Zacks Small-Cap Research

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# ADMA Biologics, Inc. (ADMA - NASDAQ)

## *1Q:17 Results and Biotest Acquisition: Valuation Implications*

Based on our DCF model and a 20% discount rate, ADMA is valued at approximately $10.00 per share. We apply an 80% blended probability of FDA approval for ADMA's suite of immunoglobulin products.

| | |
|---|---|
| Current Price (5/15/2017) | $4.26 |
| **Valuation** | **$10.00** |

## OUTLOOK

ADMA has developed an IVIG product, RI-002, with high levels of RSV antibodies that can treat immune compromised patients and address a host of other evidence-based uses. Currently ADMA is addressing deficiencies cited in a CRL issued in July 2016 for RI-002. In January 2017, ADMA announced its intent to acquire Biotest's out-of-compliance manufacturing facility in return for a 50% interest in ADMA and their two plasma collection facilities.

The success of the transaction will hinge on ADMAs ability to address the problems at the facility and obtain FDA approval to manufacture and commercialize additional IG products.

ADMA's two plasma collection centers will continue to generate cash flow and plasma inventories until transferred to Biotest. When up to full capacity, the two Atlanta-based centers are anticipated to produce up to 60k liters of plasma annually, providing the source material for RI-002.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$8.00** |
| **52-Week Low** | **$4.00** |
| **One-Year Return (%)** | **-30.2** |
| **Beta** | **2.64** |
| **Average Daily Volume (sh)** | **28,275** |
| **Shares Outstanding (mil)** | **12.9** |
| **Market Capitalization ($mil)** | **$54.9** |
| **Short Interest Ratio (days)** | **2.47** |
| **Institutional Ownership (%)** | **66** |
| **Insider Ownership (%)** | **38** |
| *Insider Ownership is post-transaction | |
| **Annual Cash Dividend** | **$0.00** |
| **Dividend Yield (%)** | **0.00** |
| **5-Yr. Historical Growth Rates** | |
| **Sales (%)** | **N/A** |
| **Earnings Per Share (%)** | **N/A** |
| **Dividend (%)** | **N/A** |
| **P/E using TTM EPS** | **N/A** |
| **P/E using 2016 Estimate** | **N/A** |
| **P/E using 2017 Estimate** | **N/A** |
| **Zacks Rank** | **N/A** |

| | |
|---|---|
| **Risk Level** | **Above Average** |
| **Type of Stock** | **Small-Growth** |
| **Industry** | **Med-Biomed/Biologics** |

## ZACKS ESTIMATES

**Revenue**
(in millions of $)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2016 | $2.1 A | $2.3 A | $2.9 A | $3.3 A | $10.7 A |
| 2017 | $2.6 A | $3.1 E | $3.1 E | $3.1 E | $12.3 E |
| 2018 | | | | | $66.6 E |
| 2019 | | | | | $118.6 E |

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2016 | -$0.43 A | -$0.50 A | -$0.34 A | -$0.35 A | -$1.61 A |
| 2017 | -$0.51 A | -$0.30 E | -$0.15 E | -$0.14 E | -$0.90 E |
| 2018 | | | | | -$0.01 E |
| 2019 | | | | | $1.37 E |

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## WHAT'S NEW

**First Quarter 2017 Financial Results**

ADMA Biologics, Inc. (NASDAQ: ADMA) filed its 1Q:17 Form 10-Q and provided a press release updating investors on financial and operational results on May 12, 2017. First quarter revenues were $2.6 million, below our estimate of $3.1 million representing a 24% increase over the prior year. The growth in revenues was attributable to increased sales of plasma from the new plasma facility in Marietta, Georgia and better spot-market pricing. Net loss of ($6.5) million was below our estimates of ($2.9) million. Higher expenses across the board relative to our estimates contributed to the difference. We note that many of these expenses are one-time in nature related to the planned acquisition of the Biotest facilities.

Blood plasma sales of $2.6 million comprise almost 99% of total revenues and compare to $2.1 million in the first quarter of 2016 and $3.3 million in the prior quarter. Gross margin fell to 37.7%, which compares to 38.8% last quarter and 39.4% last year due to contractual pricing that is not rising as fast as costs. License revenues were $36,000, flat with prior year levels, which relates to services and financial payments provided by Biotest.

