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AnPac Bio-Medical Science Co. Ltd. ANPC-$18.00 PT

Action Summary – 23 March 2020

Analyst Theodore R. O'Neill ***is initiating coverage of AnPac Bio-Medical Co. Ltd.***

- **We are initiating coverage of AnPac Bio-Medical Co. Ltd. with a Buy rating and an $18.00 price target.**
- ANPC has developed a technology and platform to test blood for cancer early, when treatment may be more successful. Its innovative and patented Cancer Differentiation Analysis (CDA) technology unlocks multiple cancer signals in blood.
- It is in the forefront of liquid biopsy with a highly patented unique technology. Liquid biopsy is an emerging area of clinical research, particularly in the context of cancer. As a minimally invasive complementary or alternative approach to tissue biopsies, liquid biopsies are less risky, painful, and costly
- It has been successfully marketing its early detection of cancer in China since 2015, has opened an office and clinical laboratory in San Jose and in the process of opening a second laboratory in Philadelphia. Based on a 2018 survey it commissioned by Frost and Sullivan among companies offering next-generation early cancer screening and detection technologies in China, it ranked first in terms of volume of commercial cancer screening and detection tests conducted and fifth in terms of revenue from commercial cancer screening and detection tests.
- We believe the U.S. market for early-stage cancer detection is between $15B-$30B.
- While access to this market requires more than just technology, the company is following through on the regulatory protocol in the U.S.
- ANPC is an American Depositary Share (ADS) which completed an IPO in January at $12/share, raising ~$16MM. Each ADS represents one Class A ordinary share of the company.

3/20 Closing price: $7.30	Market cap: $84 million	Avg. trading volume: 1,000	Shares outstanding: 11MM

GAAP estimates (EPS in dollars – Revenue in millions)

As an ADS, the company is only required to file annually. If it reports quarterly, we will update our model.

Year	Revenue	EPS
2018A	$1.4	($0.69)
2019E	$1.5	($1.39)
2020E	$2.0	($1.38)
2021E	$10.0	($1.02)

See our full model in the back of this report.

Cash balance (in millions)

- 2018A • $1.8
- 2019E • $1.2
- 2020E • $3.4
- 2021E • $1.7

Debt (in millions)

- 2018A • $3.6
- 2019E • $4.2
- 2020E • $4.0
- 2021E • $4.0

Cash Flow (in millions)

- 2018A • $0.2
- 2019E • ($0.5)
- 2020E • $2.2
- 2021E • $(1.7)

Risks/Valuation

- Risks include: Changes in healthcare reimbursement, regulatory risk, management of growth and competition
- Our $18.00 target is derived using a discounted future earnings model

Company description: AnPac Bio-Medical Co. Ltd. is a healthcare company whose mission is to detect cancer early, when it can be cured. ANPC is focused on alleviating the global burden of cancer by developing pioneering technology to detect and identify multiple deadly cancer types early. Company headquarters are in China.

Figure 1 – AnPac Bio-Medical Co. Ltd. - Trading snapshot

Source: Refinitiv Eikon

Investment Thesis

We are initiating coverage of AnPac Bio-Medical Co. Ltd. with a Buy rating and an $18.00 price target.

ANPC has developed a technology and platform to test blood for cancer early, when treatment may be more successful. Its innovative and patented Cancer Differentiation Analysis (CDA) technology unlocks multiple cancer signals in blood.

It is in the forefront of liquid biopsy with a highly patented unique technology. Liquid biopsy is an emerging area of clinical research, particularly in the context of cancer. As a minimally invasive complementary or alternative approach to tissue biopsies, liquid biopsies are less risky, painful, and costly

It has been successfully marketing its early detection of cancer in China since 2015, has opened an office and clinical laboratory in San Jose and in the process of opening a second laboratory in Philadelphia. Based on a 2018 survey it commissioned by Frost and Sullivan among companies offering next-generation early cancer screening and detection technologies in China, it ranked first in terms of volume of commercial cancer screening and detection tests conducted and fifth in terms of revenue from commercial cancer screening and detection tests.

