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# Research Update

## Apricus Biosciences, Inc.

**Rating: Speculative Buy**

Juan Noble

**APRI $0.30 (NasdaqCM)**

August 17, 2016

| | 2014A | 2015A | *2016E* | *2017E* |
|---|---|---|---|---|
| Total revenues (in millions) | $9.3 | $4.8 | ***$7.8*** | ***$15.2*** |
| Earnings (loss) per share* | ($0.55) | ($0.45) | ***($0.18)*** | ***$0.02*** |

| | | | |
|---|---|---|---|
| 52 - Week range | $1.99 – $ 0.28 | Fiscal year ends: | December |
| Shares outstanding as of July 28, 2016 | 66.4 million | Revenue/share (ttm) | $0.03 |
| Approximate float | 42.3 million | Price/Sales (ttm) | 8.8X |
| Market Capitalization | $19.9 million | Price/Sales (2017)E | 2.7X |
| Tangible Book value as of June 30, 2016 | NA | Price/Earnings (ttm) | NA |
| Price/Book | NA | Price/Earnings (2017)E | NA |

*Excludes warrant valuation adjustments.

*Apricus Biosciences, Inc., headquartered in San Diego, California, is developing pharmaceuticals to treat urological and rheumatoid disorders, and women's sexual disorders. The company's first commercialized product, Vitaros®, is a topical treatment for erectile dysfunction (ED), delivery of which is based on a proprietary permeation enhancer technology. Vitaros is aimed at patients who are unresponsive to oral ED medications and prefer a treatment that is less invasive or easier to use than other alternatives to oral drugs. Apricus' product portfolio includes specialty urology, rheumatology and women's health pharmaceuticals.*

***Key Investment Considerations:***

***Reiterating Speculative Buy rating but reducing (12-month) price target to $1.25 per share from $1.45 due to diminished valuation and further dilution.***

***APRI's revenue prospects rest largely on a Vitraros target patient population of nine million in Europe and around six million in the US. Vitaros has been on the market in major European markets since 2015 and could, upon regulatory clearance, be launched in the US by 2017.***

***In early 3Q16, Apricus rationalized its marketing partnerships, aiming to increase Vitaros growth momentum by transferring more of the responsibility for overseas Vitaros marketing to Ferring International.***

***For 2016 we project a loss of ($0.18) per share (formerly [$0.26] per share) on revenue of $7.8 million. For 2017 we project a profit of $0.02 (formerly [$0.03]) on revenue of $15.2 million.***

***In 2Q16*** *(results released August 4, 2016)* ***Apricus lost ($0.08) per share (excluding warrant revaluation) on revenue of $464,000. We projected a 2Q loss of ($0.05) per share on revenue of $2.5 million. In the year-earlier quarter, the company lost ($0.10) per share on revenue of $475,000.***

***Cash of $2.7 million at the end of 2Q16 should cover APRI's needs into 3Q16. But by our estimates, APRI will have to raise another $20 million in additional financing between 3Q16 and the end of 2017.***

***See disclosures on pages 15 - 17***

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## *Investment Recommendation*

**Reiterating Speculative Buy rating but reducing (12-month) price target to to $1.25 per share from $1.45 due to diminished valuation and further dilution.**

By 2020 APRI's revenue should increase to an estimated $75 million in license fees and milestone payments. That revenue level could be achieved even on nominal penetration of a core, sustainable overseas market for Vitaros.

A comparison group of non-major pharmaceutical stocks with market values of $50 million to $1 billion is trading at 4.6X trailing revenue vs. an APRI price to sales multiple of 8.8X. Three months earlier, the comparison group and APRI were trading at 5.3X and 11.4X, respectively. Valuation of the comparison group has compressed steadiy during the past year. APRI's price to sales multiple fell sharply in the aftermath of the March 28, 2016 disclosure of the disappointing results of the Fispemifene clinical trial,

An APRI price-to-sales valuation of 6X on estimated 2020 revenue per share of $0.52 would value the stock at $3.10 per share based on an estimated 144 million common share equivalents outstanding. Discounting that figure to reflect regulatory, execution, dilution and acceptance risks would value the stock at $1.25 per share in the year ahead.

**In our view, APRI shares are suitable mainly for highly risk tolerant accounts seeking exposure to a microcap pharmaceutical stock with high growth potential.**

## *Recent Developments*

*Ferring Distribution Agreement Amended* On July 6, 2016, Apricus amended its agreement with Ferring, extending Ferring's exclusive rights to Vitaros more broadly in Europe, Asia, Latin America and certain Caribbean nations. In connection with this amendment, Apricus is eligible to receive an additional $3.6 million in upfront and pre-commercialization milestone payments and $1.5 more in launch milestone payments than provided for in the original agreement with Ferring.

*Sandoz Agreement Terminated* On July 22, 2016 Apricus and Sandoz, by mutual agreement, terminated the agreement originally signed in 2012. That agreement gave Sandoz exclusive Vitaros rights in certain countries in Europe and Asia. The termination makes Sandoz eligible to receive a one-time $2 million payment upon transfer of marketing rights in Germany to Ferring, an an additional $1.5 million payable in quarterly installments in 2016 and 2017.

*Stock Purchase Agreement* On July 6, 2016, Apricus and Aspire Capital entered into a stock purchase agreement that commits Aspires to purchase, if Apricus chooses to sell, up to $7 million of Apricus common over the 24-month term of the agreement (until July 5, 2018). The agreement can be terminated at any time by Apricus without any cost or penalty.

## *Overview*

Apricus Biosciences, headquartered in San Diego, California, began focusing on drug delivery technology in 1995. The company's lead product, Vitaros, is a topical treatment for erectile dysfunction (ED), delivery of which is based on a proprietary permeation enhancer technology (NexACT®) which facilitates the delivery of the drug into the blood stream.

Vitaros is aimed at patients who have not responded satisfactorily to oral ED medications and prefer a treatment that is less invasive or easier to use than other alternatives. Vitaros is cleared for marketing in a number of European countries and in Canada. Vitaros is produced by two contract manufacturers in Canada and is marketed by partners

under exclusive licenses, including those listed in the table on page 3, to sell Vitaros in Canada, Europe, Latin America, most of Southeast Asia, the Mideast, Australia and New Zealand, and certain countries in Africa. Canadian rights are held by Mylan Laboratories; the timing of a Canadian Vitaros launch is still undetermined. With the October 2015 acquisition of US Vitaros marketing rights from Allergan, Apricus could, subject to regulatory clearances, gain access to the largest single market for its alprostadil product.

By 2020, the potential global ED patient population could exceed 2.5 billion, roughly a third of whom are likely to be unresponsive to PDE5 inhibitors.

Unresponsive patients represent a huge market opportunity for Vitaros, which is arguably a more attractive option than other alternative ED treatments such as intracavermosal injections of alprostadil (branded as Edex or Caverject), alprostadil suppositories (marketed as Muse), vacuum erection devices, or implantable penile prostheses. Even modest penetration of markets covered by current partners could yield annual milestone and royalty revenue estimated at $75 million by 2020. With Allergan's transfer of US Vitaros rights to Apricus, an ED patient population of 2.2 million men unresponsive to PDE5 inhibitors could be within reach in two years or so. The company is confident that additional clinical trials will not be necessary but due to non-clinical issues, the regulatory review timeline has not yet been established.

