



**Pivot Pharmaceuticals Inc.**  
**(OTCQB: PVOTF) Target Price: \$2.10**

We initiate coverage on Pivot Pharmaceuticals (OTCQB: PVOTF, "Pivot") with a price target of \$2.10 per share. With offices in Woburn, MA, and Vancouver, BC, Pivot is a late pre-clinical biotechnology company focused on developing novel therapeutics for unmet needs in women's health. We see the women's health market as having massive potential for Pivot. Despite the fact that women's health therapeutics is a large opportunity – expected to reach \$22.5 billion in 2018E – we believe women's health issues have received comparatively little attention beyond the areas of reproductive health and fertility. This should leave significant room for focused companies such as Pivot to emerge as key players in the space. With a compelling late pre-clinical pipeline focused on the treatment of women's cancer and gynecological disturbances and an experienced management team led by Boston biotech industry veteran CEO Dr. Pravin Chaturvedi, Pivot appears well-positioned to make its mark in women's health over the next many years. We see several potential catalysts ahead for the company as it advances its anticancer drugs toward clinical trials, pursues an acquisition and/or licensing of a late-stage asset, and explores a listing on the NASDAQ exchange.

**INVESTMENT HIGHLIGHTS**

**Novel portfolio targeting genetically resistant women's cancers**

Pivot is initially focused on advancing a novel portfolio of anti-cancer drug candidates (PBDs) that address significant women's cancer markets. PBDs, or (pyrrolobenzodiazepine dimers) are DNA damage response (DDR) inhibitors that can treat "genetically resistant" women's cancers, such as metastatic endometrial cancer (mEC) and basal-like triple-negative breast cancer (BL-TNBC). Pivot has indicated that its first two PBD candidates, PVT-005 and PVT-006, have shown promising data in preclinical studies for the treatment of mEC and BL-TNBC. These are orphan indications, which represent a collective market opportunity of approximately \$500mn per year, according to Pivot management. The company plans to initiate a Phase 1/2 clinical trial this year, pending funding, to evaluate safety for at least one of these candidates. In line with goals set out by management, we have assumed commercialization of PVT-005 by FY22E and PVT-006 by FY23. Importantly, Pivot should be able to benefit from better economics inherent in developing drug candidates for orphan indications, as they carry exclusivity for seven years following FDA marketing approval. Beyond these initial candidates, Pivot sees the potential for candidates targeting Non-small cell lung cancer (NSCLC), Refractory Acute Myelogenous Leukemia (AML) and Metastatic Colorectal Cancer (mCRC), among others.

**Top notch leadership team**

We see Pivot's leadership team as a key positive attribute and note that management is a critical factor in early-stage pharmaceutical companies, given the given the cost and multi-year timeline required to achieve regulatory clearance and bring drug candidates to market. The company is led by Dr. Pravin Chaturvedi is a well-known figure in the Boston biotechnology scene who previously founded and served as CEO of Scion Pharmaceuticals, which was acquired by Wyeth in 2005. Dr. Chaturvedi brings more than 25 years of industry experience to Pivot, spearheading a leadership team which, collectively, has developed and/or commercialized 12 drugs representing global sales of over \$10 billion. Pivot continues to add to its leadership team, with the recent appointments of Steven Grossman, MD, PhD and Grannum Sant, MD, FRCS, FACS to its Scientific Advisory Board.

**Initiate coverage with a price target of \$2.10**

In our view Pivot represents an intriguing risk / reward tradeoff in the microcap biotech space. The company has a strong management team and several potential clinical and corporate catalysts ahead as it seeks to emerge as a leader in the multibillion-dollar women's health market.

**Stock Details 3/31/2016**

OTCQB:	PVOTF
Sector / Industry	Healthcare / Biotechnology
<b>Price target</b>	<b>\$2.10</b>
Recent share price	\$0.55
Basic Shares o/s (Bn)	74.7
Fully Diluted Shares	80.7
F Diluted Mkt cap (in \$mn)	44.4
52-week high/low	\$1.25 / \$0.01

Source: Bloomberg, SeeThruEquity Research

**Key Financials (\$mn unless specified)**

	FY16E	FY17E	FY18E
Revenues	0.0	0.0	5.0
EBITDA	(4.9)	(5.0)	(2.0)
EBIT	(4.9)	(5.0)	(2.0)
Net income	(4.9)	(5.0)	(2.0)
EPS (\$)	(0.06)	(0.06)	(0.02)

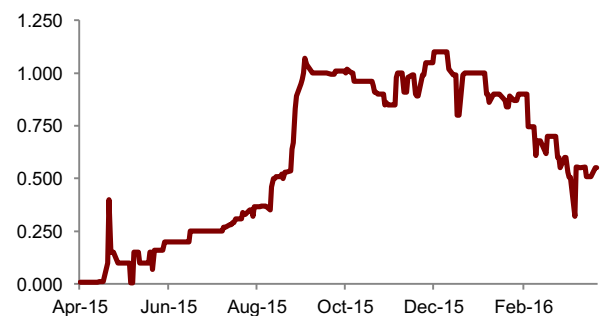
Source: SeeThruEquity Research; estimates in \$ unless noted, FY January

**Key Ratios**

	FY16E	FY17E	FY18E
Gross margin (%)	NM	NM	NM
Operating margin (%)	NM	NM	NM
Net margin (%)	NM	NM	NM
P/Revenue (x)	NM	NM	8.9
EV/EBITDA (x)	NM	NM	NM
EV/Revenue (x)	NM	NM	8.8

Source: SeeThruEquity Research

**Share Price Performance (\$, LTM)**



Source: Bloomberg

## SUMMARY TABLE

**Figure 1. Summary Table (As of March 31, 2016)**

Share data		B/S data (As of fiscal 3Q16)		Key personnel:	
Recent price:	\$0.55	Total assets:	0.2mn	CEO	Pravin Chaturvedi, PhD
Price target:	\$2.10	Total debt:	0.0mn	Chairman	Ahmad Doroudian, PhD
52-week range:	1.25 / 0.01	Equity:	0.1mn	Director	Wolfgang Renz, MD, PhD
Average volume:*	3,879	W/C:	0.1mn	Director	Patrick Frankham, PhD, MBA
Market cap:	\$44.4mn	ROE:	-63%	CFO	Moira Ong, CPA, CA, CFA
Book value/share:	\$0.00	ROA:	-19%	Scientific Advisory Board, Chair	Steven Grossman, MD, FRCS
Cash/share	\$0.00	Current ratio:	1.5		
Dividend yield:	0.00%	Asset turnover:	N/A		
Risk profile:	High / Speculative	Debt/Cap:	0.0%		