We believe the U.S. market for early-stage cancer detection is between $15B-$30B. The low estimate is based on less than half the U.S. population getting one $100 test per year and the high estimate is based on internal estimates from Guardant Health that it published January 13, 2020

While access to this market requires more than just technology, the company is following through on the regulatory protocol in the U.S.

ANPC is an American Depositary Share (ADS) which completed an IPO in January at $12/share. Each ADS represents one Class A ordinary share of the company.

Valuation Methodology

We believe ANPC is undervalued and we support that belief with a series of valuation techniques. We use three different techniques, below. For the purposes of determining our price target we use a discounted future earnings model. The following valuation techniques are being used:

1) The discounted value of all future earnings was used for our price target (see Figure 2)
2) Valuation relative to peers (see Figure 3)
3) Valuation using similar company with dominant IP pursuing similar goals at a similar time in its development (see Figure 4)

Discounted Future Earnings – Basis for Price Target

Our 12-month price target of $18.00 is based on a discounted future earnings model. This is also the most conservative of the three valuation techniques; the other two generate an implied price of $19.29 and $23. As the company is not yet profitable leaving many traditional valuation metrics unusable. For the purposes of deriving an earnings-based price target, we assume the company incurs losses for this and the following two years before reaching breakeven in 2023 as we show in Figure 2. Once it reaches breakeven, earnings accelerate initially at 20% and decline to GDP growth. The model sums up all earnings per share, discounted at 8% to arrive at a per share. Note, this model understates future novel product developments, probably understates the tax benefits, but offsetting that, the earnings never have a down year.

The implied share price is $18.26 which we round down to $18.00.

Figure 2 – AnPac Bio-Medical Co. Ltd. – Implied Price Target Calculation

	Implied price:	**$ 18.26**
Year	EPS	Discounted EPS
0	($1.19)	($1.19)
1	($0.93)	($0.86)
2	($0.50)	($0.43)
3	$0.10	$0.08
4	$0.50	$0.37
	Terminal Value	$19.74

Source: Litchfield Hills Research LLC

Valuation Relative to Peers

Here as well, we need to hypothecate a model that gets us to breakeven in 2023 consistent with the earnings model we used in Figure 2. Based on our estimates, ANPC would reach approximate breakeven with $40MM annual revenue. If we used the average 2021 Market Cap to Sales, detailed in Figure 10 (the furthest outyear we have), it would imply a market cap of $250.8MM. Using our estimated share count at estimated B/E of 13MM, that gives us an implied share price of $19.29 (see Figure 3).

Figure 3 – AnPac Bio-Medical Co. Ltd. – Summary Discount to Peers

	Implied Share Price Calculation
Average Peers 2021 Sales Multiple	6.27
Approx. B/E Revenue 2023	$40MM
Implied Market Cap	$250.8MM
Estimated Share Count	13MM
Implied Share Price	**$19.29**

Source: Litchfield Hills Research LLC and Refinitiv Eikon

Valuation using similar company with dominant IP pursuing similar goals at a similar time in its development

We believe the best comparable company pursuing a similar multi-cancer goal using well protected IP, but not yet at breakeven is Genomic Health which was acquired last year Exact Sciences. At the time of its IPO in 2005, Genomic Health had in development the ability to detect multiple cancers and assist with individualized treatments. The company had no issued patents at the time (although it would ultimately obtain 49). At the time of the IPO it had booked revenue of $1.5MM and a net income loss of $15.7MM in the first six months. We believe this is the best public company comparable and summarize the data in Figure 4. The implied market cap from this comparison is similar to the one used in Figure 3 with an implied price for ANPC of $23.

