Emergent BioSolutions Inc. Form 8-K/A August 16, 2010

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

### FORM 8-K/A CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): August 12, 2010 Emergent BioSolutions Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware 001-33137 14-1902018

(State or Other Jurisdiction of Incorporation)

(Commission File Number)

(IRS Employer Identification No.)

2273 Research Boulevard, Suite 400, Rockville,

Maryland

20850

(Zip Code)

(Address of Principal Executive Offices)

Registrant s telephone number, including area code: (301) 795-1800

#### Not applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- b Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- b Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

The following information was prepared in connection with Emergent BioSolutions Inc. s conference call held on August 12, 2010 to announce Emergent s entry on August 12, 2010 into a definitive agreement to acquire Trubion Pharmaceuticals, Inc.

#### **SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 13, 2010 EMERGENT BIOSOLUTIONS INC.

By: /s/ R. Don Elsey
R. Don Elsey
Chief Financial Officer

Emergent Acquisition of Trubion EBS Conference Call Script FINAL

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Thank you.

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Good afternoon ladies and gentlemen.

My name is Robert Burrows, I'm Vice President of Investor Relations for Emergent. Thank you for joining us today as we discuss our exciting announcement, Emergent BioSolutions acquisition of Trubion Pharmaceuticals Inc.

As is customary, our call today is open to all participants. In addition, the call is being recorded and is copyrighted by Emergent BioSolutions.

Joining me on the call this afternoon with prepared comments will be:

Fuad El-Hibri, our chairman and chief executive officer;

Don Elsey, our chief financial officer; and

Dr. Jim Jackson, our chief scientific officer.

The agenda for today s call will be as follows:

Fuad will discuss the high level rationale for why this deal makes sense;

Jim will then discuss in greater detail the scientific perspective and why he is excited about Trubion s clinical and preclinical programs;

Don will follow with a discussion of the deal terms; and

Fuad will finish up with brief concluding comments.

We then will segue to the question and answer session.

Additional members of Emergent s senior management team will be present on the call for purposes of the Q&A session.

Before we begin, I am compelled to remind everyone that during the call management may make projections and other forward-looking statements regarding future events and the company s prospects for future performance. These forward-looking statements reflect Emergent s current perspective on existing trends and information. Any such forward-looking statements are not guarantees of future performance and involve substantial risks and uncertainties. Actual results may differ materially from those projected in any forward-looking statements. You are highly encouraged to review Emergent s filings with the SEC on Forms 10K, 10Q and 8K for more information on the risks and uncertainties that could cause actual results to differ.

For the benefit of those who may be listening to the replay, this call was held and recorded on August 12, 2010. Since then, Emergent may have made announcements relating to topics discussed during today s call, so again, please reference our most recent press releases and SEC filings. Emergent BioSolutions assumes no obligation to update the

information in today s press release or as presented on this call, except as may be required by applicable laws or regulations. Today s press release may be found on our website at www.emergentbiosolutions.com, under Investors slash Press Releases.

With that introduction, I would now like to turn the call over to Fuad El-Hibri, Emergent BioSolutions chairman and ceo.

Fuad?

#### FEH Part I

Thank you, Bob.

Good afternoon everyone and thank you for joining us on today s conference call.

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As you know, earlier today we announced that we have entered into a definitive agreement to acquire Trubion Pharmaceuticals. This transaction includes upfront consideration of 96.8 million of value and up to 38.7 million of success-based milestones, resulting in a total consideration of up to 135.5 million. Trubion is a Seattle-based biotechnology company focused on developing protein therapeutics targeting the key disease areas of oncology and autoimmunity, using its novel platform technologies.

We are very excited about this acquisition.

To begin, I would like to provide some context for this acquisition. Specifically, I will review our strategic vision, which will help you understand why Trubion is such a great fit for Emergent.

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In pursuit of our mission to protect life, our strategic vision has always included the following two fundamental components:

One: to strike a balance between vaccines and therapeutics; and

Two: to build a portfolio of programs targeting multiple disease areas.

Since our inception, M&A has been instrumental to our growth and has consistently been a critical element of our strategy. In fact, including the Lansing, Michigan acquisition, we have completed four acquisitions in the last twelve years.

With respect to striking a balance between vaccines and therapeutics, as a biologics company, we recognize the significant value potential in pursuing the development of therapeutics. Main category of products in biologics are antibody-based therapeutics, which offer certain unique and highly attractive advantages, specifically:

the potential to achieve human proof-of-concept earlier and in smaller clinical trials;

the potential to share development costs over multiple indications; and,

the potential to address multiple disease areas.

With respect to building a portfolio of targeting multiple disease areas, we have so far built a pipeline of programs focused on infectious diseases only. However, we recently completed a comprehensive review to determine where we could leverage our infectious disease capabilities across other disease areas. In this review process, we took into account several criteria, which include:

opportunities for biologics;

short development timelines;

clear approval paths; and

degree of specialty focus.

Given these criteria and our core competencies in manufacturing and product development, the two disease areas that ranked highest after infectious disease were first oncology and then autoimmunity. In oncology, we're finding more and more that infectious disease and cancer are related. Certain cancers, as you know, are actually caused by viruses or bacteria.

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I hope that by providing you with this brief strategic overview you now have sufficient insight into why we have decided to acquire Trubion. With that as a backdrop, let me discuss the business, scientific and financial perspectives related to this transaction.

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From a business perspective, the acquisition of Trubion:

Provides additional clinical-stage therapeutic candidates in the targeted disease areas of oncology and autoimmunity;

It leverages our financial strengths to support the continued development of the oncology lead candidate; and

It leverages large pharma partnerships to provide sales and marketing infrastructure.

Let me take a moment to give you a brief description of Trubion s product development pipeline. This includes: a clinical-stage, CD20 directed SMIP candidate, otherwise known as SBI-087, for the treatment of Rheumatoid Arthritis, which is in Phase 2, and systemic Lupus, which is in Phase 1/2; these are being developed in partnership with Pfizer;

Then, a clinical-stage, CD37 targeted SMIP candidate, otherwise known as TRU-016, for the treatment of B-cell malignancies including CLL, which is in Phase 1/2, and NHL, which is about to enter Phase 1; these are being developed in partnership with Abbott; and

promising preclinical platform-based candidates for the treatment of selective oncology and autoimmune diseases.

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From a scientific perspective, the acquisition of Trubion:

Provides access to two novel, therapeutic platforms SMIP, and SCORPION;

Gives us access to scientific expertise for developing innovative, and what we believe will be high-value therapeutic candidates; and

Enables us to internally generate first-in-class products.

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From a financial perspective, the acquisition of Trubion:

Represents a minimal cash impact;

Results in less than a 10 percent dilution; and

Provides approximately 70 million dollars of NOLs.

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Lastly, as stated in the press release, taking this transaction into account, we are reaffirming our 2010 guidance for revenues and net income.

Looking beyond 2010, we anticipate that we will remain profitable and, with proper R&D prioritization, we may be able to achieve earnings growth in the future.

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That concludes my comments on the overall rationale for the deal. I will now turn it over to Jim who will provide greater detail on the scientific aspects of this acquisition.

Jim?

#### WJJ

Thank you, Fuad.

First as Fuad just mentioned:

The acquisition of TRBN with it s two clinical stage therapeutic products, their portfolio of preclinical candidates and their recombinant protein therapeutic platforms fit well with Emergent s growth strategy. [AND] broaden[s] our therapeutic pipeline beyond infectious disease into autoimmunity AND oncology. Their proprietary SMIP and SCORPION platform technologies provide Emergent with a means to deliver new mono-specific and multi-specific therapeutic candidates either alone OR through partnerships.

I would like now to spend a few moments discussing in more detail the Trubion clinical candidates Trubion s proprietary protein therapeutic platforms AND why we are very excited about acquiring these assets. TRBN [is focused on] engineering and developing biologics-based, FIRST-IN-CLASS recombinant protein therapeutics to serve unmet medical needs AND to provide SUPERIOR ALTERNATIVES superior in terms of either greater efficacy and/or better safety profiles TO MARKETED monoclonal antibody PRODUCTS.