\* three month average volume (number of shares) , all figures in \$ unless noted

FYE Jan	Estimates				Valuation	
	Rev (\$mn)	EBITDA (\$mn)	EPS (\$)	P/Rev (x)	EV/Rev (x)	P/E (x)
2016E	0.0	(4.9)	(0.06)	NM	NM	NM
2017E	0.0	(5.0)	(0.06)	NM	NM	NM
2018E	5.0	(2.0)	(0.02)	8.9x	8.8x	NM
2019E	5.0	(3.0)	(0.03)	8.9x	8.8x	NM
2020E	5.5	(3.0)	(0.03)	8.1x	8.1x	NM

Source: SeeThruEquity Research, company filings

## INVESTMENT THESIS

We initiate coverage on Pivot Pharmaceuticals (OTCQB: PVOTF, "Pivot") with a price target of \$2.10 per share. With offices in Woburn, MA, and Vancouver, BC, Pivot is a late pre-clinical biotechnology company focused on developing novel therapeutics for unmet needs in women's health. We see women's health as having massive potential for Pivot. Despite the fact that women's health therapeutics is a large market – expected to reach \$22.5 billion in 2018E – we believe women's health issues have received comparatively little attention beyond the areas of reproductive health and fertility, which leaves significant room for focused companies such as Pivot to emerge as key players in the space. With a compelling late pre-clinical pipeline focused on the treatment of women's cancer and gynecological disturbances and an experienced management team led by Boston biotech industry veteran CEO Dr. Pravin Chaturvedi, Pivot appears well-positioned to make its mark in women's health over the next many years. We see several potential catalysts ahead for the company as it advances its anticancer drugs toward clinical trials, pursues an acquisition and/or licensing of a late-stage asset, and explores a listing on the NASDAQ exchange.



**Pivot targeting large underserved women’s health market**

Pivot is a late pre-clinical biotechnology company focused on developing novel therapeutics for unmet needs in women’s health. Through the recent acquisition of IndUS Pharmaceuticals, Pivot is initially focused on advancing its portfolio of anti-cancer drug candidates (PBDs), which address significant women’s cancer markets. PBDs, or (pyrrolobenzodiazepine dimers) are DNA damage response (DDR) inhibitors that can treat “genetically resistant” women’s cancers. Pivot management has indicated that the PBD candidates have shown promising data in preclinical studies for the treatment of refractory cancer. Initially, we expect Pivot to focus on developing two drug candidates from its portfolio of anticancer molecules, PVT-005 and PVT-006, targeting metastatic endometrial cancer (mEC) and basal-like triple-negative breast cancer (BL-TNBC). The company estimates the market opportunity for these two candidates to be approximately \$500mn per year.

Both mEC and BL-TNBC present poor prognosis and treatment options for a smaller group of patients. While surgical interventions may help address cancers that can be physically accessed, these surgeries, followed by adjuvant chemotherapy, represent only partial treatment options for refractory and metastatic disease in mECs and BL-TNBCs following initial treatments. Pivot’s anticancer drug candidates, however, offer an opportunity to develop targeted treatment for refractory patients that have recurrent metastatic disease or DNA repair deficiencies. The company’s anticancer molecules promote apoptosis in tumor cells that have loss of specific tumor suppression functions. Importantly this suggests that Pivot’s candidates can be synergistic with current standard-of-care (SOC) chemotherapeutic patient regimens.

Given the relatively small number of patients affected in the US – 40,000 BL-TNBC and 50,000 mEC with recurrent metastatic disease – these represent orphan drug opportunities for Pivot. Pivot should benefit from initially targeting orphan indications given that they carry a longer period of exclusivity – seven years versus five years – following marketing approval of the drugs. The company also stated in a letter to shareholders that it would likely also advance another candidate (PVT-007) in the near future to broaden the portfolio. We expect Pivot to initiate clinical trials in the next twelve months for PVT-005 or PVT-006, for patients that have failed cancer chemotherapy treatments to establish the safety of adding their drugs into the combination chemotherapy first, followed by trials evaluating clinical effectiveness.

**Figure 3. Lead candidates and anticancer pipeline**

Therapeutic Area	Indication	Product	IP Protection	Phase II a/b	Est. Registration / Licensing
Women’s Cancers that Represent High Unmet Medical Needs due to Genomic Mutations	Metastatic Endometrial Cancer	PVT-005	Composition of Matter & Methods Patents		
			2017-2018		2021
	Triple-Negative Breast Cancer	PVT-006	Composition of Matter & Methods Patents		
			2018-2019		2022

Source: SeeThruEquity Research, company filings

**Looking forward to progress in 2016 after a transformational 2015**

Pivot enters calendar 2016 following many achievements at the corporate in the last year. During 2015 the company expanded its leadership team and advisory board, listed shares on the OTCQB exchange, and completed the acquisition of Boston, MA-based IndUS Pharmaceuticals – a transformative move which strengthened the company’s pipeline and brought the company key intellectual property, as well as experienced leadership in the person of CEO Dr.Pravin Chaturvedi. Looking ahead to the next twelve months we see several potential catalysts for Pivot on both the corporate and clinical fronts. On the

corporate front, we expect Pivot to continue to expand its executive team evaluate potential acquisitions and in-licensing opportunities, and complete fundraising to support at least one Phase I/Phase II clinical trial. Management has also stated its intention to pursue an up-listing to the NASDAQ, a goal we expect the company to pursue in conjunction with a larger financing and possibly an acquisition of a late stage candidate, which would both fund short term clinical goals and allow Pivot to meet shareholder's equity and minimum bid requirements. If the company is successful in listing its shares on the NASDAQ, we would see this move as a key accomplishment by management and a positive catalyst for the company, given that Pivot would likely have greater liquidity and access to potential institutional market participants restricted from investing in the OTC markets.

Assuming the company is successful in its fundraising efforts – we believe Pivot is likely to require \$7mn-\$10mn in new capital to fund operations and clinical development initiatives in 2016– we see several potential catalysts within reach on the clinical front as well. First, and most importantly, we expect the company to advance its anti-cancer drug pipeline, anchored by lead candidates PVT-005 for mEC and PVT-006 for BL-TNBC. Pivot management stated that it expects to conduct additional pre-clinical studies, which will evaluate safety and clinical efficacy of one or both of PVT-005 and PVT-006, to support the filing of an Investigational New Drug (IND). We also expect the company to make continued efforts to expand its portfolio in women's health with new assets which would potentially have a shorter time to market via a 505b(2) pathway, such as drug delivery technologies for urological and gynecological disorders. We expect to learn more about these efforts throughout 2016.