Figure 4 – AnPac Bio-Medical Co. LTD – Comparable to Genomic Health at IPO

	2019 AnPac Bio-Medical	**Genomic Health at IPO in 2005**
Goal	Multiple early cancer detection	Multiple early cancer detection
Current revenue run rate	$1.5MM	$3.0MM
Current expected loss	$12.6MM	$30MM
Issued patents	121	None
Market cap	~$50MM	~$300MM
Implied Price (assuming 13MM shares)	$23	

Source: Litchfield Hills Research LLC, company filings of both AnPac and Genomic Health

Financial Forecasts

The company does not provide guidance. Our estimates are based on the company trending towards breakeven in 2023. We expect the company to report its 2019 annual report soon and we will update our estimates following that filing. Details of our estimates are to be found in Figures 11, 12, and 13. The company completed an IPO in the U.S. for its ADS shares along with a listing on the NASDAQ Global Market in January 2020 which appears to provide sufficient funding for 2020. We expect it may raise additional capital from time-to-time until it reaches breakeven. The primary shares trade in the PRC.

Company Overview

ANPC is a biotechnology company focusing on early cancer screening and detection using a unique approach to liquid biopsy. It markets and sells a multi-cancer screening and detection test that uses its innovative, patented cancer differentiation analysis (CDA) technology. In addition to early cancer screening and detection, its CDA technology has demonstrated potential to assist physicians in cancer diagnosis, prognosis and recurrence. The CDA technology requires only a standard blood sample, which minimizes inconvenient and invasive procedures, and avoids the side effects that are inherent in other cancer testing technologies.

Currently, the most common strategy for characterizing the genetic makeup of a tumor is the extraction, or biopsy, of a sample of the affected tissue. Tissue biopsies, however, can be painful, risky, and in some cases not feasible when a tumor is difficult to access. Furthermore, tissue biopsies are not a viable monitoring technique as they cannot be repeated, and they may not be representative of the entire tumor due to tumor heterogeneity.

Liquid biopsy is an emerging area of clinical research, particularly in the context of cancer. As a minimally invasive complementary or alternative approach to tissue biopsies, liquid biopsies are less risky, painful, and costly, and are increasingly being used to analyze biomarkers in liquid samples, such as blood.

Recent studies have shown the utility of liquid biopsies for:

- Enhancing understanding of tumorigenesis, metastasis, and therapy resistance
- Detection of cancer at early stages when treatment may be most successful
- Monitoring of cancer development, disease progression, and recurrence
- Tracking response or resistance during and after treatment to allow for adjustments in real time

The CDA technology provides a comprehensive platform to accurately detect and assess an individual's overall cancer risk. The company also offers combination tests that combine its CDA test with auxiliary tests based on other cancer screening and detection technologies, such as biomarker-based tests, to detect the risk of specific cancer types.

As of September 30, 2019, its CDA technology had been shown in numerous retrospective validation studies (where the company was provided a blood sample of a known cancer patient) to verify the ability to detect 26 cancer types with high sensitivity and specificity (see Figure 5). According to research conducted by Frost & Sullivan, these 26 cancers accounted for over 80% of the cancer incidences in China from 2013 to 2018.

Figure 5 – AnPac Bio-Medical – Cancer Detection sensitivity and specificity

Cancer Type	Aggregate Sample Size	Sensitivity	Specificity
Thyroid Cancer	39	100.0%	83.6%
Gallbladder Cancer	28	100.0%	63.4%
Laryngeal Cancer	61	93.4%	88.0%
Liver Cancer	804	92.3%	93.2%
Bone Cancer	12	91.7%	91.0%
Prostatic Cancer	46	90.7%	93.2%
Ovarian Cancer	474	90.5%	90.1%
Colon Cancer	884	89.4%	91.2%
Pancreatic Cancer	162	89.3%	90.6%
Cerebral Cancer	93	89.2%	89.9%
Rectum Cancer	653	89.2%	88.0%
Kidney Cancer	55	88.9%	77.7%
Skin Cancer	18	88.9%	93.7%
Gastric Cancer	1438	88.7%	93.8%
Bile Duct Cancer	26	87.5%	94.0%
Uterine Cancer	164	87.2%	92.3%
Lymphoma	528	87.1%	92.4%
Cervical Cancer	401	87.0%	90.2%
Nasopharyngeal Cancