2013 we entered into an exclusive license agreement with AMAG related to the commercialization of MuGard in the U.S. and its territories. Under the terms of the licensing agreement, we received an upfront licensing fee of \$3.3 million and will receive a tiered, double-digit royalty on net sales of MuGard in the licensed territories. AMAG also purchased our existing MuGard inventory. The \$3.3 million license fee is accounted for as deferred revenue and is recognized over ten years, which is the life of the license agreement.

The license term expires June 6, 2023. The license can also terminate in the event of breach by either us or AMAG or by AMAG at anytime with 180 days prior notice of termination.

On March 11, 2014, we announced we had entered into an exclusive license agreement with Hanmi related to MuGard commercialization in South Korea. Under the terms of the agreement, we received an upfront licensing fee and double digit royalties on sales of MuGard in the licensed territory. The license term expires February 26, 2024. The license can also terminate in the event of breach or by Hanmi at anytime with 180 days prior notice of termination.

On August 7, 2014, we entered into an exclusive license agreement with Norgine, a leading independent European specialty pharmaceutical company, for the commercialization of MuGard in Europe. Under the terms of the license agreement, we could receive up to \$10 million in milestone payments and an escalating double digit royalty on the net sales of the oral mucositis product, MuGard, in the licensed territories. Norgine will develop, manufacture, and commercialize MuGard in the European Union, Switzerland, Norway, Iceland and Lichtenstein. Norgine anticipates launching MuGard in 2015.

#### Competition

The pharmaceutical and biotechnology industry is characterized by intense competition, rapid product development and technological change. Competition is intense among manufacturers of prescription pharmaceuticals and other product areas where we may develop and market products in the future. Most of our potential competitors are large, well established pharmaceutical, chemical or healthcare companies with considerably greater financial, marketing, sales and technical resources than are available to us. Additionally, many of our potential competitors have research and development capabilities that may allow such competitors to develop new or improved products that may compete with our product lines. Our potential products could be rendered obsolete or made uneconomical by the development of new products to treat the conditions to be addressed by our developments, technological advances affecting the cost of production, or marketing or pricing actions by one or more of our potential competitors. Our business, financial condition and results of operation could be materially adversely affected by any one or more of such developments. We cannot assure you that we will be able to compete successfully against current or future competitors or that competition will not have a material adverse effect on our business, financial condition and results of operations. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize products on their own or with the assistance of major health care companies in areas where we are developing product candidates. We are aware of certain development projects for products to treat or prevent certain diseases targeted by us, and the existence of these potential products or other products or treatments of which we are not aware, or products or treatments that may be developed in the future, may adversely affect the marketability of products developed by us.

The plasma therapeutics industry is highly competitive and driven by several large competitors including Baxter International, Inc. ("Baxter"), CSL Behring ("CSL") and Grifols SA ("Grifols"). Each of these groups produce A1PI under the name of the following, Baxter (Aralast, license of Glassia from Kamada), CSL (Zemairia) and Grifols (Prolastin) Other regional competitors include, but are not limited to, BPL, Kedrion, LFB Group SA, and Octapharma AG. We face competition from both US based and international based producers of plasma products who may have greater access to capital, production facilities and resources for both research and development as well as supplies of plasma.

Furthermore, plasma derived products also face competition from products that are not derived from plasma, and other courses of treatment.

In the area of advanced drug delivery, which is the focus of our early stage research and development activities, a number of companies are developing or evaluating enhanced drug delivery systems. We expect that technological developments will occur at a rapid rate and that competition is likely to intensify as various alternative delivery system technologies achieve similar if not identical advantages.

Even if our products are fully developed and receive required regulatory approval, of which there can be no assurance, we believe that our products can only compete successfully if marketed by a company having expertise and a strong presence in the therapeutic area. Consequently, we do not currently plan to establish an

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internal marketing organization. By forming strategic alliances with major and regional pharmaceutical companies, management believes that our development risks should be minimized and that the technology potentially could be more rapidly developed and successfully introduced into the marketplace.

ActoGeniX N.V., Alder Biopharmaceuticals, Inc., Applied Protein Sciences, LLC, Avaxia Biologics, Inc, BioAlliance Pharma S.A., BMG Pharma s.r.l., Camurus AB, DARA BioSciences, Inc. EUSA Pharma, Galera Therapeutics, Inc. Maya Biotech Ltd., NephRx, Piramal Healthcare Ltd., Soligenix, Inc. and Synedgen are developing products to treat mucositis that may compete with our mucoadhesive liquid technology. Products which are marketed to treat mucositis include Caphosol by EUSA Pharma, Gelclair by DARA BioSciences, Inc., Episil by Camurus AB, and Kepivance by Biovitrum.

Companies working on therapies and formulations that may be competitive with our vitamin mediated drug delivery system are Bristol-Myers Squibb, Centocor (acquired by Johnson & Johnson), Endocyte, GlaxoSmithKline, Imclone and Xoma which are developing targeted monoclonal antibody therapy.

BioDelivery Sciences International, Biocon Limited, Biodel, Inc. Biovail Corporation, Diasome Pharmaceuticals, Depomed Inc., Emisphere Technologies, Inc., Eurand, Flamel Technologies, Merrion Pharmaceuticals, OraMed and Xenoport are developing products which compete with our oral drug delivery system.

Many of these competitors have greater financial and other resources, including larger research and development, marketing and manufacturing organizations. As a result, our competitors may successfully develop technologies and drugs that are more effective or less costly than any that we are developing or which would render our technology and future products obsolete and noncompetitive.

In addition, some of our competitors have greater experience than we do in conducting preclinical and clinical trials and obtaining FDA and other regulatory approvals. Accordingly, our competitors may succeed in obtaining FDA or other regulatory approvals for drug candidates more rapidly than we do. Companies that complete clinical trials, obtain required regulatory agency approvals and commence commercial sale of their drugs before their competitors may achieve a significant competitive advantage. Drugs resulting from our research and development efforts or from our joint efforts with collaborative partners therefore may not be commercially competitive with our competitors' existing products or products under development.

#### **Other Key Developments**

#### \$14 Million Financing

On December 24, 2014, we announced the closing of an underwritten public offering of 3,500,000 shares of our common stock, and warrants to purchase up to an aggregate 3,500,000 shares of common stock, at an offering price of \$4.00 per share and \$.01 per warrant. The warrants have a per share exercise price of \$5.00, are exercisable immediately, and expire 5 years from the date of issuance. The gross proceeds to the Company from this offering were \$14,035,000, before deducting underwriting discounts and commissions and other estimated offering expenses. All of the shares and warrants in the offering were sold by the Company. The shares and warrants began trading on The NASDAQ Capital Market on December 19, 2014 under the symbols "PTBI" and "PTBIW," respectively. In connection with the closing of the public offering, on December 24, 2014, all of our outstanding Series A and Series B preferred stock was converted into common stock.

#### Reverse Stock Split

Our Board of Directors and majority stockholders approved an amendment to our certificate of incorporation to effect a reverse stock split of our common stock at a ratio between 1 for 5 and 1 for 50 in order to satisfy requirements for the listing of our common stock on the NASDAQ Capital Market. Our stockholders further authorized the board of directors to determine the ratio at which the reverse stock split would be effected. Our board of directors authorized the ratio of the Reverse Split on October 16, 2014 and to be effective at the opening of business on October 24, 2014. We amended our certificate of incorporation to effect the reverse split at a ratio of 1 for 50 on October 24, 2014 (the "Reverse Split"). All share and per share numbers included in this Annual Report on Form 10-K give effect to the Reverse Split.



#### Plasma Technologies LLC License

On September 22, 2014, we entered into an exclusive, worldwide licensing agreement with Licensor to obtain rights to utilize and to sub-license its patented methods for the extraction of therapeutic biologics from human plasma. Plasma biologics are biopharmaceutical proteins extracted, purified, and formulated from human blood plasma by the use of biotechnological processing techniques including precipitation, diafiltration, affinity chromatography, and ion-exchange chromatography. Because plasma biologics are biosimilar, they are less likely than recombinant or transgenic proteins to cause toxic or other adverse reactions, or cause adverse immunological responses such as the stimulation of inhibitors in recipients.

Under the terms of the licensing agreement, as amended on January 23, 2015, we paid a license fee of \$1 million in cash, will pay \$4,000,000 in cash or 1,096,151 shares of our common stock in 2017, a regulatory approval milestone payment of 513,375 shares of our common stock upon the first FDA regulatory approval of a drug derived from the Licensor's proprietary SDF process, and a tiered royalty on annual net sales of plasma fractions produced with Licensor's proprietary SDF process.

Licensor was founded to develop superior high-yield technology to extract a wide range of therapeutically useful proteins from human blood plasma. We believe that Licensor's proprietary SDF process is expected to significantly enhance yields of key value blood proteins, including A1PI, expanding market opportunities, while greatly enhancing margins. We obtained rights to utilize and sub-license to other pharmaceutical firms the recently patented improved methods for the extraction of therapeutic biologics from human plasma. We believe that Licensor's lead product, SDF Alpha, offers a low-risk, high revenue, short time-to-market respiratory product for treatment of inherited COPD (pulmonary emphysema), among other genetic A1PI deficiencies. Additionally, the ability to extract several additional therapeutically useful and important proteins, due to the process being less destructive than historical fractionation processes, may enable us to seek new therapeutic applications and address high-value-added orphan indications.

#### Miscellaneous

On November 4, 2014, we announced that Stephen T. Sonis, DMD, DMSc joined our Scientific Advisory Board ("SAB"). Dr. Sonis has collaborated with management in recent years on advancing the Company's clinical efforts of its oral mucositis treatment, MuGard.

On October 29, 2014, we announced the leading experts on our SAB. The SAB will serve as a strategic resource to the Company as it continues to develop and commercialize its proprietary plasma fractionation platform, Salt Diafiltration Process ("SDF"). The members include: Eugene J. Zurlo, B.S. (Pharmacy), M.S.; Charles H. Heldebrant, PhD; and, Allan Louderback, PhD.

On October 27, 2014, we entered into an exclusive license agreement with Norgine B.V., a European specialist pharmaceutical company, for the commercialization of MuGard in Australia and New Zealand. The terms of the agreement are congruent to our recent license with Norgine for MuGard in Europe. Norgine intends to develop, manufacture and commercialize MuGard in the new territories.

On September 12, 2014, we announced we had received notification from the European Patent Office that an additional European patent for MuGard had been granted. The patent (EP1997478) protects a wide range of liquid formulations for the prevention and treatment of mucosal diseases and disorders.

On August 7, 2014, we entered into an exclusive license agreement with Norgine, an independent European specialty pharmaceutical company, for the commercialization of MuGard in Europe. Under the terms of the license agreement, we will receive up to \$10 million in milestone payments and an escalating double digit royalty on the net sales of the oral mucositis product, MuGard, in the licensed territories. Norgine will develop, manufacture, and commercialize MuGard in the European Union, Switzerland, Norway, Iceland and Lichtenstein. Norgine anticipates launching MuGard in 2015.

On July 22, 2014 we received 510(K) marketing clearance from the FDA for ProctiGard for the treatment of symptomatic management of rectal mucositis.

On July 8, 2014, we announced we received notification from the Hong Kong Patent Office that a patent for MuGard has been granted.



On March 21, 2014, we announced we have advanced development of a new proprietary product, called ProctiGard<sup>TM</sup>, for the treatment of radiation proctitis. Radiation proctitis ("RP") is a significant unmet medical need, with no well-established standard of care. It is estimated that there are in excess of 250,000 new cases of prostate, cervical, rectal, testicular, bladder and endometrial cancer diagnosed each year. Approximately 50% of these patients require radiation therapy, and roughly 75% of patients undergoing pelvic irradiation experience radiation proctitis. We are actively seeking marketing partners globally for ProctiGard<sup>TM</sup>.

On March 11, 2014, we announced we had entered into an exclusive license agreement with Hanmi related to MuGard commercialization in South Korea. Under the terms of the agreement, we received an upfront licensing fee and double digit royalties on sales of MuGard in the licensed territory.

On February 18, 2014, we announced the online publication of the final results of our post-approval marketing study of MuGard in Cancer, the journal of the American Cancer Society. The publication, entitled "Multi-Institutional, Randomized, Double-Blind, Placebo-Controlled Trial to Assess the Efficacy of a Mucoadhesive Hydrogel (MuGard) in Mitigating Oral Mucositis Symptoms in Patients Being Treated With Chemoradiation Therapy for Cancers of the Head and Neck" is available at *http://onlinelibrary.wiley.com/doi/10.1002/cncr.28553/full*. The publication discusses the results of this post-marketing clinical trial, providing further evidence of the efficacy of MuGard in controlling symptoms caused by oral mucositis in 120 patients receiving chemoradiation therapy for the treatment of cancers of the head and neck.

#### **Corporate Information**

Our principal executive office is located at 4848 Lemmon Avenue, Suite 517, Dallas, Texas 75219. Our telephone number is (214) 905-5100. We were incorporated in Wyoming in 1974 as Chemex Corporation, and in 1983 we changed our name to Chemex Pharmaceuticals, Inc. We changed our state of incorporation from Wyoming to Delaware on June 30, 1989. In 1996 we merged with Access Pharmaceuticals, Inc., a private Texas corporation, and changed our name to Access Pharmaceuticals, Inc. On October 24, 2014 we changed our name to PlasmaTech Biopharmaceuticals, Inc.

#### Suppliers

Some materials used by us are specialized. We obtain materials from several suppliers based in different countries around the world. If materials are unavailable from one supplier we generally have alternate suppliers available.

#### Employees

As of March 31, 2015, we had seven full-time employees. We have never experienced employment-related work stoppages and consider that we maintain good relations with our personnel. In addition, to complement our internal expertise, we have contracts with scientific consultants, contract research organizations and university research laboratories that specialize in various aspects of drug development including clinical development, regulatory affairs, toxicology, process scale-up and preclinical testing.

#### Web Availability

We make available free of charge through our website, *www.plasmatechbio.com*, our annual reports on Form 10-K and other reports that we file with the Securities and Exchange Commission as well as certain of our corporate governance policies, including the charters for the audit, compensation and nominating and corporate governance committees of the Board of Directors (the "Board") and our code of ethics, corporate governance guidelines and whistleblower policy. We will also provide to any person without charge, upon request, a copy of any of the foregoing materials. Any such request must be made in writing to us at: PlasmaTech Biopharmaceuticals, Inc. c/o Investor Relations, 4848 Lemmon Avenue, Suite 517, Dallas, TX 75219.



#### **ITEM 1A. RISK FACTORS**

#### **Risks Relating to our Business and Industry**

# We have experienced a history of losses, we expect to incur future losses and we may be unable to obtain necessary additional capital to fund operations in the future.

We have recorded minimal revenue to date and have incurred an accumulated deficit of approximately \$296.1 million through December 31, 2013. Net loss allocable to common stockholders for the year ended December 31, 2014 was \$29.7 million and the net income for the year ended December 31, 2013 was \$1.5 million. Our losses have resulted principally from costs incurred in research and development activities related to our efforts to develop clinical drug candidates and from the associated administrative costs. We expect to incur additional operating losses over the next several years. We also expect cumulative losses to increase if we expand research and development efforts and preclinical and clinical trials.

We require substantial capital for our development programs and operating expenses, to pursue regulatory clearances and to prosecute and defend our intellectual property rights. We believe that our existing capital resources, interest income, royalties and revenue from our licensing agreements and collaborative agreements will be sufficient to fund our currently expected operating expenses and capital requirements for the next twelve months. We will need to raise substantial additional capital to support our ongoing and planned operations.

If we raise additional funds by issuing equity securities, further dilution to existing stockholders will result and future investors may be granted rights superior to those of existing stockholders. If adequate funds are not available to us through additional equity offerings, we may be required to delay, reduce the scope of or eliminate one or more of our research and development programs or to obtain funds by entering into arrangements with collaborative partners or others that require us to issue additional equity securities or to relinquish rights to certain technologies or drug candidates that we would not otherwise issue or relinquish in order to continue independent operations.

#### We do not have significant operating revenue and may never attain profitability.

To date, we have funded our operations primarily through private sales of common stock, preferred stock and convertible notes. Contract research payments and licensing fees from corporate alliances and mergers have also provided funding for our operations. Our ability to achieve significant revenue or profitability depends upon our licensees ability to successfully market MuGard in North America, Europe, Australia, New Zealand, Korea and China or to complete the development of our drug candidates, to develop and obtain patent protection and regulatory approvals for our drug candidates and to manufacture and commercialize the resulting drugs. We are not expecting any significant revenues in the short-term from our products or product candidates. Furthermore, we may not be able to ever successfully identify, develop, commercialize, patent, manufacture, obtain required regulatory approvals to market additional products, we may not generate revenues or royalties from commercial sales of these products for a significant number of years, if at all. Therefore, our proposed operations are subject to all the risks inherent in the establishment of a new business enterprise. In the next few years, our revenues may be limited to minimal product sales and royalties, and any amounts that we receive under strategic partnerships and research or drug development collaborations that we may establish and, as a result, we may be unable to achieve or maintain profitability in the future or to achieve significant revenues in order to fund our operations.

#### We may not successfully commercialize our drug candidates.

Our drug candidates are subject to the risks of failure inherent in the development of pharmaceutical products based on new technologies, and our failure to develop safe commercially viable drugs would severely limit our ability to become profitable or to achieve significant revenues. We may be unable to successfully commercialize our drug candidates because:

• some or all of our drug candidates may be found to be unsafe or ineffective or otherwise fail to meet applicable regulatory standards or receive necessary regulatory clearances;



- our drug candidates, if safe and effective, may be too difficult to develop into commercially viable drugs;
- it may be difficult to manufacture or market our drug candidates on a large scale;
- · proprietary rights of third parties may preclude us from marketing our drug candidates; and
- third parties may market superior or equivalent drugs.

### The success of our research and development activities, upon which we primarily focus, is uncertain.

Our primary focus is on our research and development activities and the commercialization of compounds covered by proprietary biopharmaceutical patents and patent applications. Research and development activities, by their nature, preclude definitive statements as to the time required and costs involved in reaching certain objectives. Actual research and development costs, therefore, could significantly exceed budgeted amounts and estimated time frames may require significant extension. Cost overruns, unanticipated regulatory delays or demands, unexpected adverse side effects or insufficient therapeutic efficacy will prevent or substantially slow our research and development effort and our business could ultimately suffer. We anticipate that we will remain principally engaged in research and development activities for an indeterminate, but substantial, period of time.

# We may be unable to successfully develop, market, or commercialize our products or our product candidates without establishing new relationships and maintaining current relationships and our ability to successfully commercialize, and market our product candidates could be limited if a number of these existing relationships are terminated.

Our strategy for the research, development and commercialization of our potential pharmaceutical products may require us to enter into various arrangements with corporate and academic collaborators, licensors, licensees and others, in addition to our existing relationships with other parties. Specifically, we may seek to joint venture, sublicense or enter other marketing arrangements with parties that have an established marketing capability or we may choose to pursue the commercialization of such products on our own. We may, however, be unable to establish such additional collaborative arrangements, license agreements, or marketing agreements as we may deem necessary to develop, commercialize and market our potential pharmaceutical products on acceptable terms. Furthermore, if we maintain and establish arrangements or relationships with third parties, our business may depend upon the successful performance by these third parties of their responsibilities under those arrangements and relationships.

# We may be unable to successfully manufacture our products and our product candidates in clinical quantities or for commercial purposes without the assistance of contract manufacturers, which may be difficult for us to obtain and maintain.

We have limited experience in the manufacture of pharmaceutical products in clinical quantities or for commercial purposes and we may not be able to manufacture any new pharmaceutical products that we may develop. As a result, we have established, and in the future intend to establish arrangements with contract manufacturers to supply sufficient quantities of products to conduct clinical trials and for the manufacture, packaging, labeling and distribution of finished pharmaceutical products if any of our potential products are approved for commercialization. If we are unable to contract for a sufficient supply of our potential pharmaceutical products on acceptable terms, our preclinical and human clinical testing schedule may be delayed, resulting in the delay of our clinical programs and submission of product candidates for regulatory approval, which could cause our business to suffer. Our business could suffer if there are delays or difficulties in establishing relationships with manufacturers to produce, package, label and distribute our finished pharmaceutical or biopharmaceutical or other medical products, if any. Moreover, US contract manufacturers that we may use must adhere to current Good Manufacturing Practices, as required by the FDA. In this regard, the FDA will not issue a pre-market approval or product and establishment licenses, where applicable, to a manufacturing facility for the products until the manufacturing facility passes a pre-approval plant inspection. If we are unable to obtain or retain third party manufacturing on commercially acceptable terms, we may not be able to commercialize our products as planned. Our potential dependence



upon third parties for the manufacture of our products may adversely affect our ability to generate profits or acceptable profit margins and our ability to develop and deliver such products on a timely and competitive basis.

# We are subject to extensive governmental regulation which increases our cost of doing business and may affect our ability to commercialize any new products that we may develop.

The FDA and comparable agencies in foreign countries impose substantial requirements upon the introduction of pharmaceutical products through lengthy and detailed laboratory, preclinical and clinical testing procedures and other costly and time-consuming procedures to establish safety and efficacy. All of our drugs and drug candidates require receipt and maintenance of governmental approvals for commercialization. Preclinical and clinical trials and manufacturing of our drug candidates will be subject to the rigorous testing and approval processes of the FDA and corresponding foreign regulatory authorities. Satisfaction of these requirements typically takes a significant number of years and can vary substantially based upon the type, complexity and novelty of the product.

Due to the time-consuming and uncertain nature of the drug candidate development process and the governmental approval process described above, we cannot assure you when we, independently or with our collaborative partners, might submit a New Drug Application, or NDA, for FDA or other regulatory review. Further, our ability to commence and/or complete development projects will be subject to our ability to raise enough funds to pay for the development costs of these projects. Government regulation also affects the manufacturing and marketing of pharmaceutical products. Government regulations may delay marketing of our potential drugs for a considerable or indefinite period of time, impose costly procedural requirements upon our activities and furnish a competitive advantage to larger companies or companies more experienced in regulatory affairs. Delays in obtaining governmental regulatory approval could adversely affect our marketing as well as our ability to generate significant revenues from commercial sales.

Our drug candidates may not receive FDA or other regulatory approvals on a timely basis or at all. Moreover, if regulatory approval of a drug candidate is granted, such approval may impose limitations on the indicated use for which such drug may be marketed. Even if we obtain initial regulatory approvals for our drug candidates, our drugs and our manufacturing facilities would be subject to continual review and periodic inspection, and later discovery of previously unknown problems with a drug, manufacturer or facility may result in restrictions on the marketing or manufacture of such drug, including withdrawal of the drug from the market. The FDA and other regulatory authorities stringently apply regulatory standards and failure to comply with regulatory standards can, among other things, result in fines, denial or withdrawal of regulatory approvals, product recalls or seizures, operating restrictions and criminal prosecution.

# The uncertainty associated with preclinical and clinical testing may affect our ability to successfully commercialize new products.

Before we can obtain regulatory approvals for the commercial sale of any of our potential drugs, the drug candidates will be subject to extensive preclinical and clinical trials to demonstrate their safety and efficacy in humans. Preclinical or clinical trials of future drug candidates may not demonstrate the safety and efficacy to the extent necessary to obtain regulatory approvals. In this regard, for example, adverse side effects can occur during the clinical testing of a new drug on humans which may delay ultimate FDA approval or even lead it to terminate our efforts to develop the drug for commercial use. Companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials, even after demonstrating promising results in earlier trials. The failure to adequately demonstrate the safety and efficacy of a drug candidate under development could delay or prevent regulatory approval of the drug candidate. A delay or failure to receive regulatory approval for any of our drug candidates could prevent us from successfully commercializing such candidates and we could incur substantial additional expenses in our attempt to further develop such candidates and obtain future regulatory approval.



# We may incur substantial product liability expenses due to the use or misuse of our products for which we may be unable to obtain insurance coverage.

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical products. These risks will expand with respect to our drug candidates, if any, that receive regulatory approval for commercial sale and we may face substantial liability for damages in the event of adverse side effects or product defects identified with any of our products that are used in clinical tests or marketed to the public. Product liability insurance for the biotechnology industry is generally expensive, if available at all, and as a result, we may be unable to obtain insurance coverage at acceptable costs or in a sufficient amount in the future, if at all. We may be unable to satisfy any claims for which we may be held liable as a result of the use or misuse of products which we developed, manufactured or sold and any such product liability claim could adversely affect our business, operating results or financial condition.

#### Intense competition may limit our ability to successfully develop and market commercial products.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our competitors in the U.S. and elsewhere are numerous and include, among others, major multinational pharmaceutical and chemical companies, specialized biotechnology firms and universities and other research institutions. Many of our competitors have and employ greater financial and other resources, including larger research and development, marketing and manufacturing organizations. As a result, our competitors may successfully develop technologies and drugs that are more effective or less costly than any that we are developing or which would render our technology and future products obsolete and noncompetitive.

In addition, some of our competitors have greater experience than we do in conducting preclinical and clinical trials and obtaining FDA and other regulatory approvals. Accordingly, our competitors may succeed in obtaining FDA or other regulatory approvals for drug candidates more rapidly than we can. Companies that complete clinical trials, obtain required regulatory agency approvals and commence commercial sale of their drugs before their competitors may achieve a significant competitive advantage. Drugs resulting from our research and development efforts or from our joint efforts with collaborative partners therefore may not be commercially competitive with our competitors' existing products or products under development.

# Our ability to successfully develop and commercialize our drug candidates will substantially depend upon the availability of reimbursement funds for the costs of the resulting drugs and related treatments.

Market acceptance and sales of our product candidates may depend on coverage and reimbursement policies and health care reform measures. Decisions about formulary coverage as well as levels at which government authorities and third-party payers, such as private health insurers and health maintenance organizations, reimburse patients for the price they pay for our products as well as levels at which these payors pay directly for our products, where applicable, could affect whether we are able to commercialize these products. We cannot be sure that reimbursement will be available for any of these products. Also, we cannot be sure that coverage or reimbursement amounts will not reduce the demand for, or the price of, our products. We have not commenced efforts to have our product candidates reimbursed by government or third party payors. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to commercialize our products. In recent years, officials have made numerous proposals to change the health care system in the U.S. These proposals include measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. If our products are or become subject to government regulation that limits or prohibits payment for our products, or that subjects the price of our products to governmental control, we may not be able to generate revenue, attain profitability or commercialize our products.

As a result of legislative proposals and the trend towards managed health care in the U.S., third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also impose strict prior authorization requirements and/or refuse to provide any coverage of uses of approved products for medical indications other than those for which the



FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly-approved drugs, which in turn will put pressure on the pricing of drugs.

#### The market may not accept any pharmaceutical products that we develop.

The drugs that we are attempting to develop may compete with a number of well-established drugs manufactured and marketed by major pharmaceutical companies. The degree of market acceptance of any drugs developed by us will depend on a number of factors, including the establishment and demonstration of the clinical efficacy and safety of our drug candidates, the potential advantage of our drug candidates over existing therapies and the reimbursement policies of government and third-party payers. Physicians, patients or the medical community in general may not accept or use any drugs that we may develop independently or with our collaborative partners and if they do not, our business could suffer.

#### Healthcare reform measures could hinder or prevent our product candidates' commercial success.

The U.S. government and other governments have shown significant interest in pursuing healthcare reform. Any governmentadopted reform measures could adversely impact the pricing of healthcare products and services in the U.S. or internationally and the amount of reimbursement available from governmental agencies or other third party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue, and we may need to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging due to several reasons, including policies advanced by the current executive administration in the U.S., new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably.

For example, in March 2010, President Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the PPACA. This law will substantially change the way healthcare is financed by both government health plans and private insurers, and significantly impact the pharmaceutical industry. The PPACA contains a number of provisions that are expected to impact our business and operations in ways that may negatively affect our potential revenues in the future. For example, the PPACA imposes a non-deductible excise tax on pharmaceutical manufacturers or importers that sell branded prescription drugs to U.S. government programs which we believe will increase the cost of our products. In addition, as part of the PPACA's provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the "donut hole"), we will be required to provide a discount on branded prescription drugs equal to 50% of the government-negotiated price, for drugs provided to certain beneficiaries who fall within the donut hole. Similarly, PPACA increases the level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1% and requires collection of rebates for drugs paid by Medicaid managed care organizations. The PPACA also includes significant changes to the 340B drug discount program including expansion of the list of eligible covered entities that may purchase drugs under the program. At the same time, the expansion in eligibility for health insurance benefits created under PPACA is expected to increase the number of patients with insurance coverage who may receive our products. While it is too early to predict all the specific effects the PPACA or any future healthcare reform legislation will have on our business, they could have a material adverse effect on our business and financial condition.

Congress periodically adopts legislation like the PPACA and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, that modifies Medicare reimbursement and coverage policies pertaining to prescription drugs. Implementation of these laws is subject to ongoing revision through regulatory and sub



regulatory policies. Congress also may consider additional changes to Medicare policies, potentially including Medicare prescription drug policies, as part of ongoing budget negotiations. While the scope of any such legislation is uncertain at this time, there can be no assurances that future legislation or regulations will not decrease the coverage and price that we may receive for our proposed products. Other third-party payors are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking coverage and reimbursement from Medicare and private payors. Our proposed products may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our proposed products on a profitable basis. Further federal and state proposals and health care reforms are likely which could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunities. Our results of operations could be materially adversely affected by proposed healthcare reforms, by the Medicare prescription drug coverage legislation, by the possible effect of such current or future legislation on amounts that private insurers will pay and by other health care reforms that may be enacted or adopted in the future. In September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to assure compliance with post-approval regulatory requirements, and potential restrictions on the sale and/or distribution of approved products.

### Our business could suffer if we lose the services of, or fail to attract, key personnel.

We are highly dependent upon the efforts of our senior management, including our Executive Chairman, Principal Executive Officer, and board member, Steven H. Rouhandeh; our Chief Executive Officer, Scott W. Schorer; our President and Chief Financial Officer, Harrison G. Wehner, III; our Chief Operating Officer and board member Jeffrey B. Davis; our Senior Vice President Research and Development and our Chief Accounting Officer, Stephen B. Thompson. The loss of the services of these individuals could delay or prevent the achievement of our research, development, marketing, or product commercialization objectives. We do not have employment contracts with our other key personnel. We do not maintain any 'key-man' insurance policies on any of our key employees and we do not intend to obtain such insurance. In addition, due to the specialized scientific nature of our business, we are highly dependent upon our ability to attract and retain qualified scientific and technical personnel and consultants. In view of the stage of our development and our research and development programs, we have restricted our hiring to research scientists, consultants and a small administrative staff and we have made only limited investments in manufacturing, production, sales or regulatory compliance resources. There is intense competition among major pharmaceutical and chemical companies, specialized biotechnology firms and universities and other research institutions for qualified personnel in the areas of our activities, however, and we may be unsuccessful in attracting and retaining these personnel.

# Trends toward managed health care and downward price pressures on medical products and services may limit our ability to profitably sell any drugs that we may develop.

Lower prices for pharmaceutical products may result from:

- third-party-payers' increasing challenges to the prices charged for medical products and services;
- the trend toward managed health care in the U.S. and the concurrent growth of HMOs and similar organizations that can control or significantly influence the purchase of healthcare services and products; and
- legislative proposals to reform healthcare or reduce government insurance programs.

The cost containment measures that healthcare providers are instituting, including practice protocols and guidelines and clinical pathways, and the effect of any healthcare reform, could limit our ability to profitably sell any drugs that we may successfully develop. Moreover, any future legislation or regulation, if any, relating to the healthcare industry or third-party coverage and reimbursement, may cause our business to suffer.



# Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers and business partners, as well as personally identifiable information of clinical trial participants and employees. Similarly, our business partners and third party providers possess certain of our sensitive data. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information, including our data being breached at our business partners or third-party providers, could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation which could adversely affect our business.

#### **Risks Related to our Intellectual Property**

#### It is difficult and costly to protect our proprietary rights, and we may not be able to ensure protection of such rights.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our product candidates, and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. We will only be able to protect our product candidates from unauthorized making, using, selling and offering to sell or importation by third parties to the extent that we have rights under valid and enforceable patents or trade secrets that cover these activities. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the U.S. The biotechnology patent situation outside the U.S. is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our issued patents or in third-party patents.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to produce compounds or molecules that are competitive with our product candidates but that are not covered by the claims of our patents;
- we may not have been the first to make the inventions covered by our pending patent applications;
- we may not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents and it is possible that our issued patents could be narrowed in scope, invalidated, held to be unenforceable, or circumvented;
- · we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business; or others may be able to misappropriate our trade secrets.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. While we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time consuming, and the

outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

# We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use, our technology.

If we choose to go to court to stop someone else from using the inventions claimed in our patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to these patents.

Furthermore, a third party may claim that we are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party's patents. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Because some patent applications in the U.S. may be maintained in secrecy until the patents are issued, patent applications in the U.S. and many foreign jurisdictions are typically not published until eighteen months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications or that we were the first to invent the technology. Our competitors have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications and could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the PTO, to determine priority of invention in the U.S. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our United States patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

# Pending and future litigation, including product liability claims, private securities litigation, stockholder derivative suits and contract litigation, may adversely affect our financial condition and results of operations or liquidity.

The development, manufacture and marketing of pharmaceutical products of the types that we produce entail an inherent risk of product liability claims. A number of factors could result in an unsafe condition or injury to a patient with respect to these or other products that we manufacture or sell, including inadequate disclosure of product-related risks or product-related information. In addition, we may be the subject of litigation involving contract disputes, stockholder derivative suites or private securities litigation. The outcome of litigation, particularly class action lawsuits, is difficult to assess or quantify. Plaintiffs in these types of lawsuits often seek recovery of very large or indeterminate amounts, including not only actual damages, but



also punitive damages. The magnitude of the potential losses relating to these lawsuits may remain unknown for substantial periods of time. In addition, the cost to defend against any future litigation may be significant. Product liability claims, securities and commercial litigation and other litigation in the future, regardless of the outcome, could have a material adverse effect on our financial condition, results of operations or liquidity. We are currently involved in a class action litigation, the outcome of which is uncertain and we may be required to pay damages. This litigation is described on page <u>27</u> under the heading "Legal Proceedings."

#### We may not be successful in protecting our intellectual property and proprietary rights.

Our success depends, in part, on our ability to obtain U.S. and foreign patent protection for our drug candidates and processes, preserve our trade secrets and operate our business without infringing the proprietary rights of third parties. Legal standards relating to the validity of patents covering pharmaceutical and biotechnological inventions and the scope of claims made under such patents are still developing and there is no consistent policy regarding the breadth of claims allowed in biotechnology patents. The patent position of a biotechnology firm is highly uncertain and involves complex legal and factual questions. We cannot assure you that any existing or future patents issued to, or licensed by, us will not subsequently be challenged, infringed upon, invalidated or circumvented by others. We cannot assure you that any patents will be issued from any of the patent applications owned by, or licensed to, us. Furthermore, any rights that we may have under issued patents may not provide us with significant protection against competitive products or otherwise be commercially viable.

Patents may have been granted to third parties or may be granted covering products or processes that are necessary or useful to the development of our drug candidates. If our drug candidates or processes are found to infringe upon the patents or otherwise impermissibly utilize the intellectual property of others, our development, manufacture and sale of such drug candidates could be severely restricted or prohibited. In such event, we may be required to obtain licenses from third parties to utilize the patents or proprietary rights of others. We cannot assure you that we will be able to obtain such licenses on acceptable terms, if at all. If we become involved in litigation regarding our intellectual property rights or the intellectual property rights of others, the potential cost of such litigation, regardless of the strength of our legal position, and the potential damages that we could be required to pay could be substantial.

#### **Risks Related to our Common Stock**

#### The market price of our common stock may be volatile and adversely affected by several factors.

The market price of our common stock could fluctuate significantly in response to various factors and events, including:

- our ability to integrate operations, technology, products and services;
- our ability to execute our business plan;
- operating results below expectations;
- announcements concerning product development results, including clinical trial results, or intellectual property rights of others;
- litigation or public concern about the safety of our potential products;
- our issuance of additional securities, including debt or equity or a combination thereof, which will be necessary to fund our operating expenses;
- announcements of technological innovations or new products by us or our competitors;
- loss of any strategic relationship;
- industry developments, including, without limitation, changes in healthcare policies or practices or third-party reimbursement policies; economic and other external factors;
- · period-to-period fluctuations in our financial results; and
- · whether an active trading market in our common stock develops and is maintained.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock.

# We have not paid cash dividends in the past and do not expect to pay cash dividends in the foreseeable future. Any return on investment may be limited to the value of our common stock.

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends on our capital stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as the board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if the common stock price appreciates.

#### Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expenses related to our development programs;
- addition or termination of clinical trials;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting our product candidates; and
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially.

# Provisions of our charter documents could discourage an acquisition of our company that would benefit our stockholders and may have the effect of entrenching, and making it difficult to remove, management.

Provisions of our Certificate of Incorporation and By-laws may make it more difficult for a third party to acquire control of us, even if a change in control would benefit our stockholders. In particular, shares of our preferred stock may be issued in the future without further stockholder approval and upon such terms and conditions, and having such rights, privileges and preferences, as our Board of Directors may determine, including, for example, rights to convert into our common stock. The rights of the holders of our preferred stock will be subject to, and may be adversely affected by, the rights of the holders of any of our preferred stock that may be issued in the future. The issuance of our preferred stock, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of making it more difficult for a third party to acquire control of us. This could limit the price that certain investors might be willing to pay in the future for shares of our common stock and discourage these investors from acquiring a majority of our common stock. Further, the existence of these corporate governance provisions could have the effect of entrenching management and making it more difficult to change our management.

#### Failure to achieve and maintain effective internal controls could have a material adverse effect on our business.

Effective internal controls are necessary for us to provide reliable financial reports. If we cannot provide reliable financial reports, our operating results could be harmed. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Based on our evaluation, our management concluded that there is a material weakness in our internal control over financial reporting for the year ended December 31, 2014. The material weakness identified did not result in the restatement of any previously reported financial statements or any related financial disclosure, nor does

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management believe that it had any effect on the accuracy of our financial statements for the year ended December 31, 2014. A material weakness is a deficiency, or a combination of control deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness relates to the monitoring and review of work performed by an accounting consultant in the preparation of audit and financial statements, footnotes and financial data provided to our registered public accounting firm in connection with the annual audit. All of our financial reporting was carried out by an accounting consultant. This lack of accounting staff results in a lack of segregation of duties and accounting technical expertise necessary for an effective system of internal control. We have hired additional personnel and have implemented appropriate procedures for monitoring and review of work performed by our current Chief Accounting Officer. Because of the material weakness described above, management concluded that, as of December 31, 2014, our internal control over financial reporting was not effective based on the criteria established in Internal Control — Integrated Framework, 1992, issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO").

While we continue to evaluate and improve our internal controls, we cannot be certain that these measures will ensure adequate controls over our financial processes and reporting in the future. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations. Failure to achieve and maintain an effective internal control environment could cause investors to lose confidence in our reported financial information, which could have a material adverse effect on our stock price. Failure to comply with Section 404 could also potentially subject us to sanctions or investigations by the Securities and Exchange Commission ("SEC") or other regulatory authorities.

# There can be no assurance that we will be able to comply with continued listing standards of the NASDAQ Capital Market.

We cannot assure you that we will be able to continue to comply with the minimum bid price and the other standards that we are required to meet in order to maintain a listing of our common stock on the NASDAQ Capital Market. Our failure to continue to meet these requirements may result in our common stock being delisted from the NASDAQ Capital Market.

#### Our ability to use our net operating loss carry forwards may be subject to limitation.

Generally, a change of more than 50% in the ownership of a company's stock, by value, over a three-year period constitutes an ownership change for U.S. federal income tax purposes. An ownership change may limit our ability to use our net operating loss carryforwards attributable to the period prior to the change. As a result, if we earn net taxable income, our ability to use our prechange net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability for us. At December 31, 2014, we had net operating loss carryforwards aggregating approximately \$200.8 million.

# Ownership of our shares is concentrated in the hands of a few investors which could limit the ability of our other stockholders to influence the direction of the company.

As calculated by SEC rules of beneficial ownership, SCO Capital Partners LLC and affiliates; Perceptive Advisors LLC (and affiliates Joseph Edelman), Larry N. Feinberg (Oracle Partners LP, Oracle Institutional Partners LP and Oracle Associate, LLC); and Lake End Capital LLC each beneficially owned approximately 68.3%, 11.8%, 8.0%, and 5.2%, respectively, of our common stock on an as converted basis as of December 31, 2014. Accordingly, they collectively have the ability to significantly influence or determine the election of all of our directors or the outcome of most corporate actions requiring stockholder approval. They may exercise this ability in a manner that advances their best interests and not necessarily those of our other stockholders.



#### **ITEM 2. PROPERTIES**

We maintain approximately 2,000 square feet of business office suites for administrative offices in New York. We have a lease agreement for the facility, which terminates in December 2015. We also have administrative offices in Boston, Massachusetts. We have a lease agreement for the facility, which terminates in February 2016.

We believe that our existing properties are suitable for the conduct of our business and adequate to meet our present needs.

### **ITEM 3. LEGAL PROCEEDINGS**

Alan Schmidt ("Schmidt"), a former shareholder of Genaera Corporation ("Genaera"), and a former unitholder of the Genaera Liquidating Trust (the "Trust"), filed a purported class action in the United States District Court for the Eastern District of Pennsylvania in June 2012. The lawsuit named thirty defendants, including PlasmaTech, MacroChem Corporation, which was acquired by us in February 2009, Jeffrey Davis, the then-CEO and currently a director of PlasmaTech, and Steven H. Rouhandeh and Mark Alvino, both of whom are our directors (the "PlasmaTech Defendants"). With respect to the PlasmaTech Defendants, the complaint alleged direct and derivative claims asserting that directors of Genaera and the Trustee of the Trust breached their fiduciary duties to Genaera, Genaera's shareholders and the Trust's unitholders in connection with the licensing and disposition of certain assets, aided and abetted by numerous defendants including the PlasmaTech Defendants. Schmidt seeks monetary damages, disgorgement of any distributions received from the Trust, rescission of sales made by the Trust, attorneys' and expert fees, and costs. On December 19, 2012, Schmidt filed an amended complaint (the "Amended Complaint") which asserted substantially the same allegations with respect to the PlasmaTech Defendants. On February 4, 2013, the PlasmaTech Defendants moved to dismiss all claims asserted against them. On August 12, 2013 the court granted the PlasmaTech Defendants' motions to dismiss and entered judgment in favor of the PlasmaTech Defendants on all claims. On August 26, 2013, Schmidt filed a motion for reconsideration. On September 10, 2013 Schmidt filed a Notice of Appeal with the District Court. On September 17, 2013, Schmidt filed his appeal with the U.S. Third Circuit Court of Appeals (the "Third Circuit"). On September 25, 2013, the District Court denied Schmidt's motion for reconsideration. On October 17, 2013, Schmidt amended his appeal to include the District Court's denial of his motion for reconsideration. On March 20, 2014, Schmidt filed his Brief and Joint Appendix. On May 22, 2014, the PlasmaTech Defendants filed their Oppositions to Schmidt's Brief. On May 29, 2014, Schmidt was granted an extension of time until June 23, 2014 to file his Reply Brief and filed his Reply Brief on that date. The Third Circuit held oral argument on September 12, 2014. On October 17, 2014, in a split decision, the Third Circuit reversed the District Court's decision holding, among other things, that the District Court's determination that the Amended Complaint was time-barred on statute of limitations grounds was premature. The Third Circuit did not rule upon any of the other grounds for dismissal advanced in the District Court and on appeal. The Third Circuit remanded the case to the District Court for further proceedings. On January 6, 2015, the District Court ordered the parties to file supplemental briefs on all remaining arguments for dismissal, and further ordered that a hearing on the motions to dismiss would be held on February 3, 2015. On January 23, 2015, the PlasmaTech Defendants filed their Supplemental Brief. At the February 3, 2015 hearing, Schmidt sought and was granted leave to amend his complaint for a second time. Schmidt filed his Second Amended Complaint on February 3, 2015. The Second Amended Complaint asserts substantially the same factual allegations with respect to the PlasmaTech Defendants, but eliminates all causes of action against the PlasmaTech Defendants except for aiding and abetting the Genaera directors' and officers' purported breaches of fiduciary duties, a claim for "punitive damages" and a claim for rescission of a settlement agreement between the Trust and the PlasmaTech Defendants. On March 20, 2015, the PlasmaTech Defendants filed a motion to dismiss the Second Amended Complaint. We intend to continue contesting the claims vigorously.

We are not currently subject to any other material pending legal proceedings.

### ITEM 4. MINE SAFETY DISCLOSURES

Not applicable

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#### EXECUTIVE OFFICERS OF THE REGISTRANT

Mr. Steven H. Rouhandeh became our Executive Chairman on January 1, 2015. Mr. Rouhandeh has been a director and Chairman of the Board since March 4, 2008. He has been Chief Investment Officer of SCO Capital Partners, a group of New York based life sciences funds since 1997. Mr. Rouhandeh possesses a diverse background in financial services that includes experience in asset management, corporate finance, investment banking and law. He has been active throughout recent years as an executive in venture capital and as a founder of several companies in the biotech field. His experience also includes positions as Managing Director of a private equity group at Metzler Bank, a private European investment firm and Vice President, Investment Banking at Deutsche Bank. Mr. Rouhandeh was also a corporate attorney at New York City-based Cravath, Swaine & Moore. Mr. Rouhandeh holds a J.D., from Harvard Law School, Harvard University and B.A. Political Science, from Southern Illinois University.

Mr. Scott Schorer became Chief Executive Officer on September 19, 2014. Mr. Schorer previously was Managing Director with Plasma Technologies LLC since June 1, 2014. He has served over 18 years in a variety of senior management and board positions, including as CEO and President, and has experience in all aspects of operations including research and development, intellectual property, manufacturing, sales and marketing. Additionally, Mr. Schorer has extensive experience as advisor to operating companies, venture capital firms and private equity firms. Previously, he was President, Americas, of Systagenix Wound Management from February 2009 to May 2010, was President & CEO of Innovative Spinal Technologies from January 2003 to

February 2009, and was Co-Founder, President & CEO of CentriMed. Mr. Schorer served with distinction in the US Army, 82 <sup>nd</sup> Airborne, and holds a B.E and B.A. from Dartmouth College and Thayer School of Engineering.

Mr. Harrison Wehner became President and Chief Financial Officer on September 19, 2014. Mr. Wehner previously was a Managing Director with Plasma Technologies LLC since June 1, 2014. He has over 20 years experience in investment banking advising on equity and debt finance and mergers and acquisitions advisory assignments. Previously, Mr. Wehner held various senior banking roles at CanaccordGenuity from 2012 to 2013, with CitiGroup from 2005 to 2011, and UBS from 1994 to 2005 where he worked on a variety of banking transactions in the healthcare sector, including advisory and transactional experience in the blood fractionation industry. Mr. Wehner holds a BA from The College of William and Mary, and an MBA from the Ross School of Business at the University of Michigan.

Mr. Jeffrey B. Davis became Chief Operating Officer on January 19, 2015. Mr. Davis is also a director since March 2006. Mr. Davis was our Chief Executive Officer from December 26, 2007 until September 19, 2014. Mr. Davis became Acting Chief Financial Officer, Treasurer and Secretary on November 1, 2013. Previously, Mr. Davis served in a variety of senior investment banking and management positions, and in senior management at a publicly traded healthcare technology company. Prior to that, Mr. Davis was an investment banker with various Deutsche Bank banking organizations, both in the U.S. and Europe. Mr. Davis also served in senior marketing and product management positions at AT&T Bell Laboratories, where he was also a member of the technical staff, and at Philips Medical Systems North America. Mr. Davis is currently on the board of Uluru, Inc., a public biotechnology company. Mr. Davis holds a B.S. in biomedical engineering from Boston University and an M.B.A. degree from the Wharton School, University of Pennsylvania.

David P. Nowotnik, Ph.D. is our Senior Vice President Research and Development since January 1, 2015. From November 2013 until December 2014 he was a consultant to the Company. From January 2003 through October 2013 he was our Sr. Vice President Research and Development and was Vice President Research and Development from 1998. From 1994 until 1998, Dr. Nowotnik had been with Guilford Pharmaceuticals, Inc. in the position of Senior Director, Product Development and was responsible for a team of scientists developing polymeric controlled-release drug delivery systems. From 1988 to 1994 he was with Bristol-Myers Squibb researching and developing technetium radiopharmaceuticals and MRI contrast agents. From 1977 to 1988 he was with Amersham International leading the project which resulted in the discovery and development of Ceretec.

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Mr. Stephen B. Thompson, the Company's Vice President Finance, became the Chief Accounting Officer, Secretary and Treasurer on January 1, 2015. Mr. Thompson consulted with the Company from December 1, 2013 through December 31, 2014. Prior to December 1, 2013 Mr. Thompson was our Vice President from 2000 and our Chief Financial Officer from 1996. From 1990 to 1996, he was Controller and Administration Manager of Access Pharmaceuticals, Inc., a private Texas corporation. Previously, from 1989 to 1990, Mr. Thompson was Controller of Robert E. Woolley, Inc., a hotel real estate company where he was responsible for accounting, finances and investor relations. From 1985 to 1989, he was Controller of OKC Limited Partnership, an oil and gas company, where he was responsible for accounting, finances and SEC reporting. Between 1975 and 1985 he held various accounting and finance positions with Santa Fe International Corporation.

#### PART II

# ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSURER PURCHASES OF EQUITY SECURITIES

#### Price Range of Common Stock and Dividend Policy

Our common stock has traded on The NASDAQ Capital Market ("NASDAQ") under the symbol PTBI since December 19, 2014. From November 21, 2014 until December 17, 2014 our common stock was traded under the trading symbol PTBI on the OTC Bulletin Board, or OTCQB. From October 24, 2014 until November 21, 2014 our common stock was traded under the trading symbol ACCPD. On October 24, 2014 we changed our corporate name and effected a 1 for 50 reverse stock split. Prior to October 24, 2014, our common stock was traded under the symbol ACCP since June 5, 2006.

The following table sets forth, for the periods indicated, the high and low closing prices as reported by NASDAQ and OTCQB for our common stock for fiscal years 2014 and 2013. The OTCQB quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

All per share information reflect a 1-for-50 reverse stock split effected on October 24, 2014.

	Common Stock			
	High		Low	
Fiscal Year Ended December 31, 2014				
First quarter	\$	29.50	\$	12.50
Second quarter		27.00		14.00
Third quarter		17.50		11.50
Fourth quarter		13.50		3.44
Fiscal Year Ended December 31, 2013				
First quarter	\$	30.00	\$	12.50
Second quarter		27.00		19.00
Third quarter		25.00		16.00
Fourth quarter		21.00		11.50

We have never declared or paid any cash dividends on our common stock and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. The payment of dividends, if any, in the future is within the discretion of our Board of Directors and will depend on our earnings, capital requirements and financial condition and other relevant facts. We currently intend to retain all future earnings, if any, to finance the development and growth of our business.

We were required, however, to pay dividends on our Series A preferred stock at the rate of 6% per year. We were also required to pay dividends on our Series B preferred stock at the rate of 12% per year. Both Series A and Series B preferred stock were converted into common stock on December 24, 2014. We currently have no outstanding shares of preferred stock.

The number of record holders of our common stock at March 31, 2015 was approximately 6,900. On March 30, 2015, the closing price for the common stock as quoted on NASDAQ was \$3.12. There were 19,988,801 shares of common stock outstanding at March 30, 2015.

### **Equity Compensation Plan Information**

The following table sets forth, as of December 31, 2014, information about shares of common stock outstanding and available for issuance under our existing equity compensation plans.

Plan Category	Number of securities to be issued upon exercise of outstanding options warrants and rights	Weighted- average exercise price of outstanding options warrants and rights		Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))	
	(a)		(b)	(c)	
Equity compensation plans approved by security holders:					
2005 Equity Incentive Plan	210,084	\$	21.19	226,533	
1995 Stock Awards Plan	50		620.00		
Total	210,134	\$	20.34	226,533	

## **Issuer Purchases of Equity Securities**

None.

## **Recent Sales of Unregistered Securities**

None.

### ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

# ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with our consolidated financial statements and related notes included in this Form 10-K.

PlasmaTech Biopharmaceuticals, Inc. (together with our subsidiaries, "we", "our", "PlasmaTech" or the "Company") is a Delaware corporation. We are an emerging biopharmaceutical company focused on developing a range of pharmaceutical products primarily based upon technology recently licensed from Licensor and our nanopolymer chemistry technologies. We currently have one marketed product licensed in the U.S., Europe, China, Australia, New Zealand and Korea. We also have additional products and platform technologies in various stages of development where we are seeking partners to continue development and/or to license the technology.

#### **Results of Operations**

#### Comparison of Years Ended December 31, 2014 and December 31, 2013

Product sales of MuGard in the United States totaled \$1,529,000 for the year ended December 31, 2013. We did not have any sales of MuGard in 2014 since MuGard was licensed to AMAG on June 6, 2013. We are currently receiving quarterly royalties from AMAG for the sale of MuGard under our licensing agreement.

Our licensing revenue for the year ended December 31, 2014 was \$598,000 as compared to \$435,000 for the same period of 2013, an increase of \$163,000. We recognize licensing revenue over the period of the performance obligation under our licensing agreements.

We recorded royalty revenue for MuGard of \$327,000 for the year ended December 31, 2014 and \$78,000 royalties in the same period of 2013, an increase of \$249,000.

Total research and development spending for the year ended December 31, 2014 was \$333,000, as compared to \$884,000 for the same period of 2013, a decrease of \$551,000. The decrease in research and development expenses was primarily due to:

- decreased clinical development with trials for MuGard (\$319,000);
- decreased salary and related costs (\$280,000) from reduced scientific staff;
- offset by increased scientific consulting expense (\$230,000); and
- other net decreases in research spending (\$182,000).

Product costs for MuGard in the United States were \$125,000 for the year ended December 31, 2013. There were no product costs in 2014 due to no sales of MuGard by us.

Total selling, general and administrative expenses were \$3,712,000 for the year ended December 31, 2014, as compared to \$4,834,000 for the same period of 2013, a decrease of \$1,122,000. The decrease in expenses was due primarily to the following:

- decreased net MuGard product selling expenses (\$960,000) which includes an increase of \$212,000 of MuGard product returns;
- decreased salary and related costs (\$456,000) from reduced general and administrative staff;
- decreased professional fees (\$438,000);
- net decrease other general and administrative expenses (\$135,000); and offset by
- increased stock compensation expense for options granted to employees, officers, directors and consultants (\$867,000), options were granted in 2014 and no options were granted in 2013.

Depreciation and amortization was \$11,000 for the year ended December 31, 2014 as compared to \$3,000 for the same period in 2013.


Total operating expenses for the year ended December 31, 2014 were \$4,056,000 as compared to total operating expenses of \$5,846,000 for the same period of 2013, a decrease of \$1,790,000 for the reasons listed above.

Interest and miscellaneous income was \$45,000 for the year ended December 31, 2014 as compared to \$251,000 for the same period of 2013, a decrease of \$206,000. Miscellaneous income was higher in 2013 due to sale of certain platinum inventory and to write-offs of certain accounts payables.

Interest and other expense was \$582,000 for the year ended December 31, 2014 as compared to \$279,000 in the same period of 2013, an increase of \$303,000. The increase represents interest accrued on unpaid dividends. No dividends have been paid in 2013 or 2014. All unpaid interest on accrued dividends were converted into common stock on December 24, 2014.

We recorded a gain related to warrants classified as derivative liabilities of \$271,000 for the year ended December 31, 2013. The warrants expired in November 2013 and in February 2014 so there was no derivative liability or gain/loss during the year ended December 31, 2014.

We recorded a loss for the derivative liability related to preferred stock of \$23,110,000 for the year ended December 31, 2014 and a gain of \$8,010,000 for the same period of 2013. We recorded a derivative liability per the requirements of accounting guidance due to the possibility of resetting the conversion price of our Series A Preferred Stock if we sold our common stock at a price below the original price.

Preferred stock dividends of \$2,875,000 were accrued for the year ended December 31, 2014 and \$2,898,000 for the same period of 2013, a decrease of \$23,000. Dividends were due semi-annually in either cash or common stock for the Series A Preferred Stock and due quarterly in either cash or preferred stock for the Series B Preferred Stock. All unpaid preferred stock dividends were converted into common stock on December 24, 2014.

Net loss allocable to common stockholders for the year ended December 31, 2014 was \$29,653,000, or a \$15.26 basic and diluted loss per common share as compared to a net income of \$1,551,000, or a \$3.07 basic and \$3.04 diluted income per common share, for the same period in 2013, an increased loss of \$31,204,000.

# Liquidity and Capital Resources

We have funded our operations primarily through public and private sales of common stock, preferred stock, convertible notes and through licensing agreements. Our principal source of liquidity is cash and cash equivalents. On December 24, 2014, we announced the closing of an underwritten public offering of 3,500,000 shares of common stock, and warrants to purchase up to an aggregate 3,500,000 shares of common stock, at an offering price of \$4.00 per share and \$.01 per warrant. The warrants have a per share exercise price of \$5.00, are exercisable immediately, and expire 5 years from the date of issuance. The gross proceeds to the Company from this offering were \$14,035,000, before deducting underwriting discounts and commissions and other estimated offering expenses. Licensing payments and royalty revenues provided limited funding for operations during the year ended December 31, 2014. As of December 31, 2014, our cash and cash equivalents were \$11,520,000.

As of December 31, 2014, our working capital was \$8,657,000. Our working capital at December 31, 2014 represented an increase of \$17,043,000 as compared to our working capital deficit as of December 31, 2013 of \$8,386,000. The increase in the working capital at December 31, 2014 reflects December 24, 2014 financing, the license fee from Hanmi and \$400,000 from the Grid Notes (see below) offset by twelve months of net operating costs and changes in current assets and liabilities.

On September 10, 2014, we entered into an Unsecured Grid Note, for up to \$250,000 with SCO ("Grid Note I"). As of December 31, 2014 we had drawn a total of \$250,000. The interest rate is 8% per annum and the maturity date is August 31, 2015 unless a financing of at least \$5,000,000 occurs. The financing occurred December 24, 2014 and the Grid Note I was paid in full on January 5, 2015.



On December 1, 2014, we entered into a second Unsecured Grid Note ("Grid Note II"), for up to \$250,000 with SCO. As of December 31, 2014 we had drawn a total of \$150,000. The interest rate is 8% per annum and the maturity date is November 30, 2015 unless a financing of at least \$5,000,000 occurs. The financing occurred December 24, 2014 and the Grid Note II was paid in full on January 5, 2015.

On September 22, 2014, we entered into an exclusive, worldwide licensing agreement with Licensor to obtain rights to utilize and to sub-license to other pharmaceuticals firms, its patented methods for the extraction of therapeutic biologics from human plasma. Under the terms of the licensing agreement, as amended on January 31, 2015, we paid a license fee of \$1 million in cash, will pay \$4,000,000 in cash or 1,096,151 shares of our common stock in 2017, a regulatory approval milestone payment of 513,375 shares of our common stock upon the first FDA regulatory approval of a drug derived from the Licensor's proprietary SDF process, and a tiered royalty on annual net sales of plasma fractions produced with Licensor's proprietary SDF process.

If we raise additional funds by selling equity securities, the relative equity ownership of our existing investors will be diluted and the new investors could obtain terms more favorable than previous investors.

We have incurred negative cash flows from operations since inception, and have expended, and expect to continue to expend in the future, substantial funds to complete our planned product development efforts. Since inception, our expenses have significantly exceeded revenues, resulting in an accumulated deficit as of December 31, 2014 of \$296,074,000. We expect that our capital resources, royalties from MuGard and expected receipts due under our license agreements will be adequate to fund our current level of operations into the second quarter of 2016. However, our ability to fund operations over this time could change significantly depending upon changes to future operational funding obligations or capital expenditures. As a result, we may be required to seek additional financing sources within the next twelve months. We cannot provide assurance that we will ever be able to generate sufficient product sales or royalty revenue to achieve profitability on a sustained basis or at all.

Since our inception, we have devoted our resources primarily to fund our research and development programs. We have been unprofitable since inception and to date have received limited revenues from the sale of products. We expect to incur losses for the next several years as we continue to invest in product research and development, preclinical studies, clinical trials and regulatory compliance.

We plan to expend substantial funds to conduct research and development programs, preclinical studies and clinical trials of potential products, including research and development with respect to our acquired and developed technology. Our future capital requirements and adequacy of available funds will depend on many factors, including:

- the successful development and commercialization of MuGard and our other product candidates;
- the successful development and commercialization of products derived from our recent license of Licensor technologies;
- the ability to establish and maintain collaborative arrangements with corporate partners for the research, development and commercialization of products;
- continued scientific progress in our research and development programs;
- the magnitude, scope and results of preclinical testing and clinical trials;
- the costs involved in filing, prosecuting and enforcing patent claims;
- the costs involved in conducting clinical trials;
- competing technological developments;
- the cost of manufacturing and scale-up;
- · the ability to establish and maintain effective commercialization arrangements and activities; and
- successful regulatory filings.

We have devoted substantially all of our efforts and resources to research and development conducted on our own behalf. The following table summarizes research and development spending by project category, which spending includes, but is not limited to, payroll and personnel expense, lab supplies, preclinical expense, development cost, clinical trial expense, outside manufacturing expense and consulting expense:

(in thousands)	Т	welve M Decer	onths nber 3		In	ception To
Project		2014		2013		Date <sup>(1)</sup>
MuGard	\$	301	\$	725	\$	5,316
Others <sup>(2)</sup>		32		159		40,020
Total	\$	333	\$	884	\$	45,336

(1) Cumulative spending from inception of the Company or project through December 31, 2014.

(2) Includes: ProctiGard, CobOral, CobaCyte and other projects.

Due to uncertainties and certain of the risk factors described above, including those relating to our ability to successfully commercialize our drug candidates, our ability to obtain necessary additional capital to fund operations in the future, our ability to successfully manufacture our products and our product candidates in clinical quantities or for commercial purposes, government regulation to which we are subject, the uncertainty associated with preclinical and clinical testing, intense competition that we face, market acceptance of our products and protection of our intellectual property, it is not possible to reliably predict future spending or time to completion by project or product category or the period in which material net cash inflows from significant projects are expected to commence. If we are unable to timely complete a particular project, our research and development efforts could be delayed or reduced, our business could suffer depending on the significance of the project and we might need to raise additional capital to fund operations, as discussed in the risk factors above, including without limitation those relating to the uncertainty of the success of our research and development activities and our ability to obtain necessary additional capital to fund operations in the future. As discussed in such risk factors, delays in our research and development efforts and any inability to raise additional funds could cause us to eliminate one or more of our research and development programs.

We plan to continue our policy of investing any available funds in certificates of deposit, money market funds, government securities and investment-grade interest-bearing securities. We do not invest in derivative financial instruments.

We do not believe inflation or changing prices have had a material impact on our revenue or operating income in the past three years.

#### **Climate Change**

We do not believe there is anything unique to our business which would result in climate change regulations having a disproportional effect on us as compared to U.S. industry overall.

# Sources and Availability of Raw Materials and Components

In addition, we also are subject to rules promulgated by the Securities Exchange Commission (SEC) in 2012 pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 that require us to conduct due diligence on and disclose if we are able to determine whether certain materials (including tantalum, tin, gold and tungsten), known as conflict minerals, that originate from mines in the Democratic Republic of Congo or certain adjoining countries (DRC), are used in our products. The first DRC minerals report is due in May 2015 for the 2014 calendar year and we are conducting appropriate diligence measures to comply with such requirements.

# **Critical Accounting Policies and Estimates**

The preparation of our consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reported period. In applying our accounting principles,



we must often make individual estimates and assumptions regarding expected outcomes or uncertainties. As you might expect, the actual results or outcomes are often different than the estimated or assumed amounts. These differences are usually minor and are included in our consolidated financial statements as soon as they are known. Our estimates, judgments and assumptions are continually evaluated based on available information and experience. Because of the use of estimates inherent in the financial reporting process, actual results could differ from those estimates.

#### Receivables

Receivables are reported in the balance sheets at the outstanding amount net of an allowance for doubtful accounts. We continually evaluate the creditworthiness of our customers and their financial condition and generally do not require collateral. The allowance for doubtful accounts is based upon reviews of specific customer balances, historic losses, and general economic conditions. As of December 31, 2014 and 2013, no allowance was recorded as all accounts were considered collectible.

#### Licensed Technology

On September 22, 2014, we entered into an exclusive, worldwide licensing agreement with Licensor to obtain rights to utilize and to sub-license to other pharmaceuticals firms, its patented methods for the extraction of therapeutic biologics from human plasma. Under the terms of the licensing agreement, as amended on January 23, 2015, we paid a license fee of \$1 million in cash, will pay \$4,000,000 in cash or 1,096,151 shares of our common stock in 2017, a regulatory approval milestone payment of 513,375 shares of our common stock upon the first FDA regulatory approval of a drug derived from the Licensor's proprietary SDF process, and a tiered royalty on annual net sales of plasma fractions produced with Licensor's proprietary SDF process.

The license is amortized over the life of the patent.

#### Derivative liability

In order to calculate the Derivative liability — preferred stock, we used the Monte Carlo simulation to estimate future stock prices. The use of valuation techniques requires us to make various key assumptions for inputs into the model, including assumptions about the expected future volatility of the price of our stock. In estimating the fair value at the end of December 31, 2013 balance sheet date, we based our selected volatility on the one-year historic volatility of our stock as we believe this is most representative of the expected volatility in the near future for us. The Series A Preferred Stock was converted into common stock at December 24, 2014 so there is no longer a derivative liability.

#### License Revenues and Royalties

Our revenues are generated from licensing, research and development agreements, royalties and product sales. We recognize revenue in accordance with SEC Staff Accounting Bulletin No. 104 (SAB 104), Revenue Recognition. License revenue is recognized over the remaining life of the underlying patent or period of performance obligation. Research and development revenues are recognized as services are performed. Royalties and product revenues are recognized in the period of sales.

# Stock Based Compensation Expense

We account for stock based compensation expense in accordance with FASB ASC 718, Stock Based Compensation. We have two stock-based compensation plans under which incentive and non-incentive qualified stock options and restricted shares may be granted to employees, directors and consultants. We measure the cost of the employee/director/consultant services received in exchange for an award of equity instruments based on the grant date fair value of the award. We use the Black-Scholes option pricing model to value our options which includes expected volatility, risk-free interest rate, dividend yield and estimated expected term.

Stock-based compensation expense recognized for the years ended December 31, 2014 and 2013 was approximately \$1,305,000 and \$439,000, respectively.

# **Off-Balance Sheet Transactions**

None.



# ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

# ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Financial statements required by this Item are incorporated in this Annual Report Form 10-K on pages F- $\underline{1}$  through F- $\underline{20}$  hereto. Reference is made to Item 15 of this Form 10-K.

# ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

## **ITEM 9A. CONTROLS AND PROCEDURES**

Under the supervision and with the participation of our management and consultants, including the Executive Chairman (our principal executive officer) and Chief Accounting Officer (our principal accounting officer), we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as such term is defined in Exchange Act Rules 13a-15(e) and 15d-15(e), as of the end of the period covered by this report.

#### **Evaluation of Disclosure Controls and Procedures**

We conducted an evaluation of the effectiveness of the design and operation of our "disclosure controls and procedures" ("Disclosure Controls") as of the end of the period covered by this Form 10-K. The Disclosure Controls evaluation was conducted under the supervision and with the participation of management and consultants, including our Executive Chairman and Chief Accounting Officer. Disclosure Controls are controls and procedures designed to reasonably assure that information required to be disclosed in our reports filed under the Exchange Act, such as this Form 10-K, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure Controls are also designed to provide reasonable assurance that such information is accumulated and communicated to our management, including our Executive Chairman and Chief Accounting Officer, as appropriate to allow timely decisions regarding required disclosure.

The evaluation of our Disclosure Controls included a review of the controls' objectives and design, our implementation of the controls and the effect of the controls on the information generated for use in this Form 10-K. During the course of our evaluation of our internal control over financial reporting, we advised the Audit Committee of our Board of Directors that we had identified a material weakness as defined under standards established by the Public Company Accounting Oversight Board (United States). A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness we identified is discussed in "Management's Annual Report on Internal Control Over Financial Reporting" below. Our Executive Chairman and Chief Accounting Officer have concluded that as a result of the material weakness, as of the end of the period covered by this Annual Report on Form 10-K, our Disclosure Controls were not effective.

## Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Our internal control system was designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes, in accordance with generally accepted accounting principles. Because of inherent limitations, a system of internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate due to change in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, including our principal executive officer and principal accounting officer, conducted an evaluation of the effectiveness of our internal control over financial reporting using the criteria set forth by the COSO in Internal Control — Integrated Framework for the year ended December 31, 2014.



Based on our evaluation, our management concluded that there is a material weakness in our internal control over financial reporting. The material weakness identified did not result in the restatement of any previously reported financial statements or any related financial disclosure, nor does management believe that it had any effect on the accuracy of the Company's financial statements for the current reporting period. A material weakness is a deficiency, or a combination of control deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

The material weakness relates to the monitoring and review of work performed by our then accounting consultant in the preparation of audit and financial statements, footnotes and financial data provided to the Company's registered public accounting firm in connection with the annual audit. All of our financial reporting was carried out by our then accounting consultant. This lack of accounting staff results in a lack of segregation of duties.

In order to mitigate this material weakness to the fullest extent possible, all financial reports are reviewed by the Executive Chairman as well as the Chairman of the Audit Committee for reasonableness. All unexpected results are investigated. At any time, if it appears that any control can be implemented to continue to mitigate such weaknesses, it is immediately implemented. We have hired additional personnel and implemented appropriate procedures for monitoring and review of work performed by our Chief Accounting Officer.

Because of the material weakness described above, management concluded that, as of December 31, 2014, our internal control over financial reporting was not effective based on the criteria established in Internal Control-Integrated Framework issued by COSO.

This Annual Report on Form 10-K does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to rules of the SEC that permit smaller reporting companies like us to provide only management's report in this Annual Report on Form 10-K.

This report shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that section, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

## Changes In Internal Control Over Financial Reporting

We have hired additional personnel to improve our internal control over financial reporting during the quarter ended December 31, 2014. With the new personnel we expect to positively affect, or are reasonable likely to materially affect, our internal control over financial reporting.

# **ITEM 9B. OTHER INFORMATION**

None.



#### PART III

#### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

**Directors and Reports of Beneficial Ownership**. The information required by this Item is incorporated herein by reference from the information to be contained in our 2015 Proxy Statement to be filed with the U.S. Securities and Exchange Commission in connection with the solicitation of proxies for our 2015 Annual Meeting of Stockholders (the Proxy Statement). The information under the heading "Executive Officers of the Registrant" in Part I of this Form 10-K is also incorporated by reference.

**Code of Ethics**. We have adopted a Code of Business Conduct and Ethics (the Code) that applies to all of our employees (including executive officers) and directors. The Code is available on our website at *www.plasmatechbio.com* under the heading "Investor Information." We intend to satisfy the disclosure requirement regarding any waiver of a provision of the Code applicable to any executive officer or director, by posting such information on such website. We shall provide to any person without charge, upon request, a copy of the Code. Any such request must be made in writing to PlasmaTech Biopharmaceuticals, Inc., c/o Investor Relations, 4848 Lemmon Avenue, Suite 517, Dallas, TX 75219.

Our corporate governance guidelines and the charters of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee of the Board of Directors are available on our website at *www.plasmatechbio.com* under the heading "Investor Information". We shall provide to any person without charge, upon request, a copy of any of the foregoing materials. Any such request must be made in writing to PlasmaTech Biopharmaceuticals, Inc., c/o Investor Relations, 4848 Lemmon Avenue, Suite 517, Dallas, TX 75219.

# **ITEM 11. EXECUTIVE COMPENSATION**

The information required by this Item is contained in the Proxy Statement and is incorporated herein by reference.

# ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item is contained in the Proxy Statement and is incorporated herein by reference.

# ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this Item is contained in the Proxy Statement and is incorporated herein by reference.

# ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is contained in the Proxy Statement and is incorporated herein by reference.

# PART IV

# ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

	Page
a. Financial Statements. The following financial statements are submitted as part of this report:	
Report of Independent Registered Public Accounting Firm	<u>F-1</u>
Consolidated Balance Sheets at December 31, 2014 and 2013	<u>F-2</u>
Consolidated Statements of Operations for 2014 and 2013	<u>F-3</u>
Consolidated Statements of Stockholders' Equity (Deficit) for 2014 and 2013	<u>F-4</u>
Consolidated Statements of Cash Flows for 2014 and 2013	<u>F-5</u>
Notes to Consolidated Financial Statements	<u>F-6</u>

# b. <u>Exhibits</u>

# Exhibit

EXHIDIU	
Number	Description of Document
2.1	Amended and Restated Agreement of Merger and Plan of Reorganization between the Registrant and
	Chemex Pharmaceuticals, Inc., dated as of October 31, 1995 (Incorporated by reference to Exhibit A of
	our Registration Statement on Form S-4 dated December 20, 1995, Commission File No. 33-64031)
2.2	Agreement and Plan of Merger, by and among the Registrant, Somanta Acquisition Corporation,
	Somanta Pharmaceuticals, Inc., Somanta Incorporated and Somanta Limited, dated April 19, 2007
	(Incorporated by reference to Exhibit 2.1 to our Form 8-K dated April 18, 2007)
2.3	Agreement and Plan of Merger, by and among the Registrant, MACM Acquisition Corporation and
	MacroChem Corporation, dated July 9, 2008 (Incorporated by reference to Exhibit 2.3 of our Form 10-
	Q for the quarter ended June 30, 2008)
3.1	Certificate of Incorporation (Incorporated by reference to Exhibit 3(a) of our Form 8-K dated July 12,
	1989, Commission File Number 9-9134)
3.2	Certificate of Amendment of Certificate of Incorporation filed August 13, 1992 (Incorporated by
	reference to Exhibit 3.3 of our Form 10-K for year ended December 31, 1995)
3.3	Certificate of Merger filed January 25, 1996 (Incorporated by reference to Exhibit E of our Registration
	Statement on Form S-4 dated December 20, 1995, Commission File No. 33-64031)
3.4	Certificate of Amendment of Certificate of Incorporation filed January 25, 1996 (Incorporated by
	reference to Exhibit E of our Registration Statement on Form S-4 dated December 20, 1995,
	Commission File No. 33-64031)
3.5	Certificate of Amendment of Certificate of Incorporation filed July 18, 1996 (Incorporated by reference
	to Exhibit 3.7 of our Form 10-K for the year ended December 31, 1996)
3.6	Certificate of Amendment of Certificate of Incorporation filed June 18, 1998. (Incorporated by
	reference to Exhibit 3.8 of our Form 10-Q for the quarter ended June 30, 1998)
3.7	Certificate of Amendment of Certificate of Incorporation filed July 31, 2000 (Incorporated by reference
	to Exhibit 3.8 of our Form 10-Q for the quarter ended March 31, 2001)
3.8	Certificate of Designations of Series A Junior Participating Preferred Stock filed November 7, 2001
	(Incorporated by reference to Exhibit 4.1.H of our Registration Statement on Form S-8 dated December
	14, 2001, Commission File No. 333-75136)
3.9	Amended and Restated Bylaws (Incorporated by reference to Exhibit 2.1 of our Form 10-Q for the
	quarter ended June 30, 1996)
3.10	Certificate of Designation, Rights and Preferences of Series A Cumulative Convertible Preferred Stock
	filed Nevember 0, 2007 (Incornerated by reference to Exhibit 2, 10 to our Form SP 2 filed on December

filed November 9, 2007 (Incorporated by reference to Exhibit 3.10 to our Form SB-2 filed on December 10, 2007.

Exhibit	
Number	Description of Document
3.11	Certificate of Amendment to Certificate of Designations, Rights and Preferences of Series A
	Cumulative Convertible Preferred Stock filed June 11, 2008 (Incorporated by reference to Exhibit 3.11
	of our Form 10-Q for the quarter ended June 30, 2008)
3.12	Certificate of Designations, Rights and Preferences of Series B Cumulative Convertible Preferred Stock
	filed October 26, 2012 (Incorporated by reference to Exhibit 10.3 of our Form 8-K filed October 26,
	2012)
3.13	Certificate of Amendment of Certificate of Incorporation filed July 1, 2013 increasing the aggregate
	number of shares of Common Stock which we have authority to issue to Two Hundred Million
	(200,000,000) shares with a par value of one cent (\$0.01) per share. (Incorporated by reference to
	Exhibit 3.3 of our Form 10-Q for the quarter ended June 30, 2014)
3.14	Certificate of Amendment of Certificate of Incorporation filed October 23, 2014 (Incorporated by
	reference to Exhibit 3.14 of our Form 8-K filed October 23, 2014)
3.15	Certificate of Amendment to Certificate of Designations, Rights and Preferences of Series A
	Cumulative Convertible Preferred Stock (Incorporated by reference to Exhibit 3.15 of our Form 8-K
	filed on October 23, 2014)
3.16	Amendment to Bylaws (Incorporated by reference to Exhibit 3.1 of our Form 8-K filed January 5, 2015)
3.17	Amendment to Bylaws (Incorporated by reference to Exhibit 3.1 of our Form 8-K filed March 5, 2015)
10.1*	1995 Stock Option Plan (Incorporated by reference to Exhibit F of our Registration Statement on Form
	S-4 dated December 20, 1995, Commission File No. 33-64031)
10.2*	Amendment to 1995 Stock Option Plan (Incorporated by reference to Exhibit 10.25 of our Form 10-K
	for the year ended December 31, 2001)
10.3*	401(k) Plan (Incorporated by reference to Exhibit 10.20 of our Form 10-K for the year ended December
	31, 1999)
10.4*	2005 Equity Incentive Plan (Incorporated by reference to Exhibit 1 of our Proxy Statement filed on
	April 18, 2005)
10.5	Asset Sale Agreement dated as of October 12, 2005, between the Registrant and Uluru, Inc.
	(Incorporated by reference to Exhibit 10.25 of our 10-K for the year ended December 31, 2005)
10.6	Amendment to Asset Sale Agreement dated as of December 8, 2006, between the Registrant and Uluru,
	Inc. (Incorporated by reference to Exhibit 10.16 of our Form 10-KSB filed on April 2, 2007)
10.7	License Agreement dated as of October 12, 2005, between the Registrant and Uluru, Inc. (Incorporated
	by reference to Exhibit 10.26 of our 10-K for the year ended December 31, 2005)
10.8	Form of Warrant dated February 16, 2006, issued by the Registrant to certain Purchasers (Incorporated
	by reference to Exhibit 10.31 of our Form 10-Q for the quarter ended March 31, 2006)
10.9	Form of Warrant dated October 24, 2006, issued by the Registrant to certain Purchasers (Incorporated
	by reference to Exhibit 10.27 of our Form 10-KSB filed on April 2, 2007)
10.10	Form of Warrant December 6, 2006, issued by the Registrant to certain Purchasers (Incorporated by
	reference to Exhibit 10.32 of our Form 10-KSB filed on April 2, 2007)
10.11	Board Designation Agreement dated November 15, 2007, between the Registrant and SCO Capital
	Partners LLC (Incorporated by reference to Exhibit 10.26 of our Form S-1 filed on March 11, 2008)
10.12	Form of Securities Purchase Agreement (Incorporated by reference to Exhibit 10.29 of our Form S-1
	filed on January 15, 2010)

E-1:1:4	
Exhibit Number	Description of Document
10.13	Form of Warrant (Incorporated by reference to Exhibit 10.30 of our Form S-1 filed on January 15,
	2010)
10.14	Form of Securities Purchase Agreement dated as of December 10, 2010 by and among us and the
	Purchasers named therein (Incorporated by reference to Exhibit 10.1 of our Form 8-K filed on
	December 14, 2010)
10.15	Form of Common Stock Warrant issued by us (Incorporated by reference to Exhibit 10.1 of our Form
	8-K filed on December 14, 2010)
10.16	Form of Securities Purchase Agreement dated as of November 1, 2011 by and among us and the
	Purchasers named therein (Incorporated by reference to Exhibit 10.1 of our Form 8-K filed on
	November 10, 2011)
10.17	Form of Common Stock Warrant (Five Year Warrant) issued by us (Incorporated by reference to
	Exhibit 10.3 of our Form 8-K filed on November 10, 2011)
10.18	Amendment No.1 to Warrant Agreement dated February 10, 2012 by and among us and warrant
	holders including certain affiliates named therein extending the term of certain warrants until 2015
10.10	(Incorporated by reference to Exhibit 99.1 of our Form 8-K filed on February 10, 2012)
10.19	Preferred Stock and Warrant Purchase Agreement dated October 25, 2012 by and among us and the
	Purchasers named therein (Incorporated by reference to Exhibit 10.1 of our Form 8-K filed October 26, 2012)
10.20	Investor Rights Agreement dated October 25, 2012, between the Registrant and certain Purchasers
10.20	(Incorporated by reference to Exhibit 10.2 of our Form 8-K filed on October 26, 2012)
10.21	Form of Common Stock Warrant issued by us (Incorporated by reference to Exhibit 10.3 of our Form
10.21	8-K filed on October 26, 2012)
10.22 +	License Agreement, dated June 6, 2013, by and between us and AMAG Pharmaceuticals, Inc.
	(Incorporated by reference to Exhibit 10.16 of our Form 10-Q for the quarter ended June 30, 2014)
10.23 +	License Agreement, dated September 19, 2014, by and between us and Plasma Technologies, LLC.
	(Incorporated by reference to Exhibit 10.30 of our Form 8-K filed September 24, 2014)
10.24*	Employment Letter Agreement dated September 19, 2014, by and between us and Scott Schorer.
	(Incorporated by reference to Exhibit 10.31 of our Form 8-K filed September 24, 2014)
10.25*	Employment Letter Agreement dated September 19, 2014, by and between us and Harrison Wehner.
	(Incorporated by reference to Exhibit 10.32 of our Form 8-K filed September 24, 2014)
10.26	Unsecured Grid Note \$250,000, dated September 10, 2014, by and between us and SCO Capital
	Partners LLC (Incorporated by reference to Exhibit 20.1 of our Form 8-K filed October 23, 2014)
10.27	Unsecured Grid Note \$250,000, dated December 1, 2014, by and between us and SCO Capital Partners
10.00	LLC (Incorporated by reference to Exhibit 10.35 of our Form 8-K filed December 3, 2014)
10.28	Share Exchange Agreement, dated September 10, 2014, by and among us and the Series B
	Stockholders party thereto (Incorporated by reference to Exhibit 10.33 of our Form 8-K filed October
10.29	23, 2014) Amondmant No. 1 to License Agreement, dated Sentember 10, 2014, by and between us and Plasma
10.29	Amendment No. 1 to License Agreement, dated September 19, 2014, by and between us and Plasma Technologies, LLC, dated January 23, 2015.
21	Subsidiaries of the Registrant
<i>L</i> 1	Substituties of the Registratit

Exhibit	
Number	Description of Document
23.1	Consent of Whitley Penn LLP
31.1	Principal Executive Officer Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to
	Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Principal Financial Officer Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to
	Section 302 of the Sarbanes-Oxley Act of 2002
32**	Principal Executive Officer Certification and Principal Financial Officer Certification Pursuant to 18
	U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following materials from the Company's Annual Report on Form 10-K for the year ended
	December 31, 2013 and for the fiscal year ended December 31, 2012, formatted in XBRL (Extensible
	Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of
	Operations, (iii) Consolidated Statements of Stockholders' Deficit, (iv) Consolidated Statements of
	Cash Flows, and (v) Notes to Consolidated Financial Statements, tagged as blocks of text.

\* Management contract or compensatory plan required to be filed as an Exhibit to this Form pursuant to Item 15c of the report.

- \*\* This exhibit shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of the Section, nor shall it be deemed incorporated by reference in any filings under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation language in any filing.
- + Portions of this exhibit were omitted and filed separately with the U.S. Securities and Exchange Commission pursuant to a request for confidential treatment.

# **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

	ASMATECH BIOPHARMACEUTICALS, INC. 7: /s/ Steven H. Rouhandeh
	Steven H. Rouhandeh
	Executive Chairman
	Principal Executive Officer
Date March 31, 2015 By	v: /s/ Stephen B. Thompson
	Stephen B. Thompson
	Vice President Finance
	Principal Financial Officer and
	Principal Accounting Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

/s/ Steven H. Rouhandeh
Steven H. Rouhandeh
Executive Chairman
Principal Executive Officer
Chairman of the Board
/s/ Stephen B. Thompson
Stephen B. Thompson
Vice President Finance
Principal Financial Officer and
Principal Accounting Officer
/s/ Mark J. Ahn
Mark J. Ahn, Director
/s/ Mark J. Alvino
Mark J. Alvino, Director
/s/ Jeffrey B. Davis
Jeffrey B. Davis, Director
/s/ Stephen B. Howell
Stephen B. Howell, Director

# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of PlasmaTech Biopharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of PlasmaTech Biopharmaceuticals, Inc. and subsidiaries (the "Company"), as of December 31, 2014 and 2013, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for the years then ended. The Company's management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of PlasmaTech Biopharmaceuticals, Inc. and subsidiaries as of December 31, 2014 and 2013, and the consolidated results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ WHITLEY PENN LLP

Dallas, Texas March 31, 2015

CONSOLIDATED BALANCE SHEETS

	]	December 31, 2014	]	December 31, 2013	
ASSETS					
Current assets					
Cash and cash equivalents	\$	11,520,000	\$	424,000	
Receivables		35,000		74,000	
Prepaid expenses and other current assets				77,000	
Total current assets		11,555,000		575,000	
Property and equipment, net		4,000		6,000	
Licensed technology, net		4,991,000		_	
Other assets		32,000		32,000	
Total assets	\$	16,582,000	\$	613,000	
LIABILITIES AND STOCKHOLDERS' DEFICIT					
Current liabilities					
Accounts payable	\$	1,896,000	\$	863,000	
Accrued expenses				857,000	
Short-term notes payable		400,000			
Dividends payable				6,663,000	
Current portion of deferred revenue		602,000		578,000	
Total current liabilities		2,898,000		8,961,000	
Payable due Licensor		4,000,000		_	
Derivative liability – preferred stock		—		1,190,000	
Long-term deferred revenue		4,868,000		5,241,000	
Total liabilities		11,766,000		15,392,000	
Commitments and contingencies					
Stockholders' equity (deficit)					
Convertible preferred stock A – \$.01 par value; authorized 2,000,000 shares; none issued at December 31, 2014; 2,903.3617 issued at					
December 31, 2013					
Convertible preferred stock B – \$.01 par value; authorized 2,000,000 shares; none issued at December 31, 2014; 1,000 issued at December 31,					
2013					
Common stock – \$.01 par value; authorized 200,000,000 shares; issued					
19,960,801 at December 31, 2014; issued 514,589 at December 31,					
2013		200,000		6,000	
Additional paid-in capital		300,690,000		251,640,000	
Treasury stock, at cost – none at December 31, 2014; 3 shares at					
December 31, 2013		—		(4,000)	
Accumulated deficit	(	296,074,000)		266,421,000)	
Total stockholders' equity (deficit)		4,816,000		(14,779,000)	
Total liabilities and stockholders' equity (deficit)	\$	16,582,000	\$	613,000	

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

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# CONSOLIDATED STATEMENTS OF OPERATIONS

Product costs—125,00Selling, general and administrative $3,712,000$ $4,834,000$ Depreciation and amortization11,000 $3,000$ Total expenses $4,056,000$ $5,846,000$ Loss from operations $(3,131,000)$ $(3,804,000)$ Interest and miscellaneous income $45,000$ $251,000$ Interest and other expense $(582,000)$ $(279,000)$ Gain on change in fair value of derivative-warrants— $271,000$ Gain (loss) on change in fair value of derivative-preferred stock $(23,110,000)$ $8,010,000$ (23,647,000) $8,253,000$ $(2,875,000)$ $(2,898,000)$ Net income (loss) $(2,898,000)$ $(2,898,000)$ $(2,898,000)$ Net income (loss) allocable to common stockholders $\$(29,653,000)$ $\$(15,26)$ $\$(15,26)$ Net income (loss) per common share $\$(15,26)$ $\$(15,26)$ $\$(15,26)$ $\$(15,26)$ Basic $\$(15,26)$ $\$(15,26)$ $\$(15,26)$ $\$(15,26)$ $\$(15,26)$ Diluted $\$(15,26)$ $\$(15,26)$ $\$(15,26)$ $\$(15,26)$ $\$(15,26)$		For the Decer				
Product sales       \$       \$ 1,529,00         License revenues       598,000       435,00         Royalties       327,000       78,00         Total revenues       925,000       2,042,00         Expenses       925,000       2,042,00         Research and development       333,000       884,00         Product costs        125,000         Selling, general and administrative       3,712,000       4,834,000         Depreciation and amortization       11,000       3,000         Total expenses       4,056,000       5,846,000         Loss from operations       (3,131,000)       (3,804,000         Interest and miscellaneous income       45,000       251,000         Interest and other expense       (582,000)       (279,000         Gain on change in fair value of derivative-preferred stock       (23,647,000)       8,253,000         Net income (loss)       (26,778,000)       4,449,000       (2,898,000)         Less preferred stock dividends       (2,875,000)       (2,898,000)       \$,10,000         Net income (loss) allocable to common stockholders       \$ (29,653,000)       \$ 1,551,000         Net income (loss) per common share		2014	2013			
License revenues598,000435,000Royalties $327,000$ 78,000Total revenues $925,000$ $2,042,000$ Expenses $925,000$ $2,042,000$ Expenses $$ $125,000$ Selling, general and administrative $3,712,000$ $4,834,000$ Depreciation and amortization $11,000$ $3,000$ Total expenses $4,056,000$ $5,846,000$ Loss from operations $(3,131,000)$ $(3,804,000)$ Interest and miscellaneous income $45,000$ $251,000$ Interest and other expense $(582,000)$ $(279,000)$ Gain on change in fair value of derivative-preferred stock $(23,647,000)$ $8,253,000$ Net income (loss) $(26,778,000)$ $4,449,000$ Less preferred stock dividends $(2,875,000)$ $(2,898,000)$ Net income (loss) allocable to common stockholders $§(29,653,000)$ $$1,551,000$ Net income (loss) per common share $8asic$ $$(15.26)$ $$3.00$ Basic $$(15.26)$ $$3.00$ $$(15.26)$ $$3.00$ Diluted $$(15.26)$ $$3.00$ $$(15.26)$ $$3.00$		<b>b</b>	<b>A 1 50</b> 0 0 0 0			
Royalties         327,000         78,000           Total revenues         925,000         2,042,000           Expenses         333,000         884,000           Product costs         -         125,000           Selling, general and administrative         3,712,000         4,834,000           Depreciation and amortization         11,000         3,000           Total expenses         4,056,000         5,846,000           Loss from operations         (3,131,000)         (3,804,000           Interest and miscellaneous income         45,000         251,000           Interest and other expense         (582,000)         (279,000)           Gain on change in fair value of derivative-warrants         -         271,000           Gain (loss) on change in fair value of derivative-preferred stock         (23,647,000)         8,253,000           Net income (loss)         (26,778,000)         4,449,000         (2,898,000)           Less preferred stock dividends         (2,875,000)         (2,898,000)         \$           Net income (loss) allocable to common stockholders         \$ (29,653,000)         \$ 1,551,000           Net income (loss) per common share         -         -         3,000           Basic         \$ (15.26)         \$ 3,00         \$ (15.26) <td></td> <td>*</td> <td></td>		*				
Total revenues $925,000$ $2,042,000$ ExpensesResearch and development $333,000$ $884,000$ Product costs $125,000$ Selling, general and administrative $3,712,000$ $4,834,000$ Depreciation and amortization $11,000$ $3,000$ Total expenses $4,056,000$ $5,846,000$ Loss from operations $(3,131,000)$ $(3,804,000)$ Interest and miscellaneous income $45,000$ $251,000$ Interest and other expense $(582,000)$ $(279,000)$ Gain on change in fair value of derivative-warrants $271,000$ Gain (loss) on change in fair value of derivative-preferred stock $(23,110,000)$ $8,010,000$ Net income (loss) $(26,778,000)$ $4,449,000$ Less preferred stock dividends $(2,875,000)$ $(2,898,000)$ Net income (loss) allocable to common stockholders $\$(29,653,000)$ $\$1,551,000$ Net income (loss) per common share $\$(15.26)$ $\$3.00$ Basic $\$(15.26)$ $\$3.00$ Diluted $\$(15.26)$ $\$3.00$			,			
Expenses333,000 $884,000$ Product costs-125,000Selling, general and administrative $3,712,000$ $4,834,000$ Depreciation and amortization11,000 $3,000$ Total expenses $4,056,000$ $5,846,000$ Loss from operations(3,131,000)(3,804,000Interest and miscellaneous income $45,000$ $251,000$ Interest and other expense(582,000)(279,000Gain on change in fair value of derivative-warrants- $271,000$ Gain (loss) on change in fair value of derivative-preferred stock(23,110,000) $8,010,000$ (23,647,000) $8,253,000$ (26,778,000) $4,449,000$ Less preferred stock dividends(26,778,000) $4,2898,000$ Net income (loss) allocable to common stockholders§ (29,653,000)§ 1,551,000Net income (loss) per common share- $3.000$ § (15.26)§ 3.00Diluted§ (15.26)§ 3.00§ (15.26)§ 3.00	5					
Research and development $333,000$ $884,000$ Product costs— $125,000$ Selling, general and administrative $3,712,000$ $4,834,000$ Depreciation and amortization $11,000$ $3,000$ Total expenses $4,056,000$ $5,846,000$ Loss from operations $(3,131,000)$ $(3,804,000)$ Interest and miscellaneous income $45,000$ $251,000$ Interest and other expense $(582,000)$ $(279,000)$ Gain on change in fair value of derivative-warrants— $271,000$ Gain (loss) on change in fair value of derivative-preferred stock $(23,647,000)$ $8,253,000$ Net income (loss) $(26,778,000)$ $4,449,000$ Less preferred stock dividends $(2,875,000)$ $(2,898,000)$ Net income (loss) allocable to common stockholders $\$(29,653,000)$ $\$(15.26)$ $\$(3.00)$ Net income (loss) per common share $\$(15.26)$ $\$(3.00)$ Basic $\$(15.26)$ $\$(3.00)$ Diluted $\$(15.26)$ $\$(3.00)$	Total revenues	925,000	2,042,000			
Product costs—125,00Selling, general and administrative $3,712,000$ $4,834,000$ Depreciation and amortization $11,000$ $3,000$ Total expenses $4,056,000$ $5,846,000$ Loss from operations $(3,131,000)$ $(3,804,000)$ Interest and miscellaneous income $45,000$ $251,000$ Interest and other expense $(582,000)$ $(279,000)$ Gain on change in fair value of derivative-warrants— $271,000$ Gain (loss) on change in fair value of derivative-preferred stock $(23,110,000)$ $8,010,000$ (23,647,000) $8,253,000$ $(26,778,000)$ $4,449,000$ Less preferred stock dividends $(2,875,000)$ $(2,898,000)$ Net income (loss) allocable to common stockholders $\$(29,653,000)$ $\$,1551,000$ Net income (loss) per common share $\$(15.26)$ $\$,3.00$ Basic $\$(15.26)$ $\$,3.00$ Diluted $\$(15.26)$ $\$,3.00$	Expenses					
Selling, general and administrative $3,712,000$ $4,834,000$ Depreciation and amortization $11,000$ $3,000$ Total expenses $4,056,000$ $5,846,000$ Loss from operations $(3,131,000)$ $(3,804,000)$ Interest and miscellaneous income $45,000$ $251,000$ Interest and other expense $(582,000)$ $(279,000)$ Gain on change in fair value of derivative-warrants $ 271,000$ Gain (loss) on change in fair value of derivative-preferred stock $(23,647,000)$ $8,253,000$ Net income (loss) $(26,778,000)$ $4,449,000$ Less preferred stock dividends $(2,875,000)$ $(2,898,000)$ Net income (loss) per common stockholders $\$(29,653,000)$ $\$1,551,000$ Net income (loss) per common share $\$(15.26)$ $\$3.00$ Basic $\$(15.26)$ $\$3.00$ Diluted $\$(15.26)$ $\$3.00$	Research and development	333,000	884,000			
Depreciation and amortization $11,000$ $3,000$ Total expenses $4,056,000$ $5,846,000$ Loss from operations $(3,131,000)$ $(3,804,000)$ Interest and miscellaneous income $45,000$ $251,000$ Interest and other expense $(582,000)$ $(279,000)$ Gain on change in fair value of derivative-warrants $ 271,000$ Gain (loss) on change in fair value of derivative-preferred stock $(23,110,000)$ $8,010,000$ Net income (loss) $(26,778,000)$ $4,449,000$ Less preferred stock dividends $(2,875,000)$ $(2,898,000)$ Net income (loss) allocable to common stockholders $\$(29,653,000)$ $\$1,551,000$ Net income (loss) per common share $\$(15.26)$ $\$3.00$ Diluted $\$(15.26)$ $\$3.00$	1104400 00510	—	125,000			
Total expenses $4,056,000$ $5,846,000$ Loss from operations $(3,131,000)$ $(3,804,000)$ Interest and miscellaneous income $45,000$ $251,000$ Interest and other expense $(582,000)$ $(279,000)$ Gain on change in fair value of derivative-warrants $ 271,000$ Gain (loss) on change in fair value of derivative-preferred stock $(23,110,000)$ $8,010,000$ (23,647,000) $8,253,000$ $(26,778,000)$ $4,449,000$ Less preferred stock dividends $(2,875,000)$ $(2,898,000)$ Net income (loss) allocable to common stockholders $\$(29,653,000)$ $\$1,551,000$ Net income (loss) per common share $\$(15.26)$ $\$3.00$ Diluted $\$(15.26)$ $\$3.00$		3,712,000	4,834,000			
Loss from operations $(3,131,000)$ $(3,804,00)$ Interest and miscellaneous income $45,000$ $251,000$ Interest and other expense $(582,000)$ $(279,00)$ Gain on change in fair value of derivative-warrants $ 271,000$ Gain (loss) on change in fair value of derivative-preferred stock $(23,110,000)$ $8,010,000$ (23,647,000) $8,253,000$ $(26,778,000)$ $4,449,000$ Less preferred stock dividends $(2,875,000)$ $(2,898,000)$ Net income (loss) allocable to common stockholders $\$ (29,653,000)$ $\$ 1,551,000$ Net income (loss) per common share $\$ (15.26)$ $\$ 3.00$ Diluted $\$ (15.26)$ $\$ 3.00$	Depreciation and amortization	11,000	3,000			
Interest and miscellaneous income       45,000       251,000         Interest and other expense       (582,000)       (279,000         Gain on change in fair value of derivative-warrants       —       271,000         Gain (loss) on change in fair value of derivative-preferred stock       (23,110,000)       8,010,000         (23,647,000)       8,253,000       (26,778,000)       4,449,000         Less preferred stock dividends       (2,875,000)       (2,898,000)         Net income (loss) allocable to common stockholders       \$ (29,653,000)       \$ 1,551,000         Net income (loss) per common share       —       3.00         Diluted       \$ (15.26)       \$ 3.00	Total expenses	4,056,000	5,846,000			
Interest and other expense $(582,000)$ $(279,00)$ Gain on change in fair value of derivative-warrants-271,00Gain (loss) on change in fair value of derivative-preferred stock $(23,110,000)$ $8,010,000$ $(23,647,000)$ $8,253,000$ Net income (loss) $(26,778,000)$ $4,449,000$ Less preferred stock dividends $(2,875,000)$ $(2,898,000)$ Net income (loss) allocable to common stockholders $\$ (29,653,000)$ $\$ 1,551,000$ Net income (loss) per common share $\$ (15.26)$ $\$ 3.00$ Diluted $\$ (15.26)$ $\$ 3.00$	Loss from operations	(3,131,000)	(3,804,000)			
Gain on change in fair value of derivative-warrants $ 271,00$ Gain (loss) on change in fair value of derivative-preferred stock $(23,110,000)$ $8,010,000$ $(23,647,000)$ $8,253,000$ Net income (loss) $(26,778,000)$ $4,449,000$ Less preferred stock dividends $(2,875,000)$ $(2,898,000)$ Net income (loss) allocable to common stockholders $\$ (29,653,000)$ $\$ 1,551,000$ Net income (loss) per common share $\$ (15.26)$ $\$ 3.00$ Diluted $\$ (15.26)$ $\$ 3.00$	Interest and miscellaneous income	45,000	251,000			
Gain (loss) on change in fair value of derivative-preferred stock $(23,110,000)$ $8,010,000$ (23,647,000) $(23,647,000)$ $8,253,000$ Net income (loss) $(26,778,000)$ $4,449,000$ Less preferred stock dividends $(2,875,000)$ $(2,898,000)$ Net income (loss) allocable to common stockholders $\$(29,653,000)$ $\$1,551,000$ Net income (loss) per common share $\$(15.26)$ $\$3.00$ Diluted $\$(15.26)$ $\$3.00$	Interest and other expense	(582,000)	(279,000)			
Net income (loss) $(23,647,000)$ $8,253,000$ Less preferred stock dividends $(26,778,000)$ $4,449,000$ Net income (loss) allocable to common stockholders $$(29,653,000)$ $$(2,898,000)$ Net income (loss) per common share $$(29,653,000)$ $$(1,551,000)$ Basic $$(15.26)$ $$(15.26)$ $$(15.26)$ Diluted $$(15.26)$ $$(15.26)$ $$(15.26)$	Gain on change in fair value of derivative-warrants	_	271,000			
Net income (loss)       (26,778,000)       4,449,00         Less preferred stock dividends       (2,875,000)       (2,898,00)         Net income (loss) allocable to common stockholders       \$ (29,653,000)       \$ 1,551,000         Net income (loss) per common share       \$ (15.26)       \$ 3.00         Diluted       \$ (15.26)       \$ 3.00	Gain (loss) on change in fair value of derivative-preferred stock	(23,110,000)	8,010,000			
Net income (loss)       (26,778,000)       4,449,00         Less preferred stock dividends       (2,875,000)       (2,898,00)         Net income (loss) allocable to common stockholders       \$ (29,653,000)       \$ 1,551,000         Net income (loss) per common share       \$ (15.26)       \$ 3.00         Diluted       \$ (15.26)       \$ 3.00		(23,647,000)	8,253,000			
Less preferred stock dividends       (2,875,000)       (2,898,00)         Net income (loss) allocable to common stockholders       \$ (29,653,000)       \$ 1,551,000         Net income (loss) per common share       \$ (15.26)       \$ 3.00         Diluted       \$ (15.26)       \$ 3.00	Net income (loss)		4,449,000			
Net income (loss) allocable to common stockholders $$(29,653,000)$ $$1,551,000$ Net income (loss) per common share Basic $$(15.26)$ $$3.000$ Diluted $$(15.26)$ $$3.000$	Less preferred stock dividends		(2,898,000)			
Basic       \$ (15.26)       \$ 3.0         Diluted       \$ (15.26)       \$ 3.0	•	\$(29,653,000)				
Basic       \$ (15.26)       \$ 3.0         Diluted       \$ (15.26)       \$ 3.0	Net income (loss) per common share					
		\$ (15.26)	\$ 3.07			
Weighted average number of common shares outstanding	Diluted	\$ (15.26)	\$ 3.04			
	Weighted average number of common shares outstanding					
Basic 1,942,905 504,86	Basic	1,942,905	504,863			
Diluted 1,942,905 509,47	Diluted	1,942,905	509,473			