#### **Merger with IndUS gives Pivot access to promising IP and global research footprint**

While the transaction may appear small considering the purchase price of 4.8mn Pivot shares, the acquisition of IndUS Pharmaceuticals seems to be a significant step for Pivot. The acquisition, which was consummated on November 23, 2015, provided Pivot with access to an impressive IP portfolio including patents and composition of matter supporting its promising anticancer pipeline – including PVT-005 and PVT-006. The merger also expands the company's presence in several key markets, including biotech hub Boston and India, proving the company with a truly global presence of Canada, the United States and India. We are intrigued by the further possibilities from the IP resources and research and development advantages that come with IndUS's access to India via its partnership with the Indian Institute of Chemical Technology (IICT), a Council of Scientific and Industrial Research (CSIR) institution. This is a key partnership in which IndUS has an its option for worldwide rights to small molecules and other IP from CSIR including PBDs, as well as access to exclusive additional leads from screening efforts at IICT, and potentially enabling the ability to conduct simultaneous clinical trials in India and the US for Pivots anti-cancer drugs.

#### **Combined company has top notch leadership and respected scientific advisors**

Most importantly, though, is that former IndUS CEO Dr. Pravin Chaturvedi agreed to come on board to run the combined company. In our view, a strong leadership team is a key attribute to look for in evaluating companies in the biotechnology industry – particularly among small / microcap late pre-clinical stage companies, such as Pivot, where success in prior industry experience is valuable given the cost and multi-year timeline required to achieve regulatory clearance and bring drug candidates to market. Dr. Chaturvedi is a well-known figure in the Boston biotechnology scene who previously founded and served as CEO of Scion Pharmaceuticals, which was acquired by Wyeth in 2005. Dr. Chaturvedi brings more than 25 years of industry experience to Pivot, including serving as founder if IndUS Pharmaceuticals, co-founder of Oceanyx Pharmaceuticals, as well as holding key roles at Vertex Pharmaceuticals (VRTX), and working in the preclinical group at Alkermes (ALKS) and product development for Parke-Davis/Warner-Lambert Co., (now Pfizer). Dr. Chaturvedi joins existing members of Pivot Pharmaceuticals' management team including Chairman Ahmad Doroudian, PhD, who founded Merus Labs (NASDAQ: MSLI), and CFO Moira Ong, an experienced financial executive who has served as CFO of both NASDAQ and TSX-listed companies in the past. Indeed, we see Pivot as having attractive leadership, and note that collectively the company's management team has developed and/or commercialized 12 drugs representing global sales of over \$10 billion.

Pivot has continued to expand its scientific advisory board, with two recent appointments including Steven Grossman, MD, PhD, a leading physician-scientist with an established interest in the response of tumor cells to DNA damage to improve therapeutic benefit in cancer patients, and Grannum Sant, MD, FRCS, FACS, a leading key opinion leader in the fields of urology and oncology in men's and women's health. Full biographies of Pivot's team are included later in this report on pages 14-15.

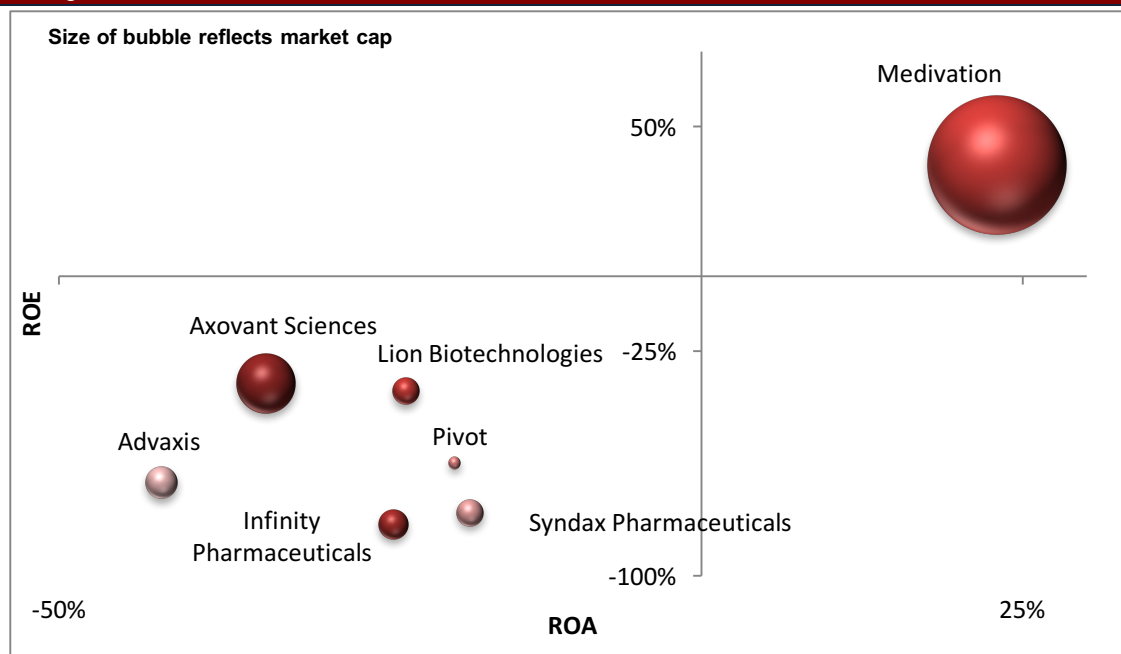
## COMPETITIVE LANDSCAPE

Pivot is an emerging biotechnology company focused on the developing therapeutics for unmet needs in women’s health. We see the market for unmet needs in women’s health as large and growing – especially considering that health issues specific to women – outside of reproductive health and fertility issues – have received comparatively less attention and funding than men’s health issues. This represents an opportunity for a focused company such as Pivot to capture share and achieve differentiation in a large market. Indeed, the global market for women’s health therapeutics was valued at approximately \$18.3 billion in 2012 and is expected to approach \$22.5 billion in 2018, representing a compound annual growth rate (CAGR) of 3.5%.

Pivot is initially focused on bringing to market an intriguing portfolio of drug candidates targeting women’s cancers that represent high unmet needs due to genomic mutations. The company will initially target orphan disease indications Triple Negative Breast Cancer (TNBC) in patients with DNA repair deficiencies and Metastatic Endometrial Cancer (mEC) in patients with recurrent metastatic disease. Collectively, these indications represent an opportunity to treat 90,000 patients per year, or \$450mn in potential annual sales. In our view the company’s choice to initially target orphan diseases is a strategic move, which should reduce competition and allow the company to benefit from a longer period of exclusivity (7-year) compared to the standard 5-year exclusivity in the US. Longer term, if it is successful in these orphan indications, we would expect Pivot to develop candidates to treat more common indications in women’s cancer, with the potential to target much larger market segments. Cancer treatment represents a massive end market, with worldwide oncology product sales expected to rise to \$114.4 billion by 2018E from \$68 billion in 2012, representing a 9% CAGR.