**VITAROS: Commercial Partnerships**

| Partner | Geography (*Launched) | Milestones | | Royalties |
|---|---|---|---|---|
| | | Upfronts & Pre- Commercialization | Total | |
| Allergan | United States[1] | Up to $20M | Up to $25M | Flat |
| Recordati | Spain*, Russia, Turkey, Ireland and Parts of Europe and Africa | Up to $3.5M | Up to $41M | Tiered |
| Ferring | Germany*, Austria, Belgium*, Denmark, Finland, Iceland, Luxemburg*, the Netherlands, Norway, Sweden*, Switzerland, the UK*, Latin America and Parts of Asia | Up to $8.1M | Up to $34M | Tiered |
| Majorelle | France*, Monaco and Parts of Africa | Up to $4.0M | Up to $21M | Tiered |
| Mylan NV | Canada | Up to $2.7M | Up to $15M | Tiered |
| Bracco | Italy* | Up to $1.3M | Up to $6.3M | Tiered |
| Ellis | Middle East | Up to $0.2M | Up to $2.1M | Tiered |
| **TOTAL** | | **~$39M** | **~$145M** | **~High Single-Digits to Double-Digits in the 10-20% Range** |

If Allergan elects to opt-in to commercial option upon FDA approval of NDA and assume all future marketing and selling activities. If Allergan does not opt-in, then Apricus may commercialize Vitaros itself and pay Allergan a double-digit royalty.

*Source: Apricus Biosciences corporate presentation August 2016*

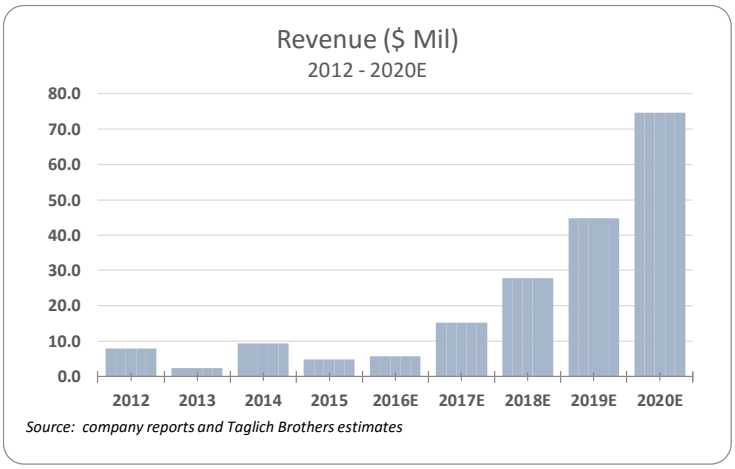
RayVa™, a rheumatology product, is now in a Phase 2a trial for the treatment of Raynaud's phenomenon, a symptom of rheumatic disease that causes numbness in the digits in response to cold temperatures or stress. RayVa also uses Apricus' proprietary permeation enhancer.

## *Outlook*

The worldwide market for erectile dysfunction medication peaked at roughly $4.3 billion in 2012, 14 years after the introduction of Viagra, the first commercialized oral PDE5 inhibitor. Research firm Transparency Market Research estimates (March 2014) that the dollar value of the market will shrink roughly 4.5% a year to $3.4 billion by 2019 due to the expiration of patents on the three leading oral PDE5 inhibitors.

The 2012 expiration of Viagra's overseas patents sharply eroded its pricing flexibility as generic manufacturers Teva Pharmaceuticals, Mylan Laboratories and Actavis launched less expensive versions of sildenafil. Generic sildenafil has also cut into the sales of Cialis and Levitra, which will drop further as their patents expire in 2017 and 2018, respectively. Other oral PDE5 inhibitors launched into the market will face a tighter pricing environment.

The encroachment of generics will shrink the dollar value of this market segment, but the demographics underlying demand suggest sustained large scale usage of ED medication. Population and demographic data published by the United Nations (UN) Department of Economic and Social Affairs show a male population in relatively well developed regions or nations, including the US, Europe, China, Japan, India, Southeast Asia (including Australia/New Zealand) and Latin America, of 2.5 billion. Applying 2003 Harvard School of Public Health ED incidence estimates by age group, we project the total potential ED patient population for those markets in 2020 at 205 million. In Vitaros' principal markets, currently Europe and Southeast Asia, the potential ED patient population is approximately 87 million.




Results of two 2013 studies (Huang and Lie, and Park et al) suggest that 30% of them, or 26 million ED patients in these markets, will not respond satisfactorily to PDE5 inhibitors, making them potential candidates for alternative ED treatments.

Vitaros is not yet cleared for US marketing but in 2016 APRI aims to begin the US regulatory review process, which the company believes will not entail additional clinical studies. A 4Q16 NDA filing could lead to a US Vitaros launch by mid-2017. The lack of a presence in the US, currently the world's largest ED pharmaceutical market, leaves a wide gap in the company's sales effort, as does the absence of licensing agreements covering India, Japan and China. But we believe that a potential Vitaros core target patient population conservatively estimated at nine million in Europe and Southeast Asia provides Apricus with substantial near-term revenue opportunities accessible through current partners. Adding an additional six million US men to the target patient population would increase revenue upside substantially. Under current license agreements, Apricus has earned around $19 million in upfront payments. If all milestones laid out in the license agreements are achieved, future milestone payments could eventually total almost $220 million. By our estimates, the company can achieve total revenue – milestone payments and royalties − of $75 million in 2020.

## *Strategy*

Vitaros was launched in the UK, Germany, Sweden, and Belgium in 2014. The product was recently launched in France and Spain. With Bracco's release of Vitaros in Italy in September 2015, all major European markets are now covered and APRI aims to increase its European market share. The October 2015 agreement with Ferring Pharmaceuticals added Latin America to Vitaros' markets. Under an April 2016 amendment to the Ferring agreement, marketing rights to Vitaros in the UK were transferred to Ferring after the agreement with Takeda was terminated in 2016. Apricus aims to secure an agreement in 2016 with another licensee that will extend Vitaros' sales to Asian markets.

With US Vitaros rights in hand, Apricus is assuming responsibility for all US R&D and regulatory submissions. Apricus paid Allergan a $1 million upfront fee. A regulatory milestone fee of $1.5 will be payable to Allergan at some stage of the regulatory review process and, if Allergan elects to commercialize Vitaros in the US, Apricus could receive up to $25 million in upfront and regulatory milestones, plus a double-digit royalty on US Vitaros sales. If Allergan does not undertake US commercialization of Vitaros, Apricus would do so, paying Allergan a double-digit royalty.

The company will earn revenue mainly from upfront fees on licensing agreements, milestone payments through 2032, and royalties based on partners' sales. Vitaros is sold by Apricus to its licensees at a transfer price that covers

its manufacturing costs. The product is manufactured by contractors in two Canadian facilities, from where it is dropped shipped to licensees' locations.