TRBN s portfolio consists of two clinical stage products; SBI-087 an anti-CD20 molecule which as Fuad mentioned, is in a phase 2 study as a treatment for rheumatoid arthritis or RA, and TRU-016 a first-in-class anti-CD37 protein therapeutic which is being evaluated in a phase 1 study as a treatment for certain B-cell malignancies (CLL and NHL). First SBI-087:

In collaboration with Pfizer, Trubion is developing SBI-087, a next generation CD20-directed product candidate. SBI-087 is an improved form of AND builds on Trubion and Pfizer's clinical experience with TRU-015. SBI-087 is based on Trubion's SMIP technology platform and has been genetically modified to be a humanized and potentially more potent derivative of TRU-015. ADDITIONALLY SBI-087 has been FORMULATED for both intravenous infusion AND s.c. administration, which could provide a clear competitive advantage over currently marketed anti-CDZO therapeutics.

Patient dosing has commenced and recruitment is currently underway in a Phase 2 trial of SBI-087 for RA evaluating the safety and efficacy at subcutaneous administration of 200mg of the drug.

In addition, patient recruitment is ongoing in a Phase 1 trial of SBI-087 for RA in Japan. Finally, Pfizer is also conducting a Phase 1 clinical trial of the drug in systemic lupus, in which patient dosing has commenced and recruitment is ongoing.

SBI-087 is licensed to Pfizer and [will be a future source for] both milestone payments and royalties.

The second very exciting clinical stage product is TRU-016 a fully human FIRST-IN-CLASS - anti-CD37 protein therapeutic. TRU-016 is the only anti-CD37 therapeutic currently in clinical development. As you are aware CD37 is a cell surface marker present at high levels on B-cells. Experiments have shown that CD37 may play a role in B-cell regulation. In addition, CD37 is known to be over-expressed in patients with CLL. Importantly CD37 is a clinically validated target for the treatment of B-cell malignancies.

Trubion and Abbott are currently conducting an open label Phase 1 clinical study with TRU-016 in individuals with relapsed chronic lymphocytic leukemia or CLL. Based on the results obtained thus far an amendment to this study has been filed to allow the treatment of BOTH naïve CLL patients AND subjects with relapsed NHL. Expansion of the clinical development program to other indications in oncology and autoimmune disorders is planned. TRU-016 is being developed as part of a 50:50 co-development partnership with Abbott.

Turning to TRBN s proprietary SMIP and SCORPION technology platforms.

First, SMIPs. These Small Modular ImmunoPharmaceuticals or SMIPs - are recombinant fusion protein molecules that can be designed to overcome many of the limitations inherent to traditional monoclonal antibody products. SMIP therapeutics are expressed in single chain polypeptides and are comprised of basically a specific binding domain, a flexible hinge region and an effector function domain designed to elicit predetermined therapeutic effects tailored to be beneficial for treating certain diseases. SMIP proteins are mono-specific therapeutics that is they are

drugs that recognize and bind only to a single target molecule either a soluble protein or a cell surface protein through the binding domain and initiate a functional activity through the effector domain. The SMIP therapeutics while similar to classic monoclonal antibodies possess unique and superior characteristics to conventional MAbs. SMIPs are also smaller than whole antibodies, which may allow for better *in vivo* penetration.

SMIPs are produced using standard cell culture expression and manufacturing technologies; they can be formulated for both infusion and injectable delivery and have been shown to be stable under standard storage conditions. Both TRU-016 and SBI-087 are SMIPs and both have achieved proof of concept in human clinical trials. Next, the SCORPION platform. This is a novel platform for the development of bi-specific and multi-specific recombinant protein therapeutics. Like SMIPs, SCORPION proteins are expressed as single-chain polypeptides HOWEVER unlike SMIPs which recognize only one target SCORPION molecules can recognize and bind multiple targets simultaneously. SCORPIONS can also be designed to contain immunoglobulin effector function domains like the SMIP therapeutics. Thus, SCORPIONS can be engineered to bind multiple targets on the same cell or different cell types and modulate cell signaling through multiple pathways.

While TRBN has thus far focused their SMIP and SCORPION technologies on the development of new first-in-class products for autoimmunity and oncology these platforms can also be leveraged to develop new candidates for infectious disease.

Trubion s core protein therapeutic platforms have the potential to generate multiple new FIRST-IN-CLASS therapeutic candidates and, as a result, add additional value to our R&D pipeline.

Post-closing, in addition to our licensed product Emergent will have a substantial product pipeline, consisting of both vaccines and therapeutics with 5 products in clinical development AND several very promising preclinical stage candidates in the areas of both ID and oncology.