Given the size of the oncology and women’s health markets, expect Pivot will compete with both other companies focused on women’s health as well as large biotechnology companies. The biotechnology industry is characterized by many small market participants developing potential new therapeutics, as well as several large global corporations, which have significant resources to grow by internal development and licensing deals / acquisitions. A key challenge for any emerging company in the biotechnology sector, including Pivot, is competing against the industry’s largest players, which have substantial financial resources, established distribution, and more experience bringing new drugs to market. In the following graphic we examined size and profitability metrics for a group of peer companies of Pivot. As illustrated in the following chart, there is a range of profitability levels among Pivot’s peers, with early-stage companies experiencing negative margins and more mature companies achieving attractive returns.

Figure 2. ROA vs. ROA– PIVOT Peers



Source: Thompson Financial, Company filings, SeeThruEquity Research

## FINANCIALS AND FUTURE OUTLOOK

### Key Assumptions

Pivot is a development stage company, which does not yet generate revenues and will be unable to generate revenues from therapeutic candidates in its clinical portfolio until they receive regulatory clearance. This can be a costly and time consuming process, which carries a degree of uncertainty. Our model assumes that Pivot is able to commercialize its initial two drug candidates, PVT-005 for mEC and PVT-006 for BL-TNBC, by FY22E and FY22E, respectively. We also assumed that the company is able to raise sufficient funding as needed to bring these products to market, with funds coming from both new equity issuances and potential license payments as Pivot seeks to engage in strategic relationships for its novel delivery technologies. Importantly, management has indicated that it is seeking to find an acquisition or license opportunity for a late stage asset, which could potentially be monetized earlier and partially fund development of its anticancer drug pipeline. We would look to update our forecast if and when such a deal is finalized. As part of our assumptions, we considered facts including: 1) Pivot's management team is experienced in bringing new drugs to market; 2) its lead candidates have shown sufficient safety data in prior trials for other indications, and 3) support for new drugs for orphan indications exists at the FDA as evidenced by longer periods of exclusivity and somewhat faster times to market. Taking all of these factors into account we applied a 40% probability factor to our forecast for Pivot in conducting our valuation and determining the price target for the company.

### Product development / Revenue forecast

**Anticancer Pipeline.** The core driver of our forecast is the development of Pivot's novel anticancer drugs, PVT-005 for mEC and PVT-006 for BL-TNBC, which utilize pyrrolobenzodiazepine dimers (PBDs) to treat genetically resistant women's cancers. In line with comments made by management, we have assumed these drugs are able to reach commercialization by 2021E and 2022E, respectively. The company has estimated the potential market size for PVT-005 for treating mEC patients with recurring metastatic disease is approximately 50,000 patients per year, representing potential annual sales of \$250mn. We have assumed initial product revenues of \$7.7mn in 2021E, growing rapidly thereafter given that the standard of care for this orphan condition is not effective, with sales approaching \$50mn by 2025E. For TNBC, we have assumed that Pivot begins commercial activities for PVT-006 in 2022E, with sales reaching \$33.9mn by 2025E and continuing to grow thereafter, as outlined in the following table. Given that the standard of care is not effective for these conditions, our forecast may prove to be conservative if Pivot is able to commercialize according to this timeline and market effectively.

Figure 4. Key assumptions for Pivot's initial anti-cancer initial candidates

Candidate	Indication	2016	FY22E	FY23E	FY24E	FY25E	FY26E
PVT-005	mEC	Phase 1/2	\$7.7	\$12.7	\$24.7	\$37.6	\$49.5
	Market Share	0%	2.5%	4.0%	7.5%	11.0%	14.0%
PVT-006	BL-TNBC	Pre-clinical	FDA	\$7.6	\$13.2	\$21.9	\$33.9
	Market Share	0%	0.0%	3.0%	5.0%	8.0%	12.0%

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Source: Company filings, SeeThruEquity Research

Pivot has indicated that its portfolio of anticancer drugs will also target much larger indications, such as Non-small Cell Lung Cancer (NSCLC), Refractory Acute Myelogenous Leukemia (AML), and Metastatic Colorectal Cancer (mCRC), which could set the stage for continued future growth. To be conservative, however, we have not included these indications in our forecast at this time.

**Drug Delivery technologies.** Pivot is also seeking to create value from its lineup of novel drug delivery technologies for the women's health market, which include PVT-001, PVT-002, PVT-003, and PVT-004. The company is pursuing a 505(b)2 regulatory pathway for these technologies, which should speed time to market for Pivot by reducing the amount of new safety and efficacy information required for active

ingredients which have already been approved for use for another indication. Pivot has identified four key areas of focus for its drug delivery technologies, as illustrated below, representing over \$1.1 billion in potential annual sales.

**Figure 5. Delivery Technologies Opportunity Summary**

Indication	Dysmenorrhea	LUTS	Kidney Stones	Menopausal Symptoms
<b>Market Potential (US annual sales)</b>	<b>\$460mn</b>	<b>\$300mn</b>	<b>\$300mn</b>	<b>\$100mn</b>

*Source: Company filings, SeeThruEquity Research*

While we believe the company could carry these candidates through to commercialization, which could occur as soon as 2019E, we have assumed Pivot seeks a licensing partner to share the cost of bringing these to market. We have modeled \$20mn in licensing fees as revenue and a non-dilutive source of funding for Pivot from FY17-FY20, plus a modest royalty stream and assumption for partner sales throughout our model. Our model assumes total royalties from these lines growing from \$0.5mn in FY20E to surpass \$10mn by FY28E. We note that while smaller in size, royalties carry high gross margins near 100%.

#### Profitability / Margins

Given that Pivot does not generate revenues at this time, we have forecast operating losses for the foreseeable future and expect the company will invest available capital to advance its clinical development. We have assumed the company can achieve robust profits once its products are commercialized, with EBITDA margins rising from 20% in FY24E to the mid-30% range at the end of our forecast in FY28E. We modeled FY16E EPS of (\$0.06) and FY17 EPS of (\$0.06).