Progress through clinical development should strengthen Apricus' pipeline considerably. A phase 2a RayVa study was completed in 2015. More advanced clinical development of RayVa should facilitate establishment of a partnership to market RayVa outside the US. Completion of stability tests for Vitaros Room Temperature (RT) are also planned, potentially enabling Apricus to launch RT through partners in 2016.

Discussions with the FDA on further regulatory submissions for RayVa have yet to take place. When phase 2 studies of RayVa are completed, Apricus aims to begin explore phase 3 studies with the FDA, potentially bringing the company closer to a New Drug Applications (NDA) in 2017.

## *2016 Second Quarter and Six-Month Results*

In 2Q16, the company lost $3.3 million, or ($0.05) per share, on revenue of $464,000. Excluding warrant valuation adjustments, APRI lost ($0.08) per share in the quarter. We projected a loss of ($0.05) per share on revenue of $2.5 million. Our 2Q forecast included a projected license fee on a new partnership agreement; no new agreements were completed during the period.

| **($ 000)** | **Quarter ending June 30:** | | | 16 v. '15 | **Six mos. Ending June 30:** | | |
|---|---|---|---|---|---|---|---|
| | 2016A | *2016E* | 2015A | % +/- | 2016 | 2015 | % +/- |
| Revenue | | | | | | | |
| License fees | 50 | *1,500* | | NA | 50 | 350 | (85.7%) |
| Royalties | 304 | *745* | 75 | 305.3% | 671 | 163 | NM |
| Milestone payments | | *250* | | | | | |
| Product sales | 110 | | 387 | (71.6%) | 369 | 424 | (13.0%) |
| Total | 464 | *2,495* | 462 | 0.4% | 1,090 | 937 | 16.3% |
| Cost of product sales | 93 | | 509 | NA | 326 | 742 | (56.1%) |
| Gross profit (loss) | 371 | *2,495* | (47) | NA | 764 | 195 | 291.8% |
| Expenses | | | | | | | |
| R&D | 2,787 | *2,000* | 3,107 | (10.3%) | 5,593 | 6,375 | (12.3%) |
| G&A | 2,294 | *2,945* | 2,669 | (14.1%) | 4,698 | 5,765 | (18.5%) |
| Total | 5,081 | *4,945* | 5,776 | (12.0%) | 10,291 | 12,140 | (15.2%) |
| Operating loss | (4,710) | *(2,450)* | (5,823) | NM | (9,527) | (11,945) | (20.2%) |
| Interest expense | (258) | *(237)* | (170) | 51.8% | (537) | (328) | 63.7% |
| Revaluation of warrant liability | 1,637 | | 747 | | 4,232 | 611 | |
| Other (expense) income | (5) | *100* | 1 | NM | (5) | 5 | NM |
| Pretax loss | (3,336) | *(2,586)* | (5,245) | NM | (5,837) | (11,657) | (49.9%) |
| Income tax | (2) | | | | (6) | | |
| Net loss | (3,338) | (2,586) | (5,245) | (36.4%) | (5,843) | (11,657) | (49.9%) |
| Avg common shares out (000) | 61,817 | *56,021* | 50,414 | | 58,433 | 49,031 | |
| Net loss per share | (0.05) | *(0.05)* | (0.10) | (48.1%) | (0.10) | (0.24) | (57.9%) |

*Source: Company reports and Taglich Brothers estimates*

In the year-earlier quarter the company lost $5.2 million, or ($0.10) per share ([$0.12) excluding warrant revaluation) on revenue of $462,000.

2Q16 revenue was flat, with a decline in product sales offset by gains in royalties. Royalties on Vitaros sales lag those sales by at least a quarter. Product sales for the quarter consisted of materials sales to an APRI contract manufacturer, and Vitaros product sold directly to contract manufacturers. Finished product is usually sold by the contract manufacturers to APRI's distributors. Cost of goods sold consists of direct material costs and the cost of manufactured samples provided free of charge to distribution partners.

Operating expenses for the quarter increased 12% to $5.1 million as G&A dropped 14% to $2.3 million due to a reduction in legal and accounting fees, and payroll expenses. R&D decreased 10% to $2.8 million due to lower consulting fees relating to development of Vitaros and RayVa, offset in part by an increase in consulting fees relating to Vitaros and RayVa. Due to a reduction in operating expenses, the operating loss for the quarter narrowed to $4.7 million from $5.8 million.

Interest expense increased 64% to $258,000 due to an increase in notes payable. The net loss for the quarter (excluding warrant revaluations) narrowed to $5 million, or ($0.08) per share, down slightly from $5.2 million, or ($0.10) per share.

For the first half of 2016, the company lost $5.8 million, or ($0.10) per share, on revenue of $1.1 million, vs. a loss of $11.6 million, or ($0.24), on revenue of $937,000 for the first six months of 2015. Excluding warrant valuation adjustments, Apricus lost ($0.17) and ($0.25), respectively, in 1H16 and 1H15.

Six-month revenue was up 16% to $1.1 million due to a fourfold increase in royalties to $671,000, offset in part by a drop in license fees from $350,000 to $50,000 due to difficult comparisons with the prior year, during which most of the company's current licensing agreements were signed.

Operating expenses dropped 15% to $10.3 million due mainly to a 12% decrease in R&D expenses to $5.6 million. The drop in operating expenses stemmed from the same factors influencing the decline in 1Q16 expenses.

Due to gross margin gains and the drop in operating expenses, the six-month operating loss narrowed to $9.5 million from $11.9 million. Interest expense increased 64% to $537,000 due to higher notes payable balances. Excluding warrant revaluations, the net loss for 1H16 narrowed to $10.1 million from $12.3 million.

*Finances* In 2Q16, Apricus burned $4.1 million in cash but decreased working capital by $690,000 due to a reduction in prepayments and an increase in payables. Cash of $3.4 million used in operations and repayment of notes payable, offset in part by the release of restricted cash, reduced cash by $4.2 million to $2.7 million at the end of the quarter.

For the first six months of 2016, the company burned $8.6 million in cash and increased working capital by $860,000 due to increases in receivables and inventory, and a reduction in accruals. Cash of $9.5 million used in operations and the repayment of notes, offset in part by proceeds from the sale of common stock, reduced cash by $1.2 million to $2.7 million as of June 30, 2016.

## *Projections*

Our revenue projections are based largely on Vitaros penetration rates for Europe and Southeast Asia (including Australia/New Zealand), markets with an estimated ED patient population of 87 million men, of whom 26 million would be unresponsive to oral PDE5 inhibitors. UN population and demographic data show that between Europe and Southeast Asia, Europe is far by the larger market based on population as well as demographics; Europe's population has a much larger proportion of men in the 45+ age group. Based on results of the 2006 Padma-Nathan et al studies, arguably the key Vitaros clinical trials, we believe that 9.*2* million men, roughly one-third of the ED patients (in markets currently covered) unresponsive to oral PDE5 inhibitors constitute a long-term sustainable core European market for alprostadil cream.

Our current projections do not include any Vitaros sales in the US. APRI aims to file a Vitaros NDA in 3Q16 after a November pre-submission meeting with the FDA that should clarify the FDA's filing expectations. An NDA filing shortly after that meeting should lead to US Vitaros regulatory clearance in time to start driving a US Vitaros sales ramp by the end of 2017. A 2007 study by Selvin et al (*Prevalence and risk factors for erectile dysfunction in the US*) concluded that an estimated 18 US million men are affected by erectile dysfunction, which correlates strongly with age and is also high among men with one or more cardiovascular risk factors, and men who are hypertensive, and diabetic. Based on results of the Padma-Nathan et al studies, we would estimate that six million US men make up a core US market for alprostadil cream.

If long-term Vitaros adopters use an average of three doses per month, a frequency well within treatment guidelines, those patients would constitute a market that even modest penetration rates could yield license fees and royalty revenue of $75 million by 2020. APRI's production is sold to licensees at transfer prices that cover only

manufacturing costs, but licensees would pay royalties at double digit rates on their sales as well as milestone payments (as much as $200 million by 2032) as they achieve certain cumulative sales goals. New license agreements, or expansion of existing ones, would add to licensing fees.

Our market penetration rate forecasts began at less than half of one percent in 2015. In May 2016 we reduced our 2016 revenue projections to reflect a slower than expected ramp. Our ramp expectations are modest, as widely accepted products, PDE5 inhibitors as well alprostadil products, are already on the market. With steady gains, Vitaros' market penetration of overseas markets presently covered by licensing agreements could reach 10% in five years.

*Operations* We anticipate more moderate losses in 2016 and a modest profit in 2017. Revenue gains should reduce cash burn and improve profitability. APRI has accumulated a US net operating loss carryforwards and capital loss carryforwards of approximately $192.1 million for federal income tax purposes. These carryforwards are available to offset future taxable income and expire beginning in 2018 through 2035 for federal income tax purposes.

*2016* As Vitaros gains more traction in 2016, we project increases in royalties and milestone payments that will almost double total revenue to $7.8 million and narrow losses to ($0.18) per share . Our 2016 estimates are largely unchanged, reflecting the net effect of a $2 million licensing fee from Ferring, a $2.6 million in payments to Sandoz in connection with the termination of the license agreement, and the issuance of an additional 21 million common shares sold to Aspire Capital. Excluding warrant valuation adjustment, the loss for share for the year should be ($0.15) per share. Our revenue forecasts rest heavily on another $1.5 million in license fees in 4Q16.

Gross profit should rise just as sharply, doubling to $7.8 million. Our P&L projections do not reflect product sales and cost of sales, as these are outside transactions that take place between distribution partners and contract manufacturers. Operating expenses will rise by 16% to $20.8 million, the net effect of management efforts to reduce 2016 cash operating expenses by 30% (vs. 2015 cash expenses) and an additional $2.6 million in payment to Sandoz. The increase in gross profit should, despite the increase in operating expenses, narrow the operating loss to $13.1 million from $21.4 million and offset another increase in interest expense.

The net loss for 2016 should narrow to $12.2 million, or ($0.18) per share, from 2015's $19 million, or ($0.38) per share. The reduction in the loss per share will be due in part to an increase in average shares outstanding to 68.8 million from 49.7 million due to the sale of more common stock to Aspire. Excluding warrant valuation adjustments, the net loss for 2016 should narrow to ($0.15) to ($0.32) per share.

*2017* We project a 2017 profit of $2.3 million, or $0.02 per share on revenue of $15.2 million. (previously $0.02 per share). The decrease in our EPS estimate stems from dilution.

Revenue should almost double to $15.2 million, with gross profit rising concomitantly. Revenue growth, still based heavily on license fees from new distribution agreements, will be drive more by royalties earned on commercial partners' sales of Vitaros overseas.

Operating expenses should drop 39% to $12.8 million due to ~30% reductions in R&D and G&A relative to 2015 cash operating expenses, and easier comparisons with 2016 expenses, which include an estimated $2.6 million in payments to Sandoz. A higher gross profit and reduced operating expenses should reverse losses, enabling the company to earn an operating profit of $2.4 million, up from an operating loss of $13.1 in 2016. Between the operating profit and a drop in interest expense stemming from steady repayment of term debt, APRI should show net income of $2.3 million, or $0.02 per share for the year.

*Finances* Since 2011 the company has raised more than $90 million in capital, most of that through common stock sales. Cash of $2.7 million at the end of 2Q16 sale should cover the company's needs into 3Q16. But by our estimates, the company could need approximately $20 million in additional financing between 3Q16 and the end of 2017. Rising working capital needs stemming from revenue gains in the years ahead would have to be supported with substantial increases in financing.

To the extent that revenue exceeds our forecasts, or expenses are lower than we project, funding needs could be less than we anticipate. We have projected further 2016-17 equity financing on the same pattern as that of the 2Q16 common stock sales.

In 2016 cash of $17.4 million used in operations (cash burn of $17.7 million and a nominal reduction in working capital) and repayment of $3.4 million in notes will be partly offset by $17.6 million in proceeds from common stock sales. But cash will drop by $3 million to $848,000 at the end of 2016.

In 2017 APRI will burn cash of $5 million. Due to rising revenue, the company should burn significantly less cash in 2017 but increases in receivables and prepayments stemming from a larger volume of business will increase working capital by an estimated $2.5 million. Proceeds of $12 million from common stock/warrant sales should cover cash of $7.5 million used in operations and $3.4 million in repayment of notes, increasing cash by $967,000 to $1.8 million at the end of 2017.

## *Recent Financings*

*Common Stock/Warrants Offerings* On March 3, 2016, Apricus completed an offering under the January 2012 agreements to sell 11.4 million common shares and warrants to purchase up to an additional 5.7 million common shares for an aggregate offering price of $10 million. Each common share was sold together with one-half of a warrant to purchase one common share at a combined offering price of $0.88 per share plus related warrant. The offering was completed in two closings. Gross proceeds from the sale of roughly 11.3 million common shares and warrants to purchase 5.7 million shares totaled $10 million. The warrants are exercisable commencing six months and a day from the date of issuance, and expire seven years after the date of issuance.

*Credit Agreement* Despite being in compliance with all loan covenants, the entire loan amount borrowed under an October 2014 loan agreement with Oxford Finance LLC and Silicon Valley Bank for term loans totaling up to $10 million was reclassified to short-term. The company will evaluate the debt classification on a quarterly basis and evaluate for reclassification should its financial condition improve.

The first and second term loans bear interest at an annual rate of 7.95% and 8.01%, respectively. The repayment schedule provides for interest-only payments in arrears until November 2015, followed by consecutive equal monthly payments of principal and interest in arrears through October 1, 2018, the maturity date.