R&D declined by 40% to $1.2 million vs. 1Q:16 due to lower validation, testing and production costs for RI-002 due to the receipt of the CRL, but was higher than 4Q:16 levels as Biotest provided rebates for some of ADMA's R&D costs in the final quarter of 2016. Plasma center expenses rose 16% to $1.5 million on hiring of additional staff and increasing center operating hours. G&A jumped 150% to $4.3 million as expenses related to the Biotest acquisition were recognized. Acquisition related amounts for legal, accounting, financial advisory and due diligence were the major expenses incurred.

Operations and capital expenditures (cash burn) consumed approximately $5.4 million in the quarter, up from $5.2 million in the same period last year. ADMA also paid down $1.1 million in principal related to its loan with Oxford Finance. The net of these movements reduced total cash and equivalents by $6.5 million to $8.8 million as of March 31, 2017.

Following the January announcement of the Biotest transaction, ADMA has continued to collaborate with Biotest with respect to the integration plan. The companies have maintained their June 2017 transaction target date. Following the transaction, ADMA will increase its efforts to address the inspection issues at the Biotest Boca facility and develop a timeline with the FDA to resolve the outstanding issues. While the remediation efforts are underway, ADMA will continue to generate revenues from the manufacturing facilities for Nabi-HB and contract manufacturing. Once the CRL and inspection issues have been resolved, the company plans to refile the BLA for RI-002 and resume production of Bivigam.

**Biotest Therapy Business Unit (BTBU) Transaction Review**

ADMA announced the acquisition of certain Biotest assets related to the manufacture of RI-002 and other plasma and immunoglobulin products on January 23, 2017. The deal also includes cash and additional financing for ADMA from Biotest in return for a 50% stake in the company and an eventual transfer of ADMA's two plasma facilities in Atlanta, Georgia. Key details of the transaction include:

ADMA Receives:

- Boca Raton Manufacturing Facility, including two buildings with plasma fractionation and purification plant
- FDA licensed products including Nabi-HB
- Cash consideration of $40 million
    - $12.5 million in cash
    - $15 million unsecured term interest-only term loan
    - $12.5 million future equity commitment

Biotest Receives:

- 50% of ADMA capital stock, less one share
- Voting common stock equal to 25% of issued and outstanding stock
- Appointment of director and observer to ADMA board
- Transfer of both currently operating plasma centers to Biotest January 1, 2019
- Right to market new, plasma-based products in Biotest territories

The Boca Raton facilities manufactured three products in 2016: BIVIGAM, an immune globulin indicated for the treatment of primary humoral immunodeficiency, Nabi-HB, a hyperimmune globulin that is rich in antibodies to the hepatitis B virus and plasma for further manufacturing. In conjunction with the January announcement of the BTBU deal, Biotest and Kedrion decided to halt production of BIVIGAM until the issues at the facility are remedied.

**Addressing the Discrepancies; The Key to Value**

In discussions with management and our review of available materials, we believe that Biotest's reluctance to change ineffective management at the facility and include outside experts to assist in the correction of deficiencies contributed to their inability to address the warning letter issued in November 2014. Biotest's physically distant German management is also less experienced in US regulatory procedures, further contributing to the failure.

The issues that require attention are not infrastructure related, as the facilities have received substantial upgrades over the last nine years, reducing the need for required capital investments. The issues raised by the FDA are related to management providing clear operating procedures and proper training of staff to follow these directions. Based on ADMA's assessment, successful management will need to be critical of operational and manufacturing processes that are out of specification and develop procedures that are less cumbersome and easier to follow. Streamlining of document flow is also necessary as is involving experts with FDA experience to critically assess the existing problems and develop approaches to address them. Since the issuance of the CRL in July 2016, ADMA management has been working closely with Biotest to address the problems and has developed a thorough understanding of the issues over this period. This understanding led to the development of the purchase agreement as ADMA is more motivated and experienced in addressing the problems.

Based on updated commentary by ADMA's management, we believe that the issues at the facilities can be resolved before year-end by installing experienced and motivated management, implementing new standard operating procedures, conducting training for management and employees and obtaining FDA approval to use the facility to develop biologic products.

The success of the asset deal and the likelihood it will add incremental value to our target price are directly dependent on ADMA management's ability to address the problems at the manufacturing plant. Up to the announcement of the deal, ADMA management had taken the lead in addressing many of the problems at the facility from Biotest which puts them in a strong position to understand the current situation and rapidly implement the necessary changes when they have control. Management understands and has outlined many of the areas where Biotest failed to make progress in addressing the problems and has a high-level plan to provide a remedy.