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

# CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	Common	Stock	Preferre Stock –		Preferred Stock – B		Additional	T.	A	Total stockholders'
D I	Shares	Amount	Shares	Amount	Shares	Amount	paid-in capital	Treasury stock	Accumulated (deficit)	equity (deficit)
Balance, December 31,										
2012	24,732,312	\$247,000	2,913.3617	\$ —	1000	\$	\$250,653,000	\$(4,000)	\$(267,972,000)	\$(17,076,000)
Common stock issued for										
services	242,631	2,000					109,000		_	111,000
Common stock	,	,					,			,
issued to directors and										
employees	429,500	5,000	_	_	_	_	162,000		_	167,000
Common stock										
issued for cash exercise										
of options	125,000	1,000	_	_	_	_	28,000		_	29,000
Preferred stock										
converted into common										
stock	200,000	2,000	(10.0000)	—	—	—	(2,000)		_	_
Stock option										
compensation expense	_	_	_		_		439,000		_	439,000
Preferred							127,000			,
dividends	_	_	_	—	_	_		_	(2,898,000)	(2,898,000)
Net income Balance,									4,449,000	4,449,000
December 31,										
2013	514,589	6,000	2,903.3617	—	1,000	_	251,640,000	(4,000)	(266,421,000)	(14,779,000)
Common stock issued for										
services	22,000	—	—	—	_	—	349,000	_	—	349,000
Preferred stock converted										
into common										
stock	4,000	—	(10.0000)	—	—	—		—		
Additional adjustments										
for reverse										
stock split	6,609	—	—	—	—	—		—	_	
Cancel treasury stock	(3)	_		_	_	_	(4,000)	4,000		
Common stock	(5)						(1,000)	1,000		
issued for										
\$4.00 share net of costs	3,500,000	35,000		_	_		12,272,000		_	12,307,000
Common stock	- ,						, , , , , , , , , , , , , , , , , , ,			<u> </u>
issued for Series A										
preferred										
stock	7,233,404	72,000	(2,893.3617)	—	—	—	(72,000)	—		
Common stock issued for										
Series A										
preferred										
stock unpaid dividends and										
interest	1,728,365	17,000					7,066,000		_	7,083,000
Elimination of derivative										
liability –										
preferred										
stock Series B	_	_	_	_	_	_	24,300,000	—	_	24,300,000
preferred										
stock issued										
for unpaid Series B										
dividends and										
interest	_	_	_	—	304	_	3,047,000	_	_	3,047,000
Series B preferred										
stock issued										

for unpaid liquidated damages	_	_	_	_	86	_	857,000	_	_	857,000
Common stock issued for Series B preferred stock, unpaid dividends and interest and liquidated										
damages	6,951,837	70,000			(1,390)	_	(70,000)	—	_	_
Stock option compensation expense	_	_		_		_	1,305,000	_	_	1,305,000
Preferred										
dividends	—	—	—	—	—	—	—	—	(2,875,000)	(2,875,000)
Net loss									(26,778,000)	(26,778,000)
Balance, December 31, 2014	19,960,801	\$200,000		\$ —		\$ —	\$300,690,000	\$ —	\$(296,074,000)	\$ 4,816,000

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

# CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year o Decem	
	2014	2013
Cash flows from operating activities:		
Net income (loss)	\$(26,778,000)	\$ 4,449,000
Adjustments to reconcile net income (loss) to net cash Provided by (used in)		
operating activities:		(271 000)
(Gain) on change in fair value of derivative-warrants		(271,000)
(Gain) loss on change in fair value of derivative-preferred stock	23,110,000	(8,010,000)
Depreciation and amortization	11,000	3,000
Stock option compensation expense	1,305,000	439,000
Stock issued to directors and employees	240.000	167,000
Stock issued for services	349,000	111,000
Change in operating assets and liabilities:	20.000	7(( 000
Receivables	39,000	766,000
Inventory		194,000
Prepaid expenses and other current assets	77,000	174,000
Other assets	22.000	10,000
Accounts payable and accrued expenses	33,000	(1,176,000)
Interest on dividends payable Deferred revenue	592,000	279,000
	(349,000)	2,866,000
Net cash provided by (used in) operating activities	1,611,000	1,000
Cash flows from investing activities:		(2,000)
Capital expenditures		(2,000)
Net cash used in investing activities	_	(2,000)
Cash flows from financing activities:	100.000	
Proceeds from short-term debt	400,000	20.000
Proceeds from exercise of stock options	12 207 000	29,000
Proceeds from stock issuances, net of costs	12,307,000	
Net cash provided by financing activities	12,707,000	29,000
Net increase in cash and cash equivalents	11,096,000	28,000
Cash and cash equivalents at beginning of year	424,000	396,000
Cash and cash equivalents at end of year	\$ 11,520,000	\$ 424,000
Supplemental cash flow information:		
Cash paid for interest	\$ 7,000	\$
Supplemental disclosure of noncash transactions		
Conversion of Series A preferred stock unpaid dividends and interest into		
shares of common stock	7,083,000	
Conversion of Series B preferred stock unpaid dividends and interest and		
liquidated damages into shares of common stock	3,904,000	
Cancel treasury stock	4,000	
Payable in cash or future issuance of shares for licensed technology	5,000,000	—
Preferred stock dividends in dividends payable	2,875,000	2,898,000

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

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Two years ended December 31, 2014

# NOTE 1 — NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### Nature of Operations

PlasmaTech Biopharmaceuticals, Inc. (together with our subsidiaries, "we", "our", "PlasmaTech" or the "Company") is a Delaware corporation. We are an emerging biopharmaceutical company focused on developing a range of pharmaceutical products primarily based upon our nanopolymer chemistry technologies, and salt diafiltration process ("SDF") technology recently licensed from Plasma Technologies LLC ("Licensor"). We currently have one marketed product licensed in the U.S., Europe, China, Australia, New Zealand and Korea. We also have additional products and platform technologies in various stages of development and are seeking partners to continue development and/or to license the technology. Our efforts have been principally devoted to research and development, resulting in significant losses.

Certain amounts have been reclassified to conform with current period classification.

A summary of the significant accounting policies applied in the preparation of the accompanying consolidated financial statements follows.

#### Principles of Consolidation

The consolidated financial statements include the financial statements of PlasmaTech Biopharmaceuticals, Inc. and our whollyowned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

#### Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amount of assets and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reported period. Actual results could differ from these estimates and assumptions.

# Segments

The Company operates in a single segment.

#### Cash and Cash Equivalents

We consider all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. At December 31, 2014 and 2013, we had no such investments. We maintain deposits primarily in two financial institutions, which may at times exceed amounts covered by insurance provided by the U.S. Federal Deposit Insurance Corporation (FDIC). We have not experienced any losses related to amounts in excess of FDIC limits.

#### Receivables

Receivables are reported in the balance sheets at the outstanding amount net of an allowance for doubtful accounts. We continually evaluate the creditworthiness of our customers and their financial condition and generally do not require collateral. The allowance for doubtful accounts is based upon reviews of specific customer balances, historic losses, and general economic conditions. As of December 31, 2014 and 2013, no allowance was recorded as all accounts are considered collectible.

# Property and Equipment

Property and equipment are recorded at cost. Depreciation is provided using the straight-line method over estimated useful lives ranging from three to five years. Expenditures for major renewals and betterments that extend the useful lives are capitalized. Expenditures for normal maintenance and repairs are expensed as incurred. The cost of assets sold or abandoned and the related accumulated depreciation are eliminated from the accounts and any gains or losses are recognized in the accompanying consolidated statements of operations of the respective period.



# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Two years ended December 31, 2014

# NOTE 1 — NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES – (continued)

#### Licensed Technology

On September 22, 2014, we entered into an exclusive, worldwide, licensing agreement with Licensor to obtain rights to utilize and to sub-license to other pharmaceuticals firms, its patented methods for the extraction of therapeutic biologics from human plasma.

Under the terms of the licensing agreement, as amended on January 23, 2015, we paid a license fee of \$1 million in cash, will pay \$4,000,000 in cash or 1,096,151 shares of our common stock in 2017, a regulatory approval milestone payment of 513,375 shares of our common stock upon the first FDA regulatory approval of a drug derived from the Licensor's proprietary SDF process, and a tiered royalty on annual net sales of plasma fractions produced with Licensor's proprietary SDF process.

The license is amortized over the life of the patent of 11 years.

#### License Revenues and Royalties

Our revenues are generated from licensing, research and development agreements, royalties and product sales. We recognize revenue in accordance with SEC Staff Accounting Bulletin No. 104 (SAB 104), *Revenue Recognition*. License revenue is recognized over the remaining life of the underlying patent. Research and development revenues are recognized as services are performed. Royalties and product sales are recognized in the period of sales.

# Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses include, but are not limited to, payroll and personnel expense, lab supplies, preclinical, development cost, clinical trial expense, outside manufacturing and consulting. The cost of materials and equipment or facilities that are acquired for research and development activities and that have alternative future uses are capitalized when acquired.

#### Selling, general and administrative expense

Selling, general and administrative expenses primarily consist of personnel, contract personnel, personnel expenses to support our administrative and operating activities, facility costs and professional expenses (i.e., legal expenses), and investor relations fees.

#### Other Income

In 2014 and 2013, we recognized miscellaneous income of \$45,000 and \$251,000, respectively, due to sales of platinum and monomers and write-offs and settlements of other accounts payable.

In some of our license agreements we are responsible for the manufacture of MuGard and have entered into supply agreements with our license partners. Terms vary with each agreement but generally we arrange for the manufacture of MuGard with a thirdparty and receive a fee to cover administration, handling and overhead costs. The income is recorded in other income.

#### Fair Value of Financial Instruments

We calculate the fair value of our assets and liabilities which qualify as financial instruments and include additional information in the notes to the consolidated financial statements when the fair value is different than the carrying value of these financial instruments. The estimated fair value of accounts receivable, accounts payable and accrued expenses and dividends payable approximate their carrying amounts due to the relatively short maturity of these instruments.

We considered the conversion options and warrants related to our Series A Cumulative Convertible Preferred Stock, prior to the conversion into common stock in 2014, to be derivatives, and we recorded the fair value of



### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Two years ended December 31, 2014

# NOTE 1 — NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES – (continued)

the derivative liabilities in our consolidated balance sheets. Changes in the fair value of the derivative liabilities are included in gain or loss on change in fair value of derivative in the consolidated statements of operations.

#### Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is provided for deferred tax assets to the extent their realization is in doubt.

We account for uncertain income tax positions in accordance with FASB ASC 740, *Income Taxes*. Interest costs and penalties related to income taxes are classified as interest expense and general and administrative costs, respectively, in our consolidated financial statements. For the years ended December 31, 2014 and 2013, we did not recognize any uncertain tax positions or interest or penalty expense related to income taxes. It is determined not to be reasonably likely for the amounts of unrecognized tax benefits to significantly increase or decrease within the next 12 months. We are currently subject to a three year statute of limitations by major tax jurisdictions for the years ended 2011, 2012 and 2013. We and our subsidiaries file income tax returns in the U.S. federal jurisdiction.

# Income (Loss) Per Share

We have presented basic income (loss) per share, computed on the basis of the weighted average number of common shares outstanding during the year, and diluted income (loss) per share, computed on the basis of the weighted average number of common shares and all dilutive potential common shares outstanding during the year. Potential common shares result from stock options, preferred stock and warrants. Common equivalent shares have not been included in the net loss per share calculations for year ended December 31, 2014 because the effect of including them would have been anti-dilutive.

Basic and diluted net income (loss) per share were determined as follows:

	For the yes Decemb			
(in thousands, except share and per share amounts)	2014	2013		
Net income (loss) allocable to common stockholders	\$ (29,653)	\$ 1,551		
Weighted average shares outstanding	1,942,905	504,863		
Basic net income (loss) per common share	\$ (15.26)	\$ 3.07		
Net income (loss) allocable to common stockholders	\$ (29,653)	\$ 1,551		
Weighted average shares outstanding	1,942,905	504,863		
Effect of dilutive options and warrants	—	4,610		
Weighted average shares outstanding assuming dilution	1,942,905	509,473		
Diluted net income (loss) per common share	\$ (15.26)	\$ 3.04		

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Two years ended December 31, 2014

# NOTE 1 — NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES – (continued)

We did not include the following securities in the table below in the computation of diluted net income (loss) per common share because the securities were anti-dilutive during the periods presented:

	For the ye Decem	ear ended ber 31,
	2014	2013
Warrants	4,164,756	637,581
Stock options	210,134	18,384
Preferred stock Series A		1,161,345
Preferred stock Series B		400,000
Total	4,374,890	2,217,310

#### Stock-Based Compensation

We account for stock based compensation expense in accordance with FASB ASC 718, *Stock Based Compensation*. We have two stock-based compensation plans under which incentive and non-incentive qualified stock options and restricted shares could be granted to employees, directors and consultants. As of January 20, 2015, no further grants can be made. We measure the cost of the employee/director/consultant services received in exchange for an award of equity instruments based on the grant date fair value of the award. We use the Black-Scholes option pricing model to value our options.

The following table summarizes stock-based compensation for the years ended December 31, 2014 and 2013 which was allocated as follows (in thousands):

	 Year ended December 31, 2014		ar ended ember 31, 2013
Research and development	\$ 104	\$	31
General and administrative	 1,201		408
Stock-based compensation expense included in operating expense	1,305		439
Total stock-based compensation expense	1,305		439
Tax benefit	 		
Stock-based compensation expense, net of tax	\$ 1,305	\$	439

#### Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP.

The standard is effective for annual periods beginning after December 15, 2016, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our consolidated financial statements and have not yet determined the method by which we will adopt the standard in 2017.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Two years ended December 31, 2014

# NOTE 2 — RELATED PARTY TRANSACTIONS

On occasion we may engage in certain related party transactions.

During 2014 and 2013, SCO and affiliates charged \$300,000 each year in investor relations fees.

In connection with the original sale and issuance of Series A Preferred Stock and warrants, we entered into a Director Designation Agreement whereby we agreed to continue SCO's right to designate two individuals to serve on the Board of Directors of PlasmaTech.

On September 10, 2014, we entered into an Unsecured Grid Note, for up to \$250,000 with SCO. As of December 31, 2014 we have drawn a total of \$250,000. The interest rate is 8% per annum and the maturity date is August 31, 2015 unless a financing of at least \$5,000,000 occurs. The financing occurred December 24, 2014 and the Grid Note was paid in full on January 5, 2015.

On September 10, 2014 we entered into a Share Exchange Agreement for Series B Preferred Stock between us and SCO Capital Partners LLC and Beach Capital LLC whereby we agreed in connection with the consummation of the an offering for the Series B Preferred Stock to be converted into Common Stock. All Series B Preferred Stock dividends payable, interest on Series B Preferred Stock dividends payable and liquidated damages will be converted into Series B Preferred Stock issued upon conversion of all accrued dividends payable, interest on dividends payable and liquidated damages thereon, subject to a liquidation preference, will be exchanged for shares of Common Stock upon consummation of an offering at the offering price pursuant to a Share Exchange Agreement dated September 10, 2014. The conversion into Common Stock occurred on December 24, 2014.

On October 23, 2014, we filed in Delaware a Certificate of Amendment to Certificate of Designations, Rights and Preferences of Series A Preferred Stock (the "Certificate of Amendment") to amend the Certificate of Amendment to allow a special mandatory conversion of the Series A Preferred Stock, under certain circumstances, including qualified financings, as described in the Certificate of Amendment. The conversion into Common Stock occurred on December 24, 2014.

On December 1, 2014, we entered into a second Unsecured Grid Note, for up to \$250,000 with SCO. As of December 31, 2014 we have drawn a total of \$150,000. The interest rate is 8% per annum and the maturity date is November 30, 2015 unless a financing of at least \$5,000,000 occurs. The financing occurred December 24, 2014 and the Grid Note was paid in full on January 5, 2015.

# NOTE 3 — PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

	Decem	ber 31,
	2014	2013
Furniture and equipment	\$ 14,000	\$ 14,000
	14,000	14,000
Less accumulated depreciation and amortization	10,000	8,000
Property and equipment, net	\$ 4,000	\$ 6,000

Depreciation and amortization on property and equipment was \$2,000 and \$3,000 for the years ended December 31, 2014 and 2013, respectively.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Two years ended December 31, 2014

# NOTE 4 — LICENSED TECHNOLOGY

On September 22, 2014, we entered into an exclusive, worldwide, licensing agreement with Licensor to obtain rights to utilize and to sub-license to other pharmaceuticals firms, its patented methods for the extraction of therapeutic biologics from human plasma. Licensed technology consists of the following:

	Decembe	er 31,
	2014	2013
Licensed technology	\$ 5,000,000	\$ —
Less accumulated amortization	9,000	
Licensed technology, net	\$4,991,000	\$

Amortization on licensed technology was \$9,000 and \$0 for the years ended December 31, 2014 and 2013, respectively. The aggregate estimated amortization expense for intangible assets remaining as of December 31, 2014 is as follows:

2015	\$ 465
2016	465
2017	465
2018	465
2019	465
Thereafter	2,666
Total	\$ 4,991

## NOTE 5 — 401(k) PLAN

We have a tax-qualified employee savings and retirement plan (the 401(k) Plan) covering all our employees. Pursuant to the 401(k) Plan, employees may elect to reduce their current compensation by up to the statutorily prescribed annual limit (\$17,500 in 2014 and 2013) and to have the amount of such reduction contributed to the 401(k) Plan. The 401(k) Plan is intended to qualify under Section 401 of the Internal Revenue Code so that contributions by employees or by us to the 401(k) Plan, and income earned on 401(k) Plan contributions, are not taxable to employees until withdrawn from the 401(k) Plan, and so that contributions by us, if any, will be deductible by us when made. At the direction of each participant, we invest the assets of the 401(k) Plan in any of 60 investment options. Company contributions under the 401(k) Plan were \$0 in 2014 and 2013.

#### NOTE 6 — DEBT

On September 10, 2014, we entered into an Unsecured Grid Note, for up to \$250,000 with SCO Capital Partners LLC. We have drawn a total of \$250,000. On December 1, 2014, we entered into a second Unsecured Grid Note, for up to \$250,000 with SCO Capital LLC. At December 31, 2014 we had drawn a total of \$150,000. The interest on both notes is 8% per annum and the maturity dates are August 31, 2015 for the first Grid Note and November 30, 2015 for the second Grid Note unless a financing of at least \$5,000,000 occurs, in which extent the notes are required to be paid in full. We had note payables totaling \$400,000 at December 31, 2014. We had interest expense totaling \$7,000 on both notes at December 31, 2014. The notes were paid in full on January 5, 2015

# NOTE 7 — COMMITMENTS AND CONTINGENCIES

#### **Operating Leases**

At December 31, 2014, we had a commitment under a non-cancelable operating lease for our New York office until December 31, 2015 totaling \$142,000 and our Boston office until December 31, 2015 totaling \$30,000



# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Two years ended December 31, 2014

## NOTE 7 — COMMITMENTS AND CONTINGENCIES – (continued)

and until February 28, 2016 totaling \$6,000. Rent expense for the years ended December 31, 2014 and 2013 was \$178,000 and \$270,000, respectively. Rent expense in 2013 included rent for our Dallas office which was closed on September 30, 2013.

# Legal

Alan Schmidt ("Schmidt"), a former shareholder of Genaera Corporation ("Genaera"), and a former unitholder of the Genaera Liquidating Trust (the "Trust"), filed a purported class action in the United States District Court for the Eastern District of Pennsylvania in June 2012. The lawsuit named thirty defendants, including PlasmaTech, MacroChem Corporation, which was acquired by us in February 2009, Jeffrey Davis, the then-CEO and currently a director of PlasmaTech, and Steven H. Rouhandeh and Mark Alvino, both of whom are our directors (the "PlasmaTech Defendants"). With respect to the PlasmaTech Defendants, the complaint alleged direct and derivative claims asserting that directors of Genaera and the Trustee of the Trust breached their fiduciary duties to Genaera, Genaera's shareholders and the Trust's unitholders in connection with the licensing and disposition of certain assets, aided and abetted by numerous defendants including the PlasmaTech Defendants. Schmidt seeks monetary damages, disgorgement of any distributions received from the Trust, rescission of sales made by the Trust, attorneys' and expert fees, and costs. On December 19, 2012, Schmidt filed an amended complaint (the "Amended Complaint") which asserted substantially the same allegations with respect to the PlasmaTech Defendants. On February 4, 2013, the PlasmaTech Defendants moved to dismiss all claims asserted against them. On August 12, 2013 the court granted the PlasmaTech Defendants' motions to dismiss and entered judgment in favor of the PlasmaTech Defendants on all claims. On August 26, 2013, Schmidt filed a motion for reconsideration. On September 10, 2013 Schmidt filed a Notice of Appeal with the District Court. On September 17, 2013, Schmidt filed his appeal with the U.S. Third Circuit Court of Appeals (the "Third Circuit"). On September 25, 2013, the District Court denied Schmidt's motion for reconsideration. On October 17, 2013, Schmidt amended his appeal to include the District Court's denial of his motion for reconsideration. On March 20, 2014, Schmidt filed his Brief and Joint Appendix. On May 22, 2014, the PlasmaTech Defendants filed their Oppositions to Schmidt's Brief. On May 29, 2014, Schmidt was granted an extension of time until June 23, 2014 to file his Reply Brief and filed his Reply Brief on that date. The Third Circuit held oral argument on September 12, 2014. On October 17, 2014, in a split decision, the Third Circuit reversed the District Court's decision holding, among other things, that the District Court's determination that the Amended Complaint was time-barred on statute of limitations grounds was premature. The Third Circuit did not rule upon any of the other grounds for dismissal advanced in the District Court and on appeal. The Third Circuit remanded the case to the District Court for further proceedings. On January 6, 2015, the District Court ordered the parties to file supplemental briefs on all remaining arguments for dismissal, and further ordered that a hearing on the motions to dismiss would be held on February 3, 2015. On January 23, 2015, the PlasmaTech Defendants filed their Supplemental Brief. At the February 3, 2015 hearing, Schmidt sought and was granted leave to amend his complaint for a second time. Schmidt filed his Second Amended Complaint on February 3, 2015. The Second Amended Complaint asserts substantially the same factual allegations with respect to the PlasmaTech Defendants, but eliminates all causes of action against the PlasmaTech Defendants except for aiding and abetting the Genaera directors' and officers' purported breaches of fiduciary duties, a claim for "punitive damages" and a claim for rescission of a settlement agreement between the Trust and the PlasmaTech Defendants. On March 20, 2015, the PlasmaTech Defendants filed a motion to dismiss the Second Amended Complaint. We intend to continue contesting the claims vigorously.

We are not currently subject to any other material pending legal proceedings.

# NOTE 8 — FAIR VALUE MEASUREMENTS

We calculate the fair value of our assets and liabilities which qualify as financial instruments and include additional information in the notes to the consolidated financial statements when the fair value is different than

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Two years ended December 31, 2014

## NOTE 8 — FAIR VALUE MEASUREMENTS – (continued)

the carrying value of these financial instruments. The estimated fair value of accounts receivable, accounts payable and accrued expenses and dividends payable approximate their carrying amounts due to the relatively short maturity of these instruments.

Generally Accepted Accounting Principles defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. This guidance establishes a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. The hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- Level 1 Quoted prices in active markets for identical assets or liabilities.
- Level 2 Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.
- Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of
  the assets and liabilities. This includes certain pricing models, discounted cash flow methodologies and similar valuation
  techniques that use significant unobservable inputs.

The guidance requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

We have segregated all financial assets and liabilities that are measured at fair value on a recurring basis (at least annually) into the most appropriate level within the fair value hierarchy based on the inputs used to determine the fair value at the measurement date in the table below.

Financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2014 and December 31, 2013 are summarized below:

(in thousands)	As of December 31,			Total Gains	
Description	2014	Level 1	Level 2	Level 3	(Losses)
Liabilities:					
Derivative liability –					
preferred stock	\$ —	\$ —	\$ —	\$ —	\$ 23,110,000
Liabilities:					
Derivative liability –					
warrants	\$ —	\$ —	\$ —	\$ —	\$ 271
preferred stock	\$ 1,190	\$ —	\$ —	\$ 1,190	\$ 8,010

In order to calculate the Level 3 Derivative liability — preferred stock, we used the Monte Carlo simulation to estimate future stock prices. The use of valuation techniques requires the Company to make various key assumptions for inputs into the model, including assumptions about the expected future volatility of the price of the Company's stock.

The Series A Preferred Stock was converted into common stock at December 24, 2014 so there is no longer a derivative liability.



## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Two years ended December 31, 2014

# NOTE 9 — PREFERRED STOCK

#### Series A Cumulative Convertible Preferred Stock

On November 7, 2007, and February 4, 2008, we entered into securities purchase agreements (the Purchase Agreements) with accredited investors to sell shares of a newly created series of our preferred stock, designated "Series A Cumulative Convertible Preferred Stock", par value \$0.01 per share, for an issue price of \$10,000 per share, (the Series A Preferred Stock) and agreed to issue warrants to purchase shares of our common stock at an exercise price of \$175.00 per share. The shares of Series A Preferred Stock were convertible into common stock at the initial conversion price of \$150.00 per share. The exercise and conversion price have changed, as described below.

As a condition to closing, we entered into an Investor Rights Agreement with each of the investors purchasing shares of Series A Preferred Stock.

In connection with the sale and issuance of Series A Preferred Stock and warrants, we entered into a Director Designation Agreement whereby we agreed to continue SCO's right to designate two individuals to serve on the Board of Directors of PlasmaTech.

The Series A Preferred Stock granted the holders of such preferred stock anti-dilution, dividend and liquidations rights that were superior to those held by the holders of our common stock. Under those terms, if PlasmaTech issued additional shares of common stock, in certain circumstances, for a price below \$150.00 per share, the conversion price of the Series A Preferred Stock would be lowered to the lowest subsequent issue price below \$150.00 per share until the shares are converted or redeemed. This would have had the effect of diluting the holders of our common stock. Under the terms of the Purchase Agreement, if PlasmaTech issued additional shares of common stock, in certain circumstances, for a price below \$175.00 per share, the exercise price of the warrants would be lowered to the lowest subsequent issue price below \$175.00 per share until the warrants were exercised or expired. Additionally, as discussed below, if we were unable to maintain an effective registration statement related to the Series A Preferred Stock, we would be required to pay liquidating damages.

On October 25, 2012, we issued Series B Preferred Stock with a conversion into common stock at \$25.00 per share in a private placement offering. Per the terms of the agreement with the outstanding Series A Preferred Stock holders their stock became convertible into shares of common stock at \$25.00 per share. At December 31, 2013 the Series A Preferred Stock was convertible into 1,164,348 shares of common stock.

All Series A Preferred Stock, Series A dividends payable and interest on Series A Preferred Stock dividends payable were converted into 8,961,769 shares of common stock just prior to the closing of the financing on December 24, 2014.

#### Derivative Liability

Effective January 1, 2009, we adopted the provisions of FASB ASC 815, "*Derivatives and Hedging*" (FASB ASC 815) (previously EITF 07-5, "*Determining Whether an Instrument (or an Embeded Feature) is Indexed to an Entity's Own Stock*"). As a result of adopting FASB ASC 815, warrants to purchase 77,091 of our common stock previously treated as equity pursuant to the derivative treatment exemption were no longer afforded equity treatment. These warrants had an exercise price of \$175.00 and expired on November 10, 2013 and February 4, 2014.

We determined that the anti-dilution provision built into the Series A Preferred Stock and warrants issued should be considered for derivative accounting. FASB ASC 815 requires freestanding contracts that are settled in a company's own stock to be designated as an equity instrument, assets or liability. Under the provisions of FASB ASC 815, a contract designated as an asset or liability must be initially recorded and carried at fair value until the contract meets the requirements for classification as equity, until the contract is exercised or



# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Two years ended December 31, 2014

# NOTE 9 — PREFERRED STOCK – (continued)

until the contract expires. We determined that the anti-dilution provision associated with the November 2007 and February 2008 preferred shares and warrants no longer met the criteria for equity accounting through the revised criteria in FASB ASC 815.

Accordingly, at January 1, 2009, we determined that the warrants and the Series A Preferred Stock conversion feature should be accounted for as derivative liabilities. The preferred stock conversion feature was determined to have no fair market value at both issuance dates as well as each reporting period until the third quarter of 2010 since management asserted that the likelihood of issuing any new equity at a price that would trigger the anti-dilution effect to be nil. During the third quarter of 2010 we were actively raising capital. With our stock price below \$150.00 a share it was possible that we would sell shares below \$150.00 per share. Since this would require an adjustment to our convertible preferred stock we recorded a derivative liability and expense at September 30, 2010. The derivative liability and expense was revalued at December 31, 2013 was \$1,190,000; and at December 24, 2014 was \$24,300,000. The change in the fair value of the derivative was a loss of \$23,110,000 in 2014 and a gain of \$8,010,000 in 2013. The Series A Preferred Stock was converted into common stock at December 24, 2014 and the amount of the derivative liability was reclassified to stockholders equity.

The warrants were valued at issuance and each reporting period since using the Black-Scholes model. On January 1, 2009 we reclassified the fair value of the warrants from equity to liability as if these warrants were treated as a derivative liability since their issue date. We recorded derivative gain of \$271,000 for the year ended December 31, 2013. Warrants to purchase 72,998 shares of our common stock expired November 10, 2013. The remaining 9,992 warrants expired February 4, 2014.

#### Series B Cumulative Convertible Preferred Stock

On October 25, 2012, we entered into a Preferred Stock and Warrant Purchase Agreement (the "Purchase Agreement") with existing investors whereby we agreed to sell 1,000 shares of a newly created series of our preferred stock, designated "Series B Cumulative Convertible Preferred Stock", par value \$0.01 per share, for an issue price of \$10,000 per share, (the "Series B Preferred Stock") and agreed to issue warrants to purchase 400,000 shares of our common stock at an exercise price of \$25.00 per share, for an aggregate purchase price of \$10,000,000. The financing consisted of \$4,703,000 of new investment and the conversion of approximately \$5,297,000 of outstanding dividends payable on our Series A Preferred Stock. Certain terms of the Series B Preferred Stock were senior in right to the Company's outstanding Series A Preferred Stock. The Series B financing was approved by the requisite percentage of the holders of the Company's Series A Preferred Stock and closed on October 25, 2012.

The shares of Series B Preferred Stock issued upon closing were convertible at the option of the holder into shares of our common stock at a conversion price of \$25.00 per share of common stock (the "Conversion Price"). The Conversion Price was not subject to adjustment, except in cases of stock splits, stock dividends or similar transactions.