*Common Stock Purchase Agreement* On July 6, 2016, Apricus and Aspire Capital entered into a stock purchase agreement commits Aspires to purchase, if Apricus chooses to sell, up to $7 million of Apricus common over the 24-month term of the agreement (until July 5, 2018). The agreement can be terminated at any time by Apricus without any cost or penalty. Apricus delivered to Aspire Capital a commitment fee of 1.5 million common shares at a value of $600,000, in consideration for Aspire Capital entering into the agreement. Apricus also sold 2.5 million common shares to Aspire for $1 million. This agreement replaces an earlier common stock purchase agreement dated August 12, 2014.

## *2015-2017 Clinical Studies*

*Vitaros (US)* Apricus seeks to overturn the FDA's 2009 decision disapproving the Vitaros NDA, which was based largely on potential safety issues (mainly low rates of tumors seen in mice) and deficiencies noted in the permeation enhancer and the manufacturing process, both of which have to be addressed before an NDA is resubmitted, potentially by 3Q16. The Investigational New Drug (IND) and New Drug Application have been transferred to Apricus by Allergan and all prior communication with the FDA is under review.

The company does not believe that any further clinical trials will be necessary. But APRI must satisfactorily address the FDA's earlier concerns regarding DDAIP, a compound that is added to topical products to increase the penetration of topicals through the skin. Essentially, DDAIP opens up the tight spaces between skin cells so active drug molecules can be more rapidly absorbed through the skin into systemic circulation. DDAIP (2.5% formulation) has been approved in Europe and Canada, approvals that predate the FDA's rejections of the Vitaros NDA in 2008. APRI is developing a Vitaros dispenser with a new material that will give the dispenser better stability and shelf life than the old dispenser. Apricus aims to resubmit an NDA in 2016; if Vitaros successfully completes an FDA review, which should take roughly six months, Vitaros could potentially be launched in the US by 2017.

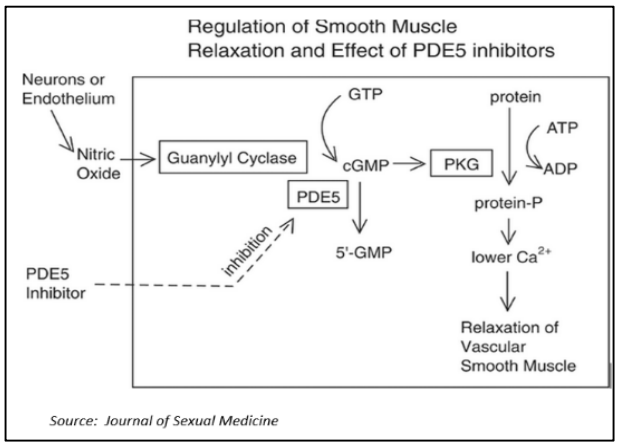
*RayVa* Apricus is developing another topical aprostadil formulation for the treatment of Raynaud's phenomenon stemming from scleroderma, an uncommon disease in which parts of the skin, joints, and blood vessels degrade and are replaced by fibrous tissue. Scleroderma also leads to thickening of the skin, joint pain and stiffness, swallowing difficulties, and cold fingertips that may turn white or blue (Raynaud's phenomenon). While there is no cure for scleroderma, treatment. RayVa, might relieve symptoms by restoring the blood flow to hand and feet that is diminished by vasoconstriction.

A phase 2a study is in progress, with patient enrollment completed in June 2015. The 35-patient study was completed in 3Q15. Each patient was treated with a placebo, followed by one of three doses of the drug. Blood flow and skin temperature changes were evaluated in each test subject. The drug was well tolerated and there were no significant safety issues. Apricus will seek guidance from the Food & Drug Administration (FDA) on a regulatory pathway that could take RayVa into further trials (phase 2b) in 2016. The next RayVa trial will be designed as an at-home, on-demand dosing trial, with patients treating themselves as they experience pain, numbness, throbbing or other disabling symptoms. The company is preparing for the next trial with study design, determination of end-point, formulation development and selection of investigators and a clinical research organization.

## *ED Drugs: How They Work and How They are Administered*

The most widely used ED drug is phosphodiesterase-5 inhibitor (PDE5), the principal variants of which are Viagra (sildenafil), Cialis (vardenafil) and Levitra (tadalafil). Taken orally, PDE5-based drugs are systemic, ingested and absorbed into the bloodstream. Bioabsorption is achieved within 30 minutes to an hour and in combination with sexual arousal, PDE5 usually results in an erection. PDE5 is the recommended first-line treatment for ED.

Alprostadil, a synthetic version of prostaglandin E1, relaxes vascular smooth muscle and results in vasodilation in the corpora cavernosa. Alprostadil widens the cavernosal arteries and relaxes the trabecular smooth muscle of the cavernosa, resulting in rapid blood inflow and expansion of the spaces in the spongy tissue within the corpora. As the expanded corporal capillaries press against the corporas' outer tissue, the outflow of blood is blocked, making the penis rigid. Alprostadil usually begins to work in about five to 20 minutes and can produce an erection that lasts about an hour.




Alprostadil has been commercialized in three dosage forms, all of which are applied directly to the penis: injectables (Edex and Caverject), a suppositories (MUSE) and, most recently, Apricus' topical cream (Vitaros).

Vitaros' alprostadil dose is formulated in a cream form containing a permeation enhancer which facilitates the delivery of the drug into the penile vasculature. Alprostadil cream is also delivered through the urethra (diagram below at right) but as the package insert states emphatically, the

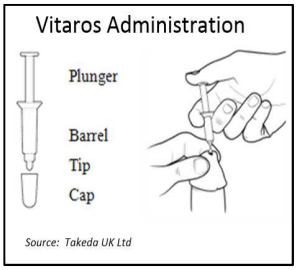
applicator tip is not inserted into the urethra, making Vitaros a much more comfortable treatment option than the more invasive injectable or suppository alprostadil alternatives.

Vitaros takes effect within five to 30 minutes after delivery of the drug and produces an erection that last from one to two hours. Patients are advised to use Vitaros no more than two to three times a week and no more than once every 24 hours. Proven efficacy and a competitive price could make Apricus' Vitaros the alprostadil treatment of choice for ED patients unresponsive to PDE5 inhibitor pills.

Marketing approval in Canada and Europe was based on data from the following clinical studies.

A 2009 open-label study (Rooney et al) evaluated 1,161 ED patients, of whom 74% reported an overall improvement in erectile function, especially after adjusting dosage strength to their particular needs. The largest dose, 300 micrograms, was observed to produce the greatest improvement in test subjects. The Rooney study did not compare alprostadil cream with a placebo or other active ED treatments.

Two 2006 randomized clinical trials (Padma-Nathan et al), evaluated 1,732 patients divided into four groups of roughly equal size, a placebo group and three treatment arms, each dosed with 100, 200 and 300 micrograms of Vitaros. The study concluded that compared to a placebo, alprostadil cream significantly improved ED in a broad range of patients. Improvements were assessed in terms of ability to achieve an erection, successful penetration during attempts at intercourse and successful completion of intercourse. Adverse events observed were limited largely to the application site.




On that last criterion, however, only 31% of the trial subjects showed a clinically relevant improvement, i.e., the ability to successfully complete intercourse. That conclusion is our basis for defining the longer-term Vitaros target patient population of ED patients who have not been responsive to PDE5 inhibitors.