#### Balance Sheet & Financial Liquidity

We see the balance sheet and financial liquidity as key areas to understand for Pivot. At the end of the company's fiscal 3Q16E (ended October 31, 2015), Pivot had cash on hand of \$0.19mn and current assets of \$0.21mn, versus total liabilities of \$0.14mn. IndUS reported current assets of 0.14mn and current liabilities of 1.4mn at the end of calendar 3Q15, though we believe approximately 1.0mn of the current liabilities converted to equity during the merger. Pivot has a going concern qualification in its financial statements. Indeed, Pivot is a late pre-clinical biotechnology company, and will require significant additional funding to support ongoing operations and to advance its clinical portfolio towards regulatory clearance – a process that is uncertain, time-consuming and costly. Therefore, the company will need to raise fresh capital to fund its initiatives, either by issuing new equity / debt, grant funding, or through strategic partnership agreements that include upfront license payments. The company also hopes to up-list to the NASDAQ Capital Markets, which will likely include the issuance of equity in order to meet shareholder's equity minimum requirements.

Readers of this analysis should understand that Pivot is not likely to have revenue or positive cash flow for several years, unless it strikes a licensing deal with a strategic partner that includes upfront payments to assist with development of one or more of its candidates. Considering this, if the company is unable to raise new capital to fund its development pipeline on palatable terms, holders of common equity could face risks such as dilution or insolvency. This risk is not uncommon for a microcap, pre-clinical stage biotechnology company, as management may feel that the company could raise new capital at a more attractive valuation in the future, with clinical data in hand, but it should be noted.

#### Estimated financing needs

Our analysis assumes that Pivot will raise \$7mn in new capital during the next twelve months to support operations, pre-clinical studies evaluating safety and efficacy, filing an IND application and the initiation of at least one clinical trial. We believe the first of the company's potential products could come to market in

2019E, by way of a 505b(2) pathway, but expect continued cash needs through 2021E related to its core oncology pipeline. In its presentation at *SeeThruEquity's Innovations* Investor Conference in February, Pivot's management team estimated that the company would need approximately \$30mn in new capital to support operations and its clinical program through the end of 2019E, as outlined in the following table.

Task	2016				2017				2018				2019				Budget
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Licenses	[Bar]				[Bar]												\$1,500,000
IP Program	[Bar]				[Bar]				[Bar]				[Bar]				\$1,000,000
CMC / API	[Bar]				[Bar]				[Bar]				[Bar]				\$2,500,000
Preclinical R&D	[Bar]				[Bar]				[Bar]				[Bar]				\$3,000,000
Regulatory	[Bar]				[Bar]				[Bar]				[Bar]				\$750,000
Clinical	[Bar]				[Bar]				[Bar]				[Bar]				\$14,000,000
Corporate & Mgmt	[Bar]				[Bar]				[Bar]				[Bar]				\$5,000,000
Business Development	[Bar]				[Bar]				[Bar]				[Bar]				\$3,000,000
<b>TOTAL</b>																	<b>\$30,750,000</b>

Source: Thompson Financial, Company filings, SeeThruEquity Research



## VALUATION

We utilize a discounted cash flow (DCF) analysis to determine our valuation and price target for Pivot. We have also included a peer group analysis for informative purposes; however, given that Pivot is a development stage company, which has not yet achieved FDA clearance for its products, we felt that a DCF valuation would be a more appropriate measure for the company. Using this methodology, we calculated a price target of \$2.10 per share. We note that Pivot will require new capital to meet its objectives. Our analysis assumes that the company raises \$7mn over the next 12 months to fund its operations and clinical programs. In aggregate, we have assumed the company raises \$35mn in new capital through 2020E, with \$15mn stemming from new equity offerings and \$20mn resulting from licensing agreements, as outlined earlier in the Financial Outlook portion of this report. If the company is unable to accomplish this, or if the dilutive impact of the capital raise is greater than we expect, or if Pivot fails to achieve regulatory clearance in the time we expect, then the results of the valuation exercise will be impacted.

### DCF

The DCF analysis assumes that Pivot is able to commercialize PVT-005 for mEC and PVT-006 for Triple Negative Breast Cancer in 2021E and 2022E, respectively. This is the primary driver of our model, and we have assumed that these two product lines generate \$164mn of revenue in 2027E, in aggregate, which would represent a market share of 23% and 25% respectively, for TNBP and mEC in 2027E. We have also assumed that the company is able to form partnerships to monetize its novel delivery technology in four indications, as outlined earlier in this report, so that these technologies contribute as a source of capital earlier in our forecast, with a conservative royalty rate thereafter.

We discounted cash flows at a weighted average cost of capital of 15% and assumed a terminal growth rate of 5.0% at the end of FY28E. We also applied a probability factor of 40% to reflect the fact that Pivot is a late pre-clinical stage company. We then arrived at an enterprise value of \$169.6mn and adjusted by the company's cash and debt at the end of FY3Q16, to arrive at a fair value of \$2.10 per share, as outlined below.

Figure 5. Discounted Cash Flow Analysis

\$000	FY17E	FY18E	FY19E	FY20E	FY21E	FY22E	FY23E	FY24E	FY25E	FY26E	FY27E	FY28E
mEC	Pre-clinical	Phase 1/2	Phase 1/2	Phase 2	Phase 3	FDA	Comm.	Comm.	Comm.	Comm.	Comm.	Comm.
Triple Negative Breast Cancer	Pre-clinical	Phase 1/2	Phase 1/2	Phase 2	Phase 3	FDA	Comm.	Comm.	Comm.	Comm.	Comm.	Comm.
Delivery technologies	Development	Partner	Partner	Partner	Clearance	Comm.	Comm.	Comm.	Comm.	Comm.	Comm.	Comm.
EBIT	(5,019)	(2,046)	(3,075)	(3,147)	(5,327)	(4,112)	(1,208)	7,775	16,725	26,886	41,741	63,537
Less: Tax	0	0	0	0	0	0	0	0	669	3,226	10,435	22,238
<b>NOPLAT</b>	<b>(5,019)</b>	<b>(2,046)</b>	<b>(3,075)</b>	<b>(3,147)</b>	<b>(5,327)</b>	<b>(4,112)</b>	<b>(1,208)</b>	<b>7,775</b>	<b>16,056</b>	<b>23,659</b>	<b>31,306</b>	<b>41,299</b>
Changes in working capital	(191)	(711)	(399)	(357)	952	955	(37)	(2,780)	(5,168)	(1,643)	(231)	486
Depreciation & Amortization	19	46	75	125	214	331	490	707	945	1,179	1,415	1,656
Capex	(102)	(143)	(200)	(340)	(600)	(840)	(1,176)	(1,646)	(1,976)	(2,193)	(2,434)	(2,702)
<b>FCFF</b>	<b>(5,293)</b>	<b>(2,854)</b>	<b>(3,599)</b>	<b>(3,719)</b>	<b>(4,761)</b>	<b>(3,665)</b>	<b>(1,931)</b>	<b>4,056</b>	<b>9,857</b>	<b>21,002</b>	<b>30,055</b>	<b>40,739</b>
Probability Factor	0.40	0.40	0.40	0.40	0.40	0.40	0.40	0.40	0.40	0.40	0.40	0.40
Dilution Factor	1.00	0.90	0.87	0.87	0.87	0.86	0.86	0.86	0.85	0.85	0.84	0.84
PV of FCFE	(2,117)	(1,032)	(1,250)	(1,292)	(1,654)	(1,267)	(664)	1,388	3,357	7,118	10,135	13,669
Sum of PV of FCFE										26,390		26,390
Terminal cash flow												426,917
PV: Terminal cash flow												143,243
<b>Enterprise value</b>												<b>169,633</b>
Less: Debt												0
Add: Cash												187
<b>Equity value</b>												<b>169,819</b>
Diluted shares (mn)												80,722.0

Fair value per share (\$)

2.10

Summary conclusions	Key assumptions		
DCF FV (\$ per share)	2.10	Beta	1.9
Recent price (\$ per share)	0.55	Cost of equity	15.0%
Upside (downside)	282.5%	Cost of debt (post tax)	10.2%
WACC	15.0%	Terminal Growth Rate	5.0%

Source: SeeThruEquity Research

Figure 6. Sensitivity of Valuation – WACC vs. Terminal Growth Rate

		WACC (%)				
		14.0%	14.5%	15.0%	15.5%	16.0%
Terminal growth rate (%)	4.00%	2.09	2.00	1.93	1.86	1.79
	4.50%	2.19	2.10	2.01	1.94	1.87
	5.00%	2.30	2.20	<b>2.10</b>	2.02	1.94
	5.50%	2.43	2.31	2.21	2.11	2.03
	6.00%	2.57	2.44	2.32	2.21	2.12
	6.50%	2.73	2.58	2.45	2.33	2.22

Source: SeeThruEquity Research

**Peer Group Analysis**

In addition to the DCF valuation methodology outlined on prior pages, we examined the valuations of similar companies in the industry. However, given that Pivot is an early stage company and that with no revenues expected until at least 2020E, we did not use the comparable group multiples to calculate the price target. We examined publicly traded peer companies, as detailed in Figure 7 below, with a focus on women's health and cancer treatment spanning both clinical stage companies and early commercial stage companies.

Our comparable companies list includes small capitalization peers targeting women's health such as Syndax Pharmaceuticals (SNDX), Galena Biopharma (GALE) and Oncothyreon (ONTY), among others. We also considered late clinical peers Axovant Sciences (AXON), women's health-focused Therapeutics MD (TXMD), Massachusetts-based Infinity Pharmaceuticals (INFI) and Lion Biotechnologies (LION), an early stage peer with a pipeline targeting cervical and neck cancer. As illustrated below, there are a range of market valuations, which we believe is driven by company-specific factors including those specific to the clinical development pipeline at each peer, as well as their potential opportunity. The average EV/Sales and P/Sales multiples in the peer group are 18.7x and 22.9x, respectively, excluding Advaxis and Syndax, whose multiples would otherwise skew the average.

**Figure 7. Peer Company Valuation Analysis (Data as of 3/29/16)**

Company	Mkt cap (\$ mn)	EV / Revenue		Price / Revenue (x)	
		TY	NY	TY	NY
Axovant Sciences	1,142	NM	NM	NM	NM
TherapeuticsMD	1,259	49.6x	16.1x	52.5x	17.0x
Infinity Pharmaceuticals	277	0.1x	0.2x	1.2x	2.1x
Lion Biotechnologies	235	NM	NM	NM	NM
Medivation	6,363	NM	NM	NM	NM
Viveve Medical	48	22.2x	8.0x	26.6x	9.6x
Syndax Pharmaceuticals	231	875.0x	875.0x	1,155.0x	1,155.0x
Advaxis	335	1,460.0x	56.2x	2,234.7x	85.9x
Aeterna Zentaris Inc.	22	NM	NM	35.6x	15.2x
Juniper Pharmaceuticals	76	1.5x	1.3x	1.8x	1.6x
Galena Biopharma	221	NM	57.2x	NM	88.4x
Myriad Genetics	2,650	3.2x	3.0x	3.5x	3.3x
Acceleron Pharma	1,020	35.4x	19.6x	39.2x	21.7x
Ignyta	210	NM	NM	NM	NM
<b>Average (Excludes Advaxis, Syndax)</b>		<b>18.7x</b>	<b>15.1x</b>	<b>23.0x</b>	<b>19.9x</b>
Pivot	44	NM	NM	NM	NM
Premium (discount)		NM	NM	NM	NM

Source: Bloomberg, SeeThruEquity Research; all data in \$ million except per share data

## RISK CONSIDERATIONS

### Financial Resources / Liquidity

We see both the balance sheet and financial liquidity as key risks for Pivot. The company has a going concern qualification from its auditor, and this analysis has assumed the company is able to raise fresh capital in order to fund ongoing operations and clinical development. At the end of the company's fiscal 3Q16E (ended October 31, 2015), Pivot had cash on hand of \$0.19mn and current assets of \$0.21mn, versus total liabilities of \$0.14mn. We do not foresee a major change to this from the acquisition of IndUS. We note that as of September 30, 2015, IndUS had current assets of 0.15mn and current liabilities of \$1.27mn – including \$0.8mn of convertible debt, which we assume was converted during the merger.

Pivot is a late pre-clinical biotechnology company, and will require significant additional funding to support ongoing operations and to advance its clinical portfolio. The company is not likely to have positive cash flow for several years, and will be unable to generate revenue from its portfolio without regulatory clearance – a process that can be time-consuming and costly. Therefore, the company will need to raise fresh capital to fund its initiatives, either by issuing equity or debt, grant funding, or through strategic partnership agreements that include upfront license payments. Our analysis assumes that Pivot will raise \$7mn in new capital during the next twelve months to support operations, pre-clinical studies evaluating safety and efficacy, filing an IND application and the initiation of at least one clinical trial. Pivot management estimated that the company would need approximately \$30mn in new capital to support operations and its clinical program through the end of 2019E.