That concludes my prepared comments and I will now turn it over to Don who will provide greater detail on the deal terms.

Don?	
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#### **RDE**

Thank you, Jim.

As Fuad stated we are really excited about this acquisition. With the experience of the Trubion organization and the product candidates in process we believe that we have a combination that will result in significant financial returns for our shareholders.

As was stated earlier, we are acquiring Trubion for an upfront consideration of \$96.8 million of value and up to \$38.7 million of success-based milestones, resulting in a total consideration of up to \$135.5 million.

Under the terms of the agreement, each share of Trubion Pharmaceuticals common stock will be converted into the right to receive an upfront payment of \$1.365 per share in cash and 0.1641 shares of Emergent BioSolutions stock. The upfront payment represents a value of \$4.55 per Trubion share, or approximately \$96.8 million, based on Trubion s total common shares outstanding, the net value of diluted stock options, and the trading average of Emergent s common stock for the five days prior to the signing of the definitive agreement. In the aggregate, Emergent will issue approximately 3.35 million shares of its common stock as part of the upfront consideration, which after the closing of the merger will represent approximately 9.2 percent of Emergent s total shares outstanding. Certain of these shares will be subject to lockup provisions.

Trubion Pharmaceuticals stockholders will also receive one Contingent Value Right (CVR) per share, which will entitle the holder to receive cash payments based upon achievement of five predefined Phase 2 and Phase 3 clinical study initiation milestones and one manufacturing-related milestone. The total potential aggregate value of the CVRs is \$38.7 million over a 36-month period, following the closing of the merger.

Upon closing we anticipate that Trubion will have approximately \$20 million in cash and \$70 million of NOLs that we expect to be able to use over the next ten years. Additionally there are a number of milestone payments from the Abbott and Pfizer partnerships we may receive over the next five years.

The acquisition of Trubion is expected to close in the fourth quarter of 2010.

Trubion s research facilities in Seattle, Washington will be maintained and the location will become a therapeutics-focused product development site for the combined company. We also expect to retain the majority of Trubion employees.

In terms of current year impact, as Fuad mentioned, we again re-affirmed the 2010 guidance of \$275 million to \$300 million in revenue and \$40 million to \$50 million of net income. As you may realize the financial statements for 2010 will reflect the consolidation of EBS and Trubion only for the time between deal closing and the end of 2010. Looking beyond 2010, we will focus carefully on pipeline optimization and identifying opportunities to realize financial synergies across the combined company both R&D as well as G&A synergies. This entails evaluation of not only the Trubion programs but the EBS programs as well to ensure that we are targeting those candidates with the greatest probability of success from both a technical and financial perspective.

That concludes my prepared comments and I will now turn it back over to Fuad who will provide some concluding remarks.

Fuad?

#### FEH Part II

Thank you, Don.

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In conclusion, the acquisition of Trubion furthers our position as a leading, fully integrated biopharmaceutical company focused on the manufacture, development and commercialization of vaccines and antibody therapeutics. We believe that this acquisition will allow the combined company to extract substantially more value from the Trubion pipeline and platform than would be possible had Trubion remained a stand-alone company. Trubion s clinical and preclinical stage programs as well as its leading edge science will expand our product

Trubion s clinical and preclinical stage programs as well as its leading edge science will expand our product development pipeline and will significantly broaden our antibody-based capabilities.

This acquisition also brings us into oncology through a co-development arrangement with Abbott and a licensing arrangement with Pfizer.

Emergent s stable vaccine franchise, substantial capital resources, and expertise in biologics combined with Trubion s world-class therapeutic platform technology and clinical-stage development programs should translate into significant value over the near and long term.

We re also excited about the potential for additional newsflow in the near term that the acquisition is expected to bring. I look forward to sharing more information with you as the transaction moves to completion.

That concludes our prepared comments. I will now turn the call over to the operator, so that we can begin the question-and-answer portion of the call.

Operator, please proceed.