## *Risks*

In our view, these are the principal risks underlying the stock:

*Competition* The market for erectile dysfunction medication is intensely competitive, with three pharmaceutical companies commanding PDE5 inhibitor market shares that could ensure long-term entrenchment. Two products, already commercialized for many years, compete in the market for Alprostadil, an alternative medication for ED patients unresponsive to PDE5 inhibitors.

*Regulatory/Legal* Commercialization of pharmaceuticals is contingent on clearing regulatory review hurdles and securing marketing clearance in multiple jurisdictions. Failure to secure timely marketing clearance could result in costly failures or delays in commercialization.

*Acceptance* Injectable and suppository (pellet) versions of alprostadil are already on the market; the injectable version is widely regarded to be very effective, much more so than the suppository. While it is formulated as a cream, Vitaros, like the suppository, is also introduced into the urethra with an applicator. Despite its efficacy, its appeal may be no better that of the other alprostadil formulations.

*Execution* Apricus' marketing strategy relies largely on its partners rather than direct selling. While all of the company's partners are established pharmaceutical firms, their capability and efforts may not be adequate to ensure substantive market penetration.

*Dilution* The company has raised a substantial amount of equity capital during the past five years, during which time the number of shares outstanding has doubled. Future efforts to raise capital will further dilute the ownership interest of current shareholders.

*Microcap Concerns* Shares of APRI have risks common to the stocks of other microcap (which we define as market capitalizations of $250 million or less) companies. These risks often underlie stock price discounts from the valuations of larger-capitalization stocks. Liquidity risk, typically caused by small trading floats and low trading volume, can lead to large spreads and high volatility in stock price. The company has approximately 43.5 million shares in the float. Average daily volume is around 519,000 shares.

*Miscellaneous Risks* The company's financial results and equity values are subject to other risks and uncertainties known and unknown, including but not limited to competition, operations, financial markets, regulatory risk, and/or other events. These risks may cause actual results to differ from expected results.

**Balance Sheets**
**($ 000)**
**2013A –2017A**

| | 2013A | 2014A | 2015A | 2Q16A | 2016E | 2017E |
|---|---|---|---|---|---|---|
| ASSETS | | | | | | |
| Current assets | | | | | | |
| Cash + equivalents | 21,405 | 11,400 | 3,887 | 2,723 | 848 | 1,816 |
| Accts receivable | 59 | 678 | 519 | 687 | 906 | 1,687 |
| Restricted cash | 332 | 290 | 280 | | | |
| Inventory | 336 | 275 | 469 | 778 | 200 | 200 |
| Prepayments & other | 132 | 646 | 1,136 | 737 | 611 | 1,139 |
| Total | 22,264 | 13,289 | 6,291 | 4,925 | 2,565 | 4,841 |
| Fixed assets (net) | 955 | 1,358 | 1,290 | 1,163 | 1,434 | 1,365 |
| Other long term assets | 91 | 162 | 274 | 78 | 150 | 150 |
| TOTAL ASSETS | 23,310 | 14,809 | 7,855 | 6,166 | 4,149 | 6,356 |
| LIABILITIES AND EQUITY | | | | | | |
| Current liabilities | | | | | | |
| Notes payable | | 153 | 9,475 | 8,070 | 6,163 | 2,719 |
| Accts pay | 926 | 860 | 1,580 | 1,601 | 1,503 | 1,184 |
| Accruals | 3,071 | 5,667 | 4,566 | 3,344 | 4,059 | 3,197 |
| Deferred revenue | 1,800 | 226 | 137 | 250 | 310 | 310 |
| Total | 5,797 | 6,906 | 15,758 | 13,265 | 12,034 | 7,410 |
| Term loan | | 4,626 | | | | |
| Derivative liabilities | | | 1,841 | 2,211 | | |
| Deferred revenue | | 1,000 | | | | |
| Other long term liabilities | 91 | 358 | 200 | 131 | 75 | 75 |
| Shareholders' equity | 10,972 | 1,919 | (9,944) | (9,441) | (7,959) | (1,129) |
| TOTAL LIABILITIES AND EQUITY | 16,860 | 14,809 | 7,855 | 6,166 | 4,149 | 6,356 |

*Source: Company reports & Taglich Brothers estimates*

**Annual Income Statements**
**($ 000)**
**2013A –2017E**

| | 2013A | 2014A | 2015A | 2016E | 2017E |
|---|---|---|---|---|---|
| Revenue | | | | | |
| License fees | 941 | 8,454 | 3,600 | 3,550 | 3,000 |
| Royalties | | 36 | 650 | 2,981 | 6,930 |
| Milestone payments | | | | 1,250 | 5,250 |
| Product sales | | 769 | 589 | | |
| Grants | 21 | | | | |
| Contract services | 1,549 | | | | |
| Total | 2,511 | 9,259 | 4,839 | 7,781 | 15,180 |
| Cost of product sales | 23 | 918 | 922 | | |
| Cost of services | 2,608 | | | | |
| Gross profit | (120) | 8,341 | 3,917 | 7,781 | 15,180 |
| Expenses | | | | | |
| R&D | 5,123 | 21,288 | 14,649 | 8,593 | 5,250 |
| G&A | 13,554 | 11,418 | 10,516 | 12,248 | 7,530 |
| Gain on contract settlement | (534) | (910) | | | |
| Recovery on sale of subsidiary | (255) | (50) | | | |
| Deconsolidation of foreign subsidiaries | (641) | (846) | | | |
| Other expense (income) | | | 102 | | |
| Total | 17,247 | 30,900 | 25,267 | 20,841 | 12,780 |
| Operating income (loss) | (17,367) | (22,559) | (21,350) | (13,060) | 2,400 |
| Interest expense | (727) | (339) | (845) | (933) | (481) |
| Gain on sale of investment | 2,600 | | | | |
| Revaluation of warrant liability | | | 3,236 | 1,637 | |
| Other (expense) income | (376) | 503 | (64) | 195 | 400 |
| Loss - Continuing operations | (15,870) | (22,395) | (19,023) | (12,160) | 2,319 |
| Income tax expense | | | | | |
| Loss - continuing operations | (15,870) | (22,395) | (19,023) | (12,160) | 2,319 |
| (Loss) income - discontinued operations | (1,068) | 691 | | | |
| Net income (loss) | (16,938) | (21,704) | (19,023) | (12,160) | 2,319 |
| Average common shares outstanding (000) | 34,413 | 39,540 | 49,729 | 68,805 | 109,405 |
| Loss per share | | | | | |
| Continuing operations | (0.46) | (0.57) | (0.38) | (0.18) | |
| Continuing operations before warrant revaluation | | | (0.32) | (0.15) | |
| Discontinued operations | (0.03) | 0.02 | | | |
| Net loss per share | (0.49) | (0.55) | (0.38) | (0.18) | 0.02 |

*Source: Company reports and Taglich Brothers estimates*

**Quarterly Income Statements**
**($ 000)**
**2015E - 2017E**

| | 1Q15A | 2Q15A | 3Q15A | 4Q15A | **2015A** | 1Q16A | 2Q16A | 3Q16E | 4Q16E | **2016E** | 1Q17E | 2Q17E | 3Q17E | 4Q17E | **2017E** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Revenue | | | | | | | | | | | | | | | |
| License fees | 350 | | 1,000 | 2,250 | **3,600** | | 50 | 2000 | 1,500 | **3,550** | | 1,500 | | 1,500 | **3,000** |
| Royalties | 88 | 75 | 188 | 299 | **650** | 367 | 304 | 1,118 | 1,192 | **2,981** | 1,341 | 1,490 | 1,863 | 2,236 | **6,930** |
| Milestone payments | | | | | | | | 500 | 750 | **1,250** | 900 | 1,100 | 1,250 | 2,000 | **5,250** |
| Product sales | 37 | 387 | 85 | 80 | **589** | 259 | 110 | | | | | | | | |
| Total | 475 | 462 | 1,273 | 2,629 | **4,839** | 626 | 464 | 3,618 | 3,442 | **7,781** | 2,241 | 4,090 | 3,113 | 5,736 | **15,180** |
| Cost of product sales | 233 | 509 | 142 | 38 | **922** | 233 | 93 | | | | | | | | |
| Gross profit | 242 | (47) | 1,131 | 2,591 | **3,917** | 393 | 371 | 3,618 | 3,442 | **7,781** | 2,241 | 4,090 | 3,113 | 5,736 | **15,180** |
| Expenses | | | | | | | | | | | | | | | |
| R&D | 3,268 | 3,107 | 4,611 | 3,663 | **14,649** | 2,806 | 2,787 | 1,500 | 1,500 | **8,593** | 1,500 | 1,250 | 1,250 | 1,250 | **5,250** |
| G&A | 3,096 | 2,669 | 2,412 | 2,339 | **10,516** | 2,404 | 2,294 | 4,750 | 2,800 | **12,248** | 2,300 | 2,245 | 1,995 | 1,995 | **7,530** |
| Total | 6,364 | 5,776 | 7,023 | 6,104 | **25,267** | 5,210 | 5,081 | 9,195 | 7,245 | **20,841** | 5,995 | 5,440 | 4,940 | 4,940 | **12,780** |
| Operating loss | (6,122) | (5,823) | (5,892) | (3,513) | **(21,350)** | (4,817) | (4,710) | (5,577) | (3,803) | **(13,060)** | (3,754) | (1,350) | (1,827) | 796 | **2,400** |
| Interest expense | (146) | (157) | (254) | (288) | **(845)** | (279) | (258) | (211) | (185) | **(933)** | (159) | (133) | (107) | (82) | **(481)** |
| Revaluation of warrant liability | | | | 3,236 | **3,236** | | 1,637 | | | **1,637** | | | | | |
| Other (expense) income | (144) | 735 | 1,112 | (1,767) | **(64)** | | (5) | 100 | 100 | **195** | 100 | 100 | 100 | 100 | **400** |
| Pretax loss | (6,412) | (5,245) | (5,034) | (2,332) | **(19,023)** | (5,096) | (3,336) | (5,688) | (3,888) | **(12,160)** | (3,813) | (1,383) | (1,834) | 814 | **2,319** |
| Income tax | | | | | | (4) | (2) | | | | | | | | |
| Net loss | (6,412) | (5,245) | (5,034) | (2,332) | **(19,023)** | (5,100) | (3,338) | (5,688) | (3,888) | **(12,160)** | (3,813) | (1,383) | (1,834) | 814 | **2,319** |
| Average common shares out. (000) | 47,632 | 50,414 | 50,414 | 50,454 | **49,729** | 56,021 | 61,817 | 71,548 | 85,834 | **68,805** | 97,263 | 105,834 | 114,405 | 120,120 | **109,405** |
| Net loss per share | (0.13) | (0.10) | (0.10) | (0.05) | **(0.38)** | (0.09) | (0.05) | (0.08) | (0.05) | **(0.18)** | (0.04) | (0.01) | (0.02) | 0.01 | **0.02** |

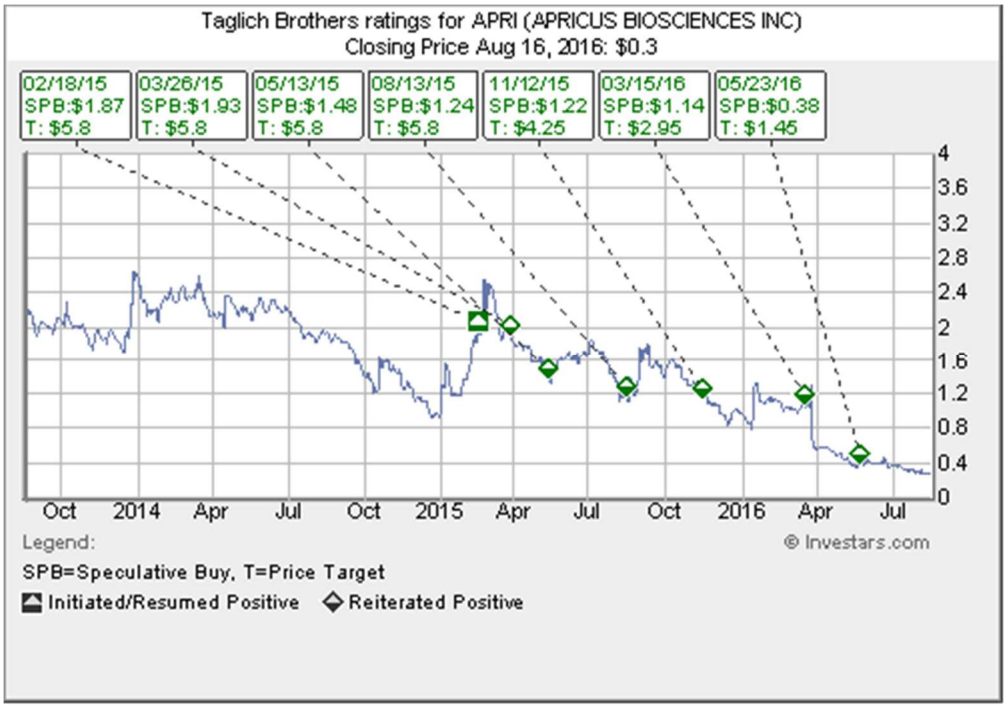
*Source: Company reports and Taglich Brothers estimates*