The Series B Preferred Stock was entitled to a liquidation preference, senior to the liquidation preference of the Series A Preferred Stock, equal to the greater of (i) (A) two times (2x) the Stated Value for the Series B Preferred Stock, plus any accumulated and unpaid dividends (whether or not declared) on the Series B Preferred Stock if such liquidation takes place prior to the fifth anniversary of the original issue date or (B) three times (3x) the Stated Value for the Series B Preferred Stock, plus any accumulated and unpaid dividends (whether or not declared) on the Series B Preferred Stock if such liquidation took place on or after to the fifth anniversary of the original issue date, or (ii) the cash or other property distributable upon such liquidation with respect to the shares of Common Stock into which such shares of Series B Preferred Stock, including any accrued dividends thereon, could have been converted immediately prior to such payment. "Stated Value" shall mean \$10,000 per share of Series B Preferred Stock, as it may be increased from time to



# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Two years ended December 31, 2014

# **NOTE 9** — **PREFERRED STOCK** – (continued)

time as set forth in the Certificate of Designations. The Series B Preferred Stock is also entitled to a dividend of 12% per annum, payable quarterly in cash or additional Stated Value, at the election of the majority holders at time of payment.

We had the right, but not the obligation, and with the written consent of the majority holders, to force conversion ("Mandatory Conversion") of all, but not less than all, of the outstanding Series B Preferred Stock into common stock as long as the closing price of our common stock exceeds \$250.00 for at least 20 consecutive trading days immediately prior to the conversion and the average daily trading volume is not less than 4,000 shares per day for at least 20 consecutive trading days immediately prior to such date on which the Company gave notice of such conversion. The Company's ability to cause a Mandatory Conversion was subject to certain other conditions, including that a registration statement covering the common stock issuable upon such Mandatory Conversion was in effect and able to be used.

The common stock purchase warrants issued are for an aggregate of 400,000 shares of our common stock at an exercise price of \$25.00. The warrants can also be exercised on a cashless basis. The warrants will expire six years from the date of issuance.

The warrant exercise price is subject to equitable adjustment for stock splits, dividends, combinations, and reorganizations only.

The Share Exchange Agreement dated September 10, 2014 between us and the Series B Preferred Stock holders approved the conversion of all Series B Preferred Stock, Series B dividends payable, interest on Series B Preferred Stock dividends payable and liquidated damages, subject to the closing of an offering of at least \$10 million.

All Series B Preferred Stock, Series B dividends payable, interest on Series B Preferred Stock dividends payable and liquidated damages were converted into 6,951,837 shares of common stock just prior to the closing of the financing on December 24, 2014.

# Liquidated Damages

Pursuant to the terms of an Investor Rights Agreement with the Purchasers of Series A Preferred Stock, we were required to maintain an effective registration statement. The Securities and Exchange Commission declared the registration statement effective November 13, 2008 relating to a portion of such securities, and as a result, we accrued \$857,000 in potential liquidated damages as of December 31, 2013 and December 31, 2012. Potential liquidated damages are capped at 10% of each holder's investment. The accrued liquidated damages of \$857,000 were converted into common stock at December 24, 2014.

# Preferred Stock Dividends - Series A

Unpaid preferred stock dividends and interest of \$6,913,416 accrued at December 24, 2014 was converted into common stock at December 24, 2014

#### Preferred Stock Dividends - Series B

Unpaid preferred stock dividends and interest of \$3,046,553 accrued at December 31, 2014 was converted into common stock at December 24, 2014.

# NOTE 10 — STOCKHOLDERS' EQUITY

# 2014 Financing

On December 24, 2014, we closed an underwritten public offering of 3,500,000 shares of common stock, and warrants to purchase up to an aggregate 3,500,000 shares of common stock, at an offering price of \$4.00 per share and \$.01 per warrant. The warrants have a per share exercise price of \$5.00, are exercisable immediately, and expire 5 years from the date of issuance. The gross proceeds to the Company from this



### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Two years ended December 31, 2014

# NOTE 10 — STOCKHOLDERS' EQUITY – (continued)

offering were \$14,035,000, before deducting underwriting discounts and commissions and other estimated offering expenses. All of the shares and warrants in the offering were sold by the Company. In addition the underwriter received warrants to purchase 87,500 shares of common stock at \$5.00 per share. The warrants are exercisable on December 18, 2015 and expire on December 18, 2019.

Just before the financing closed on December 24, 2014, the Series A and Series B preferred stock and unpaid dividends and interest and liquidated damages were converted into common stock.

#### Warrants

There were warrants to purchase a total of 4,164,756 shares of common stock outstanding at December 31, 2014. All warrants were exercisable at December 31, 2014 except the 87,500 warrants issued to the underwriter which are exercisable after December 18, 2015. The warrants had various exercise prices and terms as follows:

Summary of Warrants	Warrants Outstanding	Exercise Price	Expiration Date
2014 Financing 12/24/14 <sup>(a)</sup>	3,500,000	\$ 5.00	12/24/19
2014 Financing 12/24/14 agent warrants <sup>(a)</sup>	87,500	5.00	12/18/19
2012 Series B private placement <sup>(b)</sup>	400,001	25.00	10/24/18
2011 November private placement <sup>(c)</sup>	42,898	100.00	11/10 & 30/16
2011 November placement agent warrants <sup>(c)</sup>	744	83.50 & 100.00	11/10 & 30/16
2010 December registered direct offering <sup>(d)</sup>	18,625	153.00	12/14/15
2010 January registered direct offering <sup>(e)</sup>	20,837	150.00	1/26/15
2010 January placement agent warrants <sup>(e)</sup>	2,505	187.50	1/26/15
2006 convertible note <sup>(f)</sup>	76,370	66.00	2/16/15
2006 convertible note <sup>(f)</sup>	7,729	66.00	10/24/15
2006 convertible note <sup>(f)</sup>	7,547	66.00	12/06/15
Total	4,164,756		

<sup>(</sup>a) In connection with an offering on December 24, 2014, warrants to purchase 3,500,000 share of common stock at \$5.00 per share were purchased and issued for \$0.01 per warrant. All of the warrants are exercisable immediately and expire on December 24, 2019.

Also in connection with the offering on December 24, 2014, the underwriter received warrants to purchase 87,500 shares of common stock at \$5.00 per share. The warrants are exercisable on December 18, 2015 and expire on December 18, 2019.

- (b) In connection with a private placement offering on October 25, 2012, warrants to purchase 400,001 shares of common stock at \$25.00 per share were issued. All of the warrants are exercisable immediately and expire on October 24, 2018.
- (c) In connection with a private placement offering on November 10 and 30, 2011, warrants to purchase 42,898 shares of common stock at \$100.00 per share were issued. All of the warrants are exercisable immediately and 37,148 warrants expire November 10, 2016 and 5,750 warrants expire November 30, 2016.

Also in connection with a private placement offering on November 10 and 30, 2011, placement agent warrants to purchase 372 shares of common stock at \$83.50 per share were issued. Also in connection with a private placement offering on November 10 and 30, 2011, placement agent warrants to purchase 372 shares of common stock at \$100.00 per share were issued. All the placement agent warrants are exercisable immediately and 372 warrants expire November 10, 2016 and 372 warrants expire November 30, 2016.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Two years ended December 31, 2014

# NOTE 10 — STOCKHOLDERS' EQUITY – (continued)

- (d) In connection with a registered direct offering on December 14, 2010, warrants to purchase 18,625 shares of common stock at \$153.00 per share were issued. All of the warrants are exercisable immediately and expire December 14, 2015.
- (e) In connection with a registered direct offering on January 26, 2010, warrants to purchase 20,837 shares of common stock at \$150.00 per share were issued. All of the warrants were exercisable immediately and expired on January 26, 2015.

In addition, we issued warrants for placement agent fees to purchase 2,505 shares of our common stock at an exercise price of \$187.50 per share. All of the warrants were exercisable immediately and expired on January 26, 2015.

(f) In connection with the convertible note offerings in 2006, warrants to purchase a total of 91,646 shares of common stock at \$66.00 per share were issued. All of the warrants are exercisable immediately and originally were scheduled to expire six years from date of issue. On February 10, 2012 these warrants were extended an additional three years. On February 16, 201576,370 warrants expired, 7,729 warrants expire on October 24, 2015 and 7,547 warrants expire on December 6, 2015.

# NOTE 11 — STOCK OPTION PLANS

Our stock-based employee compensation plans described below:

# 2005 Equity Incentive Plan

We have a stock awards plan, (the 2005 Equity Incentive Plan), under which 500,000 shares of our authorized but unissued common stock were reserved for issuance to employees, consultants, or to non-employee members of the Board or to any board of directors (or similar governing authority) of any affiliate of the Company. The 2005 Equity Incentive Plan replaced the previously approved stock option plan (the 1995 Stock Awards Plan). No further grants can be made under the plan after January 20, 2015.

For the 2005 Equity Incentive Plan, the fair value of options was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions used for grants in fiscal 2014: dividend yield of 0%; volatility of 102%; risk-free interest rate of 0.79%; and expected lives of 5.5 years. The weighted average fair value of options granted was \$0.29 per share during 2014. No options were granted in 2013.

Summarized information for the 2005 Equity Incentive Plan is as follows:

	Options	Weighted- average exercise price
Outstanding options at January 1, 2013	53,275	\$ 68.00
Expired/forfeited	(21,991)	87.50
Exercised	(2,500)	11.50
Outstanding options at December 31, 2013	28,784	59.00
Granted, fair value of \$14.50 per share	212,500	18.50
Expired/forfeited	(31,200)	37.61
Outstanding options at December 31, 2014	210,084	20.29
Exercisable at December 31, 2014	65,034	27.20

There was no intrinsic value related to the outstanding or exercisable options under this plan at December 31, 2013, respectively. The intrinsic value of options under this plan related to the outstanding and exercisable options were \$11,000 and \$10,000, respectively at December 31, 2013.

The total intrinsic value of options exercised during 2013 was \$3,000 and during 2014 was none.



# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Two years ended December 31, 2014

# NOTE 11 — STOCK OPTION PLANS – (continued)

Further information regarding options outstanding under the 2005 Equity Incentive Plan at December 31, 2014 is summarized below:

	Number of	Number of Weighted average N		Number of	Weighted-average			
Range of exercise prices	options outstanding	Remaining life in years	Exercise price	options exercisable	Remaining life in years	]	Exercise price	
\$11.50 - 18.50	200,000	8.7	\$ 18.33	54,950	8.5	\$	17.86	
\$30.50 - 42.50	4,000	5.1	\$ 32.19	4,000	5.1	\$	32.19	
\$69.00	1,400	5.0	\$ 69.00	1,400	5.0	\$	69.00	
\$113.50 - 157.50	4,684	6.5	\$ 119.99	4,684	6.5	\$	119.99	
	210,084			65,034				

# 1995 Stock Awards Plan

Under the 1995 Stock Awards Plan, as amended, 10,000 shares of our authorized but unissued common stock were reserved for issuance to optionees including officers, employees, and other individuals performing services for us. At December 31, 2014, there were no additional shares available for grant under the 1995 Stock Awards Plan. A total of 50 options were outstanding and exercisable under this plan at December 31, 2014.

Summarized information for the 1995 Stock Awards Plan is as follows:

	Options	Weighted- average exercise price
Outstanding options at January 1, 2013	790	\$ 793.50
Expired	(690)	760.50
Outstanding options at December 31, 2013	100	1,022.50
Expired	(50)	1,425.00
Outstanding options at December 31, 2014	50	620.00
Exercisable at December 31, 2014	50	620.00

There was no intrinsic value related to outstanding or exercisable options under this plan at December 31, 2014 or 2013.

Further information regarding options outstanding under the 1995 Stock Awards Plan at December 31, 2014 is summarized below:

	Number of	Weighted average		Number of	Weighted-average	
	Options	Remaining life in	Exercise	options	Remaining	Exercise
Range of exercise prices	outstanding	years	price	exercisable	life in years	price
\$620.00	50	1.0	\$ 620.00	50	1.0	\$ 620.00

# NOTE 12 — INCOME TAXES

Income tax expense differs from the statutory amounts as follows:

	2014	2013
Income taxes at U.S. statutory rate	\$ (9,105,000)	\$ 1,513,000
Current year reserve	1,254,000	224,000
Expenses not deductible	7,851,000	(1,737,000)
Total tax expense	\$	\$

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Two years ended December 31, 2014

# NOTE 12 — INCOME TAXES – (continued)

Deferred taxes are provided for the temporary differences between the financial reporting bases and the tax bases of our assets and liabilities. The temporary differences that give rise to deferred tax assets were as follows:

	December 31,		
	2014	2013	
Deferred tax assets			
Net operating loss carryforwards	\$ 68,263,000	\$ 63,087,000	
General business credit carryforwards	2,486,000	2,362,000	
State credits	2,061,000	3,053,000	
Property and equipment	_	_	
Stock options	542,000	473,000	
Derivatives	(92,000)	(92,000)	
Deferred revenue	92,000	1,072,000	
Intangible assets	464,000	418,000	
Accrued interest	253,000	253,000	
Other	231,000	231,000	
Gross deferred tax assets	74,300,000	70,857,000	
Valuation allowance	(74,300,000)	(70,857,000)	
Net deferred taxes	\$	\$	

At December 31, 2014, we had approximately \$200,744,000 of net operating loss carryforwards and approximately \$2,486,000 of general business credit carryforwards. These carryforwards expire as follows:

	Net operatin loss carryforward	0	neral business credit arryforwards
2013	\$ -	_	\$ —
2014	-		—
2015	-	_	—
2016	-		_
Thereafter	200,744,00	00	2,486,000
	\$ 200,744,00	00	\$ 2,486,000

As a result of a merger on January 25, 1996, a change in control occurred for federal income tax purposes, which limits the utilization of pre-merger net operating loss carryforwards of approximately \$3,100,000 to approximately \$530,000 per year.

Additionally, we acquired MacroChem Corporation on February 25, 2009 and Somanta Pharmaceuticals, Inc. on January 4, 2008. Both corporations were loss companies at the time of the acquisition. Therefore, the net operating losses related to those acquisitions may be subject to annual limitations as provided by IRC Sec. 382.

# AMENDMENT TO LICENSE AGREEMENT

THIS AMENDMENT ("Amendment No. 1") is made as of 23 January 2015 to the License Agreement dated 19<sup>th</sup> September 2014 (the "License Agreement") between Plasma Technologies, LLC, (hereinafter referred to as "PLASMATECH") a South Carolina limited liability company with an address c/o Eugene J. Zurlo, 36 Prioleau Street, Unit N, Charleston, SC 29401 and PlasmaTech Biopharmaceuticals, Inc., a Delaware corporation having a place of business at 1325 Avenue of the Americas, 27<sup>th</sup> Floor, New York, NY USA ('LICENSEE").

PLASMATECH and LICENSEE are hereinafter referred to as a "Party" and collectively "Parties" to this Amendment No. 1.

In consideration of the mutual covenants, terms and conditions set forth below and for other good and valuable consideration which the Parties hereto hereby acknowledge, the Parties agree as follows:

1. As of the date of this amendment, Section 3.1(a) is amended and restated as follows:

( a ) <u>Effective Date Payment</u>. In consideration of the rights and licenses granted by PLASMATECH herein, LICENSEE shall deliver to PLASMATECH a combination of cash and common shares in LICENSEE in the amount of five million dollars (\$5,000,000.00). One million dollars (\$1,000,000.00) will be paid in cash. The remaining four million dollars (\$4,000,000.00) will be paid at the option of the LICENSEE in cash and/or shares of common stock (such shares of common stock, for this purpose, being valued at the price to the public in the offering, net of transaction expenses and underwriting fees) on January 15, 2017.

2. Except as expressly set forth in this Amendment No. 1, all terms of the License Agreement shall remain in full force and effect.

3. This Amendment No. 1 may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. This Amendment No. 1, to the extent signed and delivered by means of a facsimile machine or by exchanging PDF signatures, shall be treated in all manner and respects and for all purposes as an original agreement or instrument and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person.

IN WITNESS whereof the Parties hereto have caused this Amendment No. 1 to be signed by their duly authorized officers.

Signed for and on behalf of **Plasma Technologies LLC** 

/s/ Eugene J. Zurlo

Name: Eugene J. Zurlo Title: Manager Signed for and on behalf of **PlasmaTech Biopharmaceuticals, Inc.** 

<u>/s/ Steven H. Rouhandeh</u> Name: Steven H. Rouhandeh Title: Chairman

# Subsidiaries of the Registrant

MacroChem Corporation, a Delaware company Virium Pharmaceuticals, Inc., a Delaware company Somanta Pharmaceuticals, Inc., a Delaware company Tacora Corporation, a Delaware company Virologix Corporation, a Delaware company

# CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 31, 2015, accompanying the consolidated financial statements included in the Annual Report of PlasmaTech Biopharmaceuticals, Inc. and subsidiaries on Form 10-K for the years ended December 31, 2014 and 2013. We hereby consent to the incorporation by reference of said report in the Registration Statements of PlasmaTech Biopharmaceuticals, Inc. on Form S-1 (File Nos. 333-197220, 333-179603, 333-178415, 333-166453, 333-162687, 333-149633, and 333-135734), Form S-4 (File No. 333-143587), and Form S-8 (File Nos. 333-189985, 333-169067, 333-161642, 333-75136, 333-125796, and 333-114269).

/s/ Whitley Penn LLP Dallas, Texas March 31, 2015

#### PRINCIPAL EXECUTIVE OFFICER CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Steven H. Rouhandeh, certify that:

- 1. I have reviewed this Annual Report on Form 10-K of PlasmaTech Biopharmaceuticals, Inc.
- Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 31, 2015

/s/ Steven H. Rouhandeh Steven H. Rouhandeh Executive Chairman Principal Executive Officer

#### PRINCIPAL FINANCIAL OFFICER CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Stephen B. Thompson, certify that:

- 1. I have reviewed this Annual Report on Form 10-K of PlasmaTech Biopharmaceuticals, Inc.
- Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 31, 2015

/s/ Stephen B. Thompson Stephen B. Thompson Vice President Finance Principal Financial and Accounting Officer

# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350 AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

This certification set forth below is hereby made solely for the purposes of satisfying the requirements of Section 906 of the Sarbanes-Oxley Act of 2002 and may not be relied upon or used for any other purposes.

A signed original of this written statement required by Section 906 has been provided to PlasmaTech Biopharmaceuticals, Inc. and will be retained by PlasmaTech Biopharmaceuticals, Inc. and furnished to the SEC or its staff upon its request.

Pursuant to Section 906 of the Public Company Accounting Reform and Investor Act of 2002 (18 U.S.C. 1350, as adopted, the "Sarbanes-Oxley Act"), Steven H. Rouhandeh, Executive Chairman of PlasmaTech Biopharmaceuticals, Inc. (the "Company"), and Stephen B. Thompson, Vice President Finance of the Company hereby certify that to their knowledge the Annual Report on Form 10-K for the period ended December 31, 2014 of the Company filed with the Securities and Exchange Commission on the date hereof (the "Report") fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the period specified.

Signed at the City of Dallas, in the State of Texas, this 31st day of March, 2015.

/s/ Steven H. Rouhandeh/s/ Stephen B. ThompsonSteven H. RouhandehStephen B. ThompsonExecutive ChairmanVice President FinancePrincipal Executive OfficerPrincipal Financial and Accounting Officer