#### Additional Information and Where to Find It

This communication is being made in connection with the proposed merger (the Merger ) among Emergent BioSolutions Inc. ( Emergent ), Trubion Pharmaceuticals, Inc. ( Trubion ) and certain of Emergent s direct and indirect wholly-owned subsidiaries. Emergent intends to file with the Securities and Exchange Commission (the SEC) a registration statement on Form S-4, which will contain a prospectus relating to the securities Emergent intends to issue in the proposed Merger. Trubion intends to file a preliminary proxy statement in connection with the proposed Merger and to mail a definitive proxy statement and other relevant documents to Trubion s stockholders. Stockholders of Emergent and Trubion and other interested persons are advised to read, when available, the registration statement and Trubion s preliminary proxy statement, and amendments thereto, and definitive proxy statement in connection with Trubion s solicitation of proxies for the special meeting to be held to approve the Merger because these documents will contain important information about Trubion, Emergent and the proposed Merger. The definitive proxy statement will be mailed to stockholders as of a record date to be established for voting on the Merger. Stockholders will also be able to obtain a copy of the documents filed with the SEC, without charge, once available, at the SEC s website at http://www.sec.gov or by directing a request to: Emergent BioSolutions Inc., Attn: Investor Relations, 2273 Research Boulevard, Suite 400, Rockville, Maryland 20850, or Trubion Pharmaceuticals, Inc., Attention: Investor Relations, 2401 4th Avenue, Suite 1050, Seattle, Washington, 98121.

#### **Participants in Solicitation**

Emergent, Trubion and their respective directors and officers may be deemed participants in the solicitation of proxies from Trubion s stockholders. Information regarding Emergent s directors and officers is available in Emergent s proxy statement for its 2010 annual meeting of stockholders and its 2009 annual report on Form 10-K, which were filed with the SEC and are available at the SEC s website at http://www.sec.gov. Information regarding Trubion s directors and officers is available in Trubion s proxy statement for its 2010 annual meeting of stockholders and its 2009 annual report on Form 10-K, which were filed with the SEC and are available at the SEC s website at http://www.sec.gov. Information regarding Trubion s directors and officers will also be contained in Trubion s proxy statement in connection with the Merger when it becomes available. Emergent s and Trubion s stockholders may obtain additional information about the interests of Trubion s directors and officers in the Merger by reading Trubion s proxy statement when it becomes available.

### **Emergent BioSolutions Forward-Looking Statement**

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, including statements regarding our strategy and how the acquisition of Trubion will impact that strategy, the financial impact of the merger on Emergent s 2010 forecast, the provision of expected cash and NOLs, the anticipated timing for the transaction and anticipated future operations, and any other statements containing the words believes, expects, anticipates, plans, estimates and sir expressions, are forward-looking statements. There are a number of important factors that could cause the company s actual results to differ materially from those indicated by such forward-looking statements, including the parties ability to consummate the transaction; the conditions to the completion of the transaction, including the effectiveness of Emergent's registration statement on Form S-4 or the regulatory approvals required for the transaction may not be obtained on the terms expected or on the anticipated schedule; and the parties ability to meet expectations regarding the timing, completion and financial and tax treatments of the merger; the possibility that the parties may be unable to achieve expected synergies and operating efficiencies in the merger within the expected time-frames or at all and to successfully integrate Trubion s operations into those of Emergent; such integration may be

more difficult, time-consuming or costly than expected; operating costs, partner loss and business disruption (including, without limitation, difficulties in maintaining relationships with employees, partners, licensors and others) may be greater than expected following the transaction; the retention of certain key employees of Trubion may be difficult; the parties are subject to intense competition and increased competition is expected in the future; the failure to protect either party—s intellectual property rights may weaken its competitive position; third parties may claim that either party—s products infringe their intellectual property rights; the rate and degree of market acceptance and clinical utility of the parties—products; the success of ongoing and planned development programs, preclinical studies and clinical trials; the ability to identify and acquire or in license products and product candidates that satisfy Emergent—s selection criteria; the potential benefits of the parties existing collaboration agreements and the ability to enter into selective additional collaboration arrangements; the timing of and ability to obtain and maintain regulatory approvals for other product candidates; commercialization, marketing and manufacturing capabilities and strategy; and other factors identified in Emergent—s Quarterly Report on Form 10-Q for the quarter ended June 30, 2010 and subsequent reports filed with the SEC. The company disclaims any intention or obligation to update any forward-looking statements as a result of developments occurring after the date of this press release.