**Annual Cash Flow Statements**
**($ 000)**
**2013A –2017E**

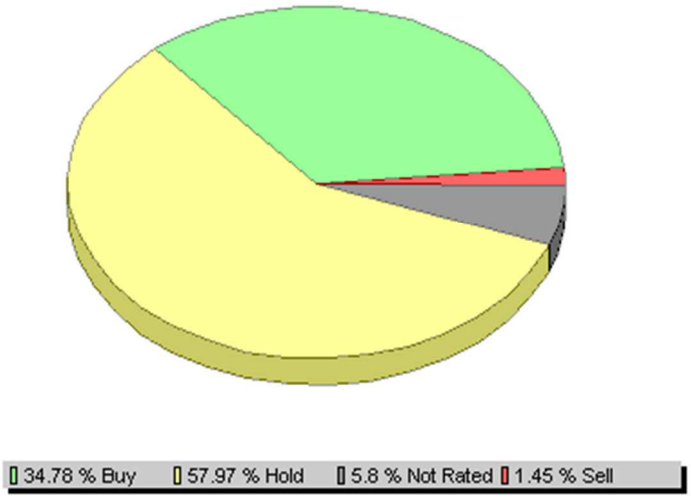
| | 2013A | 2014A | 2015A | 2Q16A (quarter only) | 2016E | 2017E |
|---|---|---|---|---|---|---|
| Operating activities | | | | | | |
| Net loss | (16,938) | (21,786) | (19,023) | (3,338) | (15,418) | (6,216) |
| (Loss) gain from disc opns | (1,068) | 691 | | | | |
| Net loss - continuing operations | (15,870) | (22,477) | (19,023) | (3,338) | (15,418) | (6,216) |
| Shares issued - fispemifene in-license agreement | | 5,904 | | | | |
| Deconsolidation - foreign subsidiaries | (641) | (846) | | | | |
| Gain on contract settlement | (534) | (910) | | | | |
| Depreciation/ amortization | 77 | 170 | 300 | 72 | 236 | 189 |
| Non cash interest expense | | 163 | 267 | 94 | 71 | (149) |
| Loss on debt extinguishment | | 51 | | | | |
| Stock based compensation | 1,992 | 1,731 | 1,210 | 739 | 1,694 | 1,200 |
| Derivative liability revaluation | 274 | (517) | (3,236) | (1,637) | (4,232) | |
| Loss on disposal of fixed assets | | | 102 | | | |
| (Recovery) loss on sale of subsidiary | (255) | (50) | | | | |
| Other | 131 | | 50 | | | |
| Cash burn/throwoff | (14,826) | (16,781) | (20,330) | (4,070) | (17,650) | (4,976) |
| Changes in working capital | (769) | (1,250) | (2,312) | 690 | 242 | (2,489) |
| Net cash used in/fromfrom operations | (15,595) | (18,031) | (22,642) | (3,380) | (17,408) | (7,465) |
| Investing activities | | | | | | |
| Capital expenditures | (573) | (580) | (337) | (12) | (78) | (120) |
| Release of restricted cash | | | | 280 | 280 | |
| Proceeds - sale of fixed assets | 3,657 | | 5 | | | |
| Proceeds - sale of subsidiaries | 255 | 50 | | | | |
| Investing activities | 3,339 | (530) | (332) | 268 | 202 | (120) |
| Proceeds - issuance of stock | 16,612 | 5,913 | 10,869 | (199) | 17,605 | 12,000 |
| Proceeds -warrants | 46 | | | | | |
| Proceeds - term loan | | 4,729 | 5,000 | | | |
| Payment - convertible notes | | (2,750) | (495) | | | |
| Proceeds - exercise of options | | | 83 | | | |
| Release (deposit) of restricted cash | | 42 | 10 | (100) | | |
| Repayment - notes | | | | (771) | (3,433) | (3,444) |
| Repayment - capital lease obligations | (27) | (27) | (6) | (2) | (5) | (4) |
| Repurchase/retirement of stock | | (42) | | | | |
| Net cash from financing - continuing opns | 16,631 | 7,865 | 15,461 | (1,072) | 14,167 | 8,552 |
| Cash flows - discontinued opns | | | | | | |
| Cash from (used in) operations | 38 | 16 | | | | |
| Cash from (used in) investing activities | 1,650 | 675 | | | | |
| Net cash from (used in) discontinued opns | 1,688 | 691 | | | | |
| Net change in cash | 6,063 | (10,005) | (7,513) | (4,184) | (3,039) | 967 |
| Cash - beginning | 15,380 | 21,405 | 11,400 | 6,907 | 3,887 | 848 |
| Cash - ending | 21,405 | 11,400 | 3,887 | 2,723 | 848 | 1,816 |

*Source: Company reports and Taglich Brothers estimates*

## Price Chart




## Taglich Brothers Current Ratings Distribution




**Investment Banking Services for Companies Covered in the Past 12 Months**

| Rating | # | % |
|---|---|---|
| Buy | 2 | 7 |
| Hold | | |
| Sell | | |
| Not Rated | | |

## Important Disclosures

At this writing, no Taglich Brothers employees owned or controlled any of Apricus Biosciences' common shares. Taglich Brothers, Inc. does not have an investment banking relationship with the subject of this report and was not a manager or co-manager of any offering for the company within the last three years.

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## Analyst Certification

**I, Juan Noble, the research analyst of this report, hereby certify that the views expressed in this report accurately reflect my personal views about the subject securities and issuers; and that no part of my compensation was, is, or will be directly or indirectly related to the specific recommendations or views contained in this report.**

## Public companies mentioned in this report

| | | | |
|---|---|---|---|
| Actavis plc | (NYSE: ACT) | Novartis AG | (NYSE: NVS) |
| Bayer AG | (OTC: BAYRY) | Pfizer | (NYSE: PFE) |
| Eli Lilly | (NYSE: LLY) | Takeda Pharmaceutical | (OTC: TKPHF) |
| Mylan Laboratories | (NYSE: MYL) | Teva Pharmaceutical | (NYSE: TEVA) |

## Meaning of Ratings

**Buy** – The growth prospects, degree of investment risk, and valuation make the stock attractive relative to the general market or comparable stocks.

**Speculative Buy** – Long term prospects of the company are promising but investment risk is significantly higher than it is in our BUY-rated stocks. Risk-reward considerations justify purchase mainly by high risk-tolerant accounts. In the short run, the stock may be subject to high volatility and could continue to trade at a discount to its market.

**Neutral** – Based on our outlook the stock is adequately valued. If investment risks are within acceptable parameters, this equity could remain a holding if already owned.

**Sell** – Based on our outlook the stock is significantly overvalued. A weak company or sector outlook and a high degree of investment risk make it likely that the stock will underperform relative to the general market.

**Dropping Coverage** – Research coverage discontinued due to the acquisition of the company, termination of research services, non-payment for such services, diminished investor interest, or departure of the analyst.

**Some notable Risks within the Microcap Market**

**Stocks in the Microcap segment of the market have many risks that are not as prevalent in Large-cap, Blue Chips or even Small-cap stocks. Often it is these risks that cause Microcap stocks to trade at discounts to their peers. The most common of these risks is liquidity risk, which is typically caused by small trading floats and very low trading volume which can lead to large spreads and high volatility in stock price. In addition, Microcaps tend to have significant company specific risks that contribute to lower valuations. Investors need to be aware of the higher probability of financial default and higher degree of financial distress inherent in the microcap segment of the market.**

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From time to time our analysts may choose to withhold or suspend a rating on a company. We continue to publish informational reports on such companies; however, they have no ratings or price targets. In general, we will not rate any company that has too much business or financial uncertainty for our analysts to form an investment conclusion, or that is currently in the process of being acquired.