**New Products**

Along with the acquisition of the BTBU, ADMA also has obtained the rights to sell other products including BIVIGAM and Nabi-HB. The facilities also sell plasma intermediates to Biotest and have the ability and capacity to sell other plasma products including RI-002. Currently, the facilities provide contract manufacturing services to one client who is sourcing rabies immunoglobulin.

Nabi-HB is a hyperimmune immune globulin with antibodies to hepatitis B surface antigen. The biologic was approved by the FDA in March 1999. The product is specifically intended to be used in specific settings, including

- Acute exposure to blood containing HBsAg
- Perinatal exposure of infants born to HBsAg-positve mothers
- Sexual exposure to HBsAg-positive persons
- Household exposure to persons with acute HBV infection

BIVIGAM is an intravenous immune globulin for the treatment of primary humoral immunodeficiency. It was approved by the FDA in December 2012 and was the first polyspecific intravenous immune globulin manufactured in the U.S. BIVIGAM is a purified, sterile, ready-to-use preparation of concentrated human immunoglobulin G (IgG) sourced from human plasma. BIVIGAM contains a broad spectrum of neutralizing IgG subclasses similar to that of normal plasma; those antibodies are directed against bacterial and viral pathogens and their toxins in order to avoid recurrent serious opportunistic infections. The product is intended to be used in individuals that are missing some of the body's immune defense abilities and to address primary humoral immunodeficiency (PI).

Contract manufacturing revenues are derived from producing immuneglobulin on behalf of third parties.

Biotest revenues or intermediates are byproducts of other immunoglobulin processing and will continue to be transferred to Biotest for inputs in other products. Revenues from this product are expected to be from 15% to 20% of other immunoglobulin revenues, and include byproducts such as albumin, Factor VIII, Factor IX and others that are part of the fractionation process.

## Our Forecasts

We refresh our discounted cash flow model to reflect the Biotest Therapy Business Unit (BTBU) transaction. Following the close of the transaction, resolution of the outstanding inspection issues and approval by the FDA, we anticipate sharp revenue growth from the various products that are currently produced and awaiting approval.

ADMA is targeting a June close to the acquisition, following which we anticipate an immediate effort to bring in the necessary experts to address the issues outlined in the warning letter and CRL. This is expected to be followed by an FDA re-inspection and lifting of the warning letter. Following a positive nod by the FDA, ADMA will resubmit its BLA for RI-002 and resume production of Bivigam. We anticipate both of these events occurring near the end of 2017. This will result in Bivigam revenues in early 2018. It remains unclear whether or not the resubmission of the BLA will require a two or six month review, and our conservative estimates assume the six month period suggesting a response by the agency in early 3Q:18 and ultimate production shortly after.

Sales of RI-002 will initially be approximately $15 million in 2H:18, over $50 million in 2019 and reaching over $100 million by 2020. Previous sales levels achieved under Biotest management for Bivigam were approximately $50 million, and we anticipate a slow ramp up back to this level beginning in early 2018. Nabi-HB sales were just under $8 million in 2015 and 2016 and we anticipate similar levels of sales in 2017, rising at modest rates in future years. Contract manufacturing was just under $8 million in 2016, and we anticipate a reset slightly lower at $7.0 million in 2017, increasing modestly over the next several years.

Intermediates/Biotest Revenues are byproducts of immunoglobulin fractionation. Based on historical relationships, from 15% to 20% of specialty plasmas yield Intermediates revenues, therefore we maintain this proportion in our forecast model. Both plasma centers should be fully mature by 2018 and generate revenues between $6 and $7 million per year. We take a conservative view and forecast at the low end of this range for the company's two existing plasma centers. As part of the agreement to acquire BTBU, the two currently operational plasma centers will be transferred to Biotest in 2019. In early 2017, ADMA announced a lease to begin improvements on a space in Marietta, Georgia for a third plasma center which we anticipate will be online by the end of 2017 and begin to generate revenues by late 2018. We anticipate a slow ramp-up over the next few years to annual revenue of between $6 and $7 million.