### Competition

Although women's health needs have been comparatively underserved by the healthcare industry, particularly for issues beyond reproductive health and fertility, the market for developing new therapeutic treatments for women's health, in general, and cancer, in particular, is large and highly competitive. The biopharmaceutical industry is characterized by several large, established companies, which have access to greater financial resources, more established product distribution, more experience in securing regulatory clearance for new products, and more extensive research facilities as they develop treatments for women's health issues. Pivot faces competition from these large companies as well as many smaller companies seeking to develop new therapeutic treatments for unmet needs in women's health.

### Dilution potential

As mentioned above, we expect Pivot to raise new capital to fund its operation and clinical pipeline. While we expect the company could gain access to non-dilutive funding from research grants, licensing agreements, or strategic partnerships, we do see a risk of dilution for holders of common equity, as the company will likely need to issue new equity during 2016 and also in the 2017-2019 time period. Specifically there is risk that shareholders may experience dilution from the issuance of common equity, convertible preferred equity, options, convertible debt, and warrants, among others.

### Regulation Risk

Pivot operates in a highly regulated market. In the United States, Pivot is regulated by the FDA, and its products can not be sold without clearance by the FDA. This is a process that involves considerable money and time, due to requirements for clinical studies demonstrating the need, efficacy and safety of the candidates. It is worth noting that most countries have their own unique regulators over medical products, and therefore regulatory clearance in one area does not necessarily guarantee clearance in countries governed by different regulatory bodies.

### Pre-clinical stage company

Pivot is a late pre-clinical stage biotechnology company, which does not generate revenues and does not have products available for commercial use. The company's planned products target large markets, and Pivot's management team is optimistic about its prospects of its pipeline, but it is important to acknowledge that the company must conduct costly and time-consuming clinical studies in order to demonstrate the effectiveness and safety of its clinical candidates before they can be cleared for commercial use in the United States by the FDA. It is important to note that there is considerable uncertainty when predicting the timing, cost, regulatory outcome and scope for future sales and earnings for a pre-clinical stage biotechnology company.

## Management Team

### Dr. Pravin Chaturvedi, PhD – CEO, Director

Dr. Chaturvedi was the Founder and Chairman of IndUS Pharmaceuticals and co-founder of Oceanix Pharmaceuticals, previously serving as the Chief Executive Officer of both organizations and served as the Chief Scientific Officer of Napo Pharmaceuticals. In addition, he is the Chair of the Research Advisory Council for the Health Sciences Center of West Virginia University and is an adjunct faculty member at Georgetown Medical School. Prior to IndUS Pharmaceuticals, he served as the President and Chief Executive Officer of Scion Pharmaceuticals. During his 25+ year career in the pharmaceutical industry, Dr. Chaturvedi has participated in the discovery and/or development activities for many new chemical entities (NCEs), culminating in the successful development and commercialization of several new drugs that are currently marketed by various companies. Prior to Scion, he served as the Head of Lead Evaluation at Vertex Pharmaceuticals, and previously in the pre-clinical group at Alkermes. He started his R & D career with the Product Development group at Parke-Davis/Warner-Lambert Company (now Pfizer). Dr. Chaturvedi holds a PhD in Pharmaceutical Sciences from West Virginia University and a Bachelor of Science in Pharmacy from the University of Bombay.

### Ahmad Doroudian, PhD – Chairman, Director

Dr. Doroudian is an accomplished executive with over 25 years experience in management and development of private and publicly traded pharmaceutical companies. From 2009 to February 2014 he was the Founder, CEO and Director of Merus Labs Inc., a publicly listed specialty pharmaceutical company (MSL:TSX and MSLI:NASDAQ) engaged in licensing and acquisition of legacy brands and innovative near-market products. From 2003 to 2009 he was involved in early stage financing of private and publicly listed companies. From 1994 to 2002 Dr. Doroudian was the Founder and CEO of PanGeo (Pharmex Industries) where he assembled a team that completed over \$100 MM in debt and equity and guided numerous acquisitions and licensing transactions. From 1990 to 1996 he was manager of operations at Novapharm (Teva), in charge of management of manufacturing, supply chain and process development facilities in Vancouver, British Columbia. Dr. Doroudian holds an M.Sc. in Pharmaceutics and a PhD in Biopharmaceutics (Pharmacokinetics and drug metabolism) from the University of British Columbia

### Moira Ong, CPA, CA – Chief Financial Officer

Moira Ong is a Chartered Professional Accountant with over 16 years of experience in accounting and consulting. Moira was the Chief Financial Officer of Neurokine Pharmaceuticals Inc. and was an officer in the finance capacity of Merus Labs International Inc. from March 2010 through December 2012. In addition to holding her Chartered Professional Accountant (CPA, CA) designation, Moira is also a Chartered Financial Analyst (CFA).

### Wolfgang Renz, MD, PhD – Director

Wolfgang Renz is President of International Business at Physicians Interactive. Formerly, he served as Corporate Vice President of Business Model & Healthcare Innovation at Boehringer Ingelheim, one of the world's largest pharmaceutical companies. For over a decade, he has been involved in developing medicines and technology to help people lead healthier, more productive lives. At Boehringer Ingelheim, he led a team of specialists to find, test, and develop the disruptive technologies that will shape the way health care will be delivered in the future. In addition, he also serves as Adjunct Professor of Surgery at McGill University's Faculty of Medicine in Montreal, Canada. Prof. Renz holds a medical degree and a PhD from Freiburg University and is board certified in Germany in emergency medicine.

### Patrick Frankham, PhD – Director

Dr. Patrick Frankham founded several healthcare startup enterprises including healthcare information technology, services and pharmaceuticals companies. Dr. Frankham has over 20 years of experience in the biopharmaceutical and services industries across several therapeutic areas. His professional experience includes public and private companies as well as multinational corporations. Notable prior organizations where he held increasing leadership roles in Preclinical, Regulatory, Medical and Business Development include Phoenix International Life Sciences (MDS Pharma Services), AeternaZentaris, BioAxone

Biosciences, ICON Clinical Research & Boehringer Ingelheim GmbH. While at Boehringer Ingelheim, he developed novel business models to optimize therapeutics by combining mobile technology and therapies. He is currently Vice President International, Physicians Interactive. Dr Frankham obtained his PhD in Molecular Endocrinology, Université Laval, Québec, Canada and his MBA in Management & Finance, University of Liverpool, UK.