**Exhibit I – Combined Company Revenues**

| **ADMA Biologics, Inc.** | **2017** | **2018** | **2019** |
|---|---|---|---|
| RI-002 Revenues | $0 | $15,197,759 | $52,149,517 |
| Growth | | | 243.1% |
| Bivigam Revenues | $0 | $17,000,000 | $35,000,000 |
| Growth | | | 105.9% |
| Nabi-HB Revenues | $7,700,000 | $7,931,000 | $8,168,930 |
| Growth | | 3.0% | 3.0% |
| Contract Manufacturing | $7,000,000 | $7,070,000 | $7,140,700 |
| Growth | | 1.0% | 1.0% |
| Intermediates Sold to Biotest | $1,155,000 | $6,019,314 | $14,297,767 |
| Growth | | | 137.5% |
| Plasma Center #1 | $6,096,582 | $6,365,424 | |
| Growth | | 4.4% | transferred to Biotest |
| Plasma Center #2 | $6,096,582 | $6,365,424 | |
| Growth | | 4.4% | transferred to Biotest |
| Plasma Center #3 | $0 | $500,000 | $1,650,000 |
| Growth | | | 230.0% |
| License Revenue | $143,708 | $148,019 | $152,460 |
| Growth | | 3.0% | 3.0% |
| **Total Revenues** | **$28,048,163** | **$66,596,940** | **$118,559,373** |
| Growth | | 137.4% | 78.0% |

Gross margin is initially anticipated to be in the mid-30% range for RI-002 due to initial inefficiencies and improve to 65% over the next several years. Gross margin for Bivigam is expected to start in the low 30% range and increase to 50% over the next several years. Nabi-HB is currently estimated to have 55% margins, which we anticipate will rise to 65% over the next two years. Contract manufacturing is expected to maintain gross margins of 50% over the forecast period while Intermediates/Biotest Revenues will be in the 30% range. For all manufactured products, gross margin will vary based on the weight of each revenue line, and is expected to be in the high 30% range in 2018 rising to the high 50% as we reach steady state revenues. Plasma center gross margins have been very consistent over time at 40% and we forecast this level to continue.

Pro forma General and administrative, research and development and capital expenditures are expected to be approximately $30 million in 2017, and increase at a mid-single digit rate, in line with inflation over the forecast period.

Our expense estimates reflect the delay in approval of RI-002 and a delay in hiring of personnel to support the marketing of the biologic. No additional expenses, such as re-filing costs or consultant fees are anticipated as a result of the CRL or resubmission activities

Following an anticipated FDA approval of RI-002, we expect ADMA to hire between 25-30 sales representatives. Personnel for patient support, medical affairs, quality assurance, regulatory affairs, scientific affairs, reimbursement, inventory and logistics, human resources, and financial and operational management are also expected to be hired. In order to fulfill orders for RI-002, ADMA may also use a network of national distributors. If the product launch occurs in 2H:18, we do not anticipate an overall profit for ADMA until 2019. Revenues from plasma sales are expected to expand to $12 million in 2017 as both centers move to near full capacity of between $6 and $7 million per year. ADMA has also announced that they have signed a lease for space that will be built out over the next several quarters for a third plasma collection center.

Given the deal announcement regarding Biotest, it is possible that ADMA will not require outside funding before the launch of RI-002, assuming the FDA removes the warning letter and grants approval in-line with our expectations. We will update our cash flow analysis as additional detail regarding the operational profile of the Biotest facilities becomes available. As outlined in the deal terms, Biotest will provide $12.5 million in cash, $15 million in debt financing and an additional $12.5 million in equity financing when needed as part of a future deal, providing a total of $40 million in additional funding. Including the near $9 million in cash currently on the balance sheet, this provides almost $49 million in liquidity as ADMA addresses the outstanding discrepancies and launches products. Based on our cash flow estimates, this is sufficient cash to support operations until 2019 when ADMA is forecasted to be cash flow positive.

Including the impacts from the merger, cash burn for 2017 is expected to be approximately ($17) million due to merger related expenses and the addition of the BTBU cost structure to the corporation. R&D and sales expenses will be at minimal levels until there is more clarity on RI-002's progress, however, general and administrative expenses are expected to continue at first quarter levels for the majority of the year reflecting expenses related to the BTBU acquisition. We have a high degree of confidence that the BTBU deal will close, at which time we will provide further refinements to our forecasts. We also highlight the increasing contributions from the maturing plasma centers that should provide a tailwind to cash flow.

Our discounted cash flow model uses a 20% discount rate compared to the 15% used previously, which reflects the higher risk of both merger integration and addressing the FDA's concerns. We also apply an overall 89% probability of ultimate revenues for the four independent immunoglobulin revenue lines to account for the specific risk of each.

**Exhibit II – Probability Weighted Success**

| Probability of Success | | Relative Weight |
|---|---|---|
| GM RI-002 | 60.0% | 11% |
| GM Bivigam | 75.0% | 13% |
| GM Nabi-HB | 100.0% | 35% |
| GM Contract Manufacturing | 100.0% | 29% |
| **Probability Adjustment** | | **89%** |

There are outstanding details regarding the close of the BTBU transaction, the resolution of the CRL and the sales and profitability of the BTBU itself. As management works through the specifics of the transaction and resubmission, we will adjust our model and valuation accordingly.

**2017 Milestones**

- Close Biotest Therapy Business Unit (BTBU) transaction
  - Anticipated in June 2017
- Integrate BTBU into existing operations
- Establish timeline with FDA for reinspection, resubmission and approval
- Maximize revenues from BTBU
- Address issues in warning letter and CRL during 2H:17
- Resubmit BLA for RI-002 year-end 2017
- Resume production of Bivigam year-end 2017
- Launch new plasma collection center[1]
- Begin production of RI-002 by 2H:18

**Summary**

ADMA reported a quarter that reflected continued year over year growth of plasma center sales, and a decline in R&D costs offset by increases in G&A expenses reflecting activities related to the BTBU deal. We update our model to reflect the BTBU acquisition and take a conservative view with respect to ramp up of RI-002 and Bivigam sales. We have not included other potential products that can be produced in the Biotest facility despite additional excess capacity. As part of the deal, the ADMA will transfer their two currently owned plasma collection facilities to Biotest in 2019 and also receive financing of up to $40 million. The BTBU deal provides substantial value in assets that will transform ADMA into a vertically integrated plasma products company. While the ultimate value of the transaction will depend on ADMA management's ability to address the deficiencies at the facility and obtain FDA approval to launch new products, we believe they will rapidly address them followed by a timely review. We update our DCM model to generate a target of $10 per share.

[1] ADMA signed a lease for space to build a new plasma collection center in February 2017.