## Scientific Advisory Board

### Steven Grossman, M.D., Ph.D. – Chairman

Dr. Steven Grossman serves as the Dianne Nunnally Hoppes Chair in Cancer Research and is Professor & Chair of the Division of Hematology, Oncology and Palliative Care at Virginia Commonwealth University (VCU). He is also the Deputy Director of the VCU Massey Cancer Center. Dr. Grossman is a renowned physician-scientist with a long standing interest in basic and translational initiatives involving response of tumor cells to DNA damage to improve therapeutic benefit in cancer patients. He received both his PhD and MD degrees from the University of Chicago and has an undergraduate degree in biology from Princeton University. Dr. Grossman completed a residency in internal medicine at the Harvard Medical School affiliated Brigham and Women's Hospital in Boston, and completed his post-doctoral fellowships at Harvard Medical School with Dr. Elliot Kieff, and in medical oncology at the Dana-Farber Cancer Institute with Dr. David Livingston.

### Grannum Sant, M.D., F.R.C.S., F.A.C.S.

Dr. Grannum Sant is a renowned key opinion leader (KOL) in the fields of urology and oncology in men's and women's health. He served as the Professor and Chair of Urology at Tufts University School of Medicine prior to joining the pharmaceutical industry as the Vice-President of Medical Affairs in Oncology and Urology at Sanofi-Aventis. He subsequently served as the Head of US and Global Medical Affairs at Genzyme and has retained his academic appointment as Professor of Urology at Tufts University School of Medicine. He currently serves as a Senior Medical Director at OPKO Urology, chairs the Scientific Advisory Board for Cellanix Diagnostics, and is a member of EmpiraMed's SAB. Dr. Sant is a board certified physician in adult and pediatric urology and is the President-Elect of the Academy of Physicians in Clinical Research. He received his medical degree from Trinity College in Dublin (Ireland) and completed his residencies in general surgery at Albert Einstein College of Medicine (NY) and Royal College of Surgeons (Scotland). He subsequently completed his residency in urology at Tufts University School of Medicine and received his Fellowships from the Royal College of Surgeons (FRCS) and American College of Surgeons (FACS). Dr. Sant is an accomplished physician-scientist and has published widely in the fields of urology and cystitis and received multiple research grants for his research initiatives.

## FINANCIAL SUMMARY

**Figure 8. Income Statement**

Figures in \$mn unless specified	FY16E	FY17E	FY18E	FY19E	FY20E	FY21E
<b>Revenue</b>	<b>0.0</b>	<b>0.0</b>	<b>5.0</b>	<b>5.0</b>	<b>5.5</b>	<b>6.2</b>
YoY growth	NM	NM	NM	0.0%	9.6%	12.4%
Cost of Sales	0.0	0.0	0.0	0.0	0.0	2.8
<b>Gross Profit</b>	<b>0.0</b>	<b>0.0</b>	<b>5.0</b>	<b>5.0</b>	<b>5.5</b>	<b>3.4</b>
Margin	NM	NM	100.0%	100.0%	100.0%	55.0%
Operating expenses	4.9	5.0	7.0	8.1	8.6	8.7
EBIT	(4.9)	(5.0)	(2.0)	(3.1)	(3.1)	(5.3)
Margin	NM	NM	(40.9%)	(61.5%)	(57.4%)	(86.5%)
<b>EBITDA</b>	<b>(4.9)</b>	<b>(5.0)</b>	<b>(2.0)</b>	<b>(3.0)</b>	<b>(3.0)</b>	<b>(5.1)</b>
Margin	NM	NM	(40.0%)	(60.0%)	(55.2%)	(83.0%)
Other income/ (expense)	0.0	0.0	0.0	0.0	0.0	0.0
Profit before tax	(4.9)	(5.0)	(2.0)	(3.1)	(3.1)	(5.3)
Tax	0.0	0.0	0.0	0.0	0.0	0.0
<b>Net income</b>	<b>(4.9)</b>	<b>(5.0)</b>	<b>(2.0)</b>	<b>(3.1)</b>	<b>(3.1)</b>	<b>(5.3)</b>
Margin	NM	NM	(40.9%)	(61.5%)	(57.4%)	(86.5%)
<b>EPS (per share)</b>	<b>(0.06)</b>	<b>(0.06)</b>	<b>(0.02)</b>	<b>(0.03)</b>	<b>(0.03)</b>	<b>(0.06)</b>

Source: SeeThruEquity Research

**Figure 9. Balance Sheet**

Figures in \$mn unless specified	FY16E	FY17E	FY18E	FY19E	FY20E	FY21E
Current assets	0.2	2.1	3.7	4.2	7.0	6.4
Other assets	0.0	0.1	0.2	0.3	0.5	0.9
<b>Total assets</b>	<b>0.2</b>	<b>2.2</b>	<b>3.9</b>	<b>4.6</b>	<b>7.6</b>	<b>7.3</b>
Current liabilities	0.1	0.2	0.5	0.8	1.5	3.2
Other liabilities	0.0	0.0	0.0	0.0	0.1	0.1
Shareholders' equity	0.1	2.1	3.4	3.7	6.0	4.1
<b>Total liab and shareholder equity</b>	<b>0.2</b>	<b>2.2</b>	<b>3.9</b>	<b>4.6</b>	<b>7.6</b>	<b>7.3</b>

Source: SeeThruEquity Research

**Figure 10. Cash Flow Statement**

Figures in \$mn unless specified	FY16E	FY17E	FY18E	FY19E	FY20E	FY21E
Cash from operating activities	(0.1)	(3.2)	(1.3)	(2.0)	(2.0)	(2.8)
Cash from investing activities	0.0	(0.1)	(0.1)	(0.2)	(0.3)	(0.6)
Cash from financing activities	0.3	5.0	2.0	2.0	4.0	2.0
<b>Net inc/(dec) in cash</b>	<b>0.2</b>	<b>1.7</b>	<b>0.5</b>	<b>(0.2)</b>	<b>1.7</b>	<b>(1.4)</b>
Cash at beginning of the year	0.0	0.2	1.9	2.4	2.2	3.9
<b>Cash at the end of the year</b>	<b>0.2</b>	<b>1.9</b>	<b>2.4</b>	<b>2.2</b>	<b>3.9</b>	<b>2.6</b>

Source: SeeThruEquity Research

### **About Pivot Pharmaceuticals, Inc.**

Pivot is an emerging pharmaceutical company engaged in the development of novel therapies to address unmet medical needs in women's health including oncology and urology. The Company has a strategic emphasis on innovative drugs that will provide new treatment options for women's cancers as well as for unmet gynecological and urological problems. Pivot has a portfolio of novel anticancer candidates for the treatment of gynecological and breast cancers and it is also developing novel treatments to address disturbances such as lower urinary tract symptoms (LUTS). The Company has a global drug development platform that combines the strengths of the United States, Canada and India which allows accelerated drug development strategies to provide novel therapeutic options to address unmet medical needs in women's health. PivotPharma.com





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