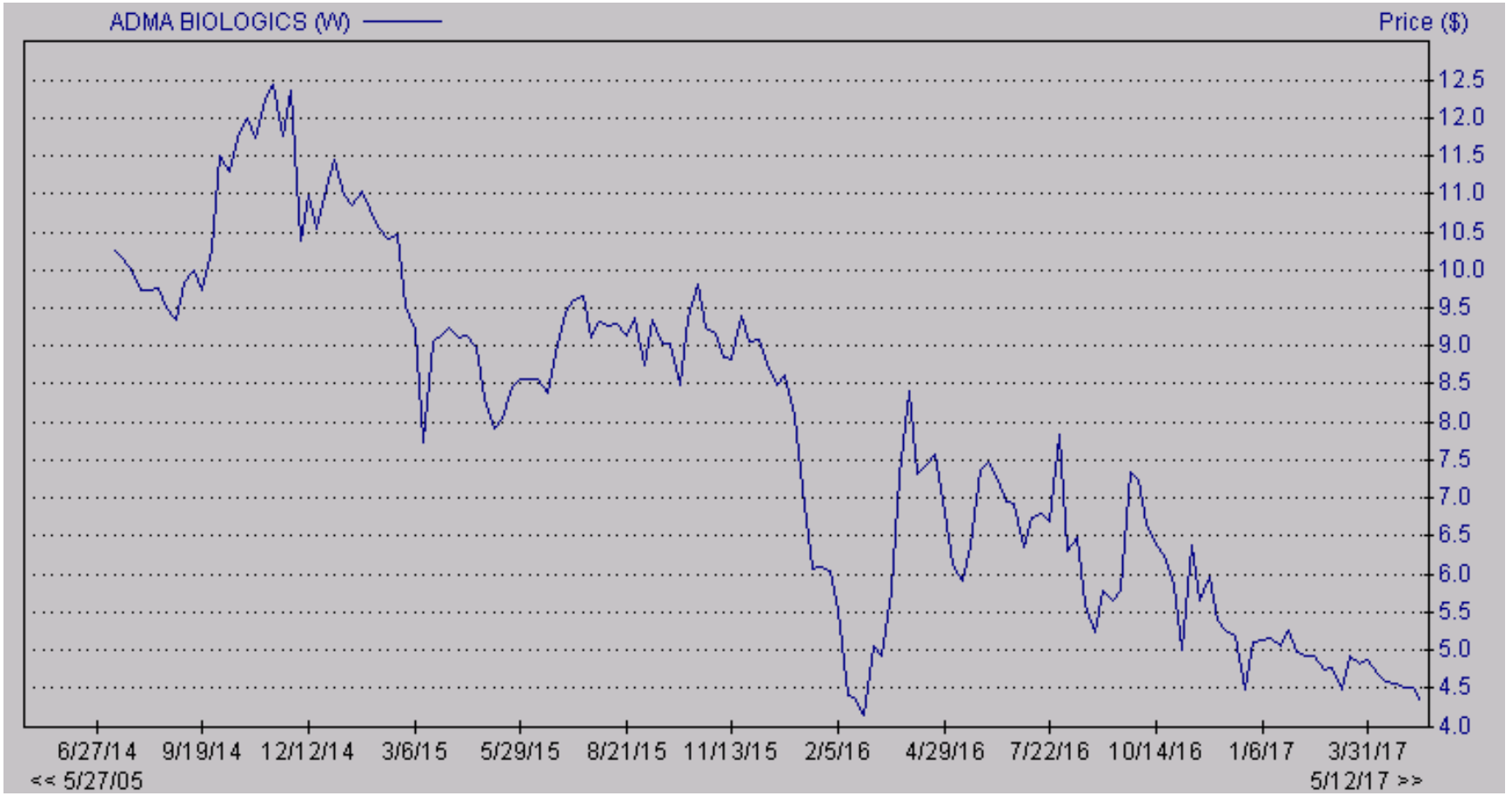
## PROJECTED FINANCIALS

### ADMA Biologics, Inc. - Income Statement

| ADMA Biologics, Inc. | 2016 A | Q1 A | Q2 E | Q3 E | Q4 E | 2017 E | 2018 E | 2019 E |
|---|---|---|---|---|---|---|---|---|
| **Total Revenues** | **$10.7** | **$2.6** | **$2.7** | **$3.2** | **$3.7** | **$12.3** | **$66.6** | **$118.6** |
| *YOY Growth* | *49%* | *24%* | *20%* | *10%* | *12%* | *16%* | *440%* | *78%* |
| Cost of Product Revenue | $6.4 | $1.6 | $1.6 | $2.0 | $2.3 | $7.1 | $40.7 | $61.7 |
| *Product Gross Margin* | *39.5%* | *37.7%* | *39%* | *39%* | *39%* | *42%* | *61%* | *52%* |
| Research and development | $7.7 | $1.2 | $0.6 | $0.6 | $0.6 | $3.0 | $3.1 | $3.3 |
| Plasma centers | $5.4 | $1.5 | $1.4 | $1.4 | $1.4 | $5.7 | $6.6 | $0.8 |
| General and administrative | $8.5 | $4.3 | $2.5 | $2.5 | $2.5 | $11.8 | $13.0 | $13.0 |
| Income from operations | ($17.3) | ($5.9) | ($3.4) | ($3.2) | ($3.0) | ($15.2) | $3.1 | $39.7 |
| *Operating Margin* | *-163%* | *-226%* | *-125%* | *-99%* | *-81%* | *-123%* | *5%* | *34%* |
| Other income (expense) | ($2.2) | ($0.6) | ($0.6) | ($0.6) | ($0.6) | ($2.2) | ($3.4) | ($3.4) |
| Pre-Tax Income | ($19.5) | ($6.5) | ($4.0) | ($3.8) | ($3.6) | ($17.4) | ($0.3) | $36.3 |
| Income Taxes Paid | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| *Tax Rate* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* |
| **Net Income** | **($19.5)** | **($6.5)** | **($4.0)** | **($3.8)** | **($3.6)** | **($17.4)** | **($0.3)** | **$36.3** |
| *Net Margin* | *-183%* | *-249%* | *-145%* | *-116%* | *-96%* | *-141%* | *0%* | *31%* |
| **Reported EPS** | **($1.61)** | **($0.51)** | **($0.30)** | **($0.15)** | **($0.14)** | **($0.90)** | **($0.01)** | **$1.37** |
| *YOY Growth* | *-11.3%* | *17.8%* | *-40.3%* | *-56.6%* | *-60.9%* | *-44.2%* | *-99%* | *-14056%* |
| Basic Shares Outstanding | 12.15 | 12.89 | 13.37 | 25.80 | 25.82 | 19.47 | 26.00 | 26.50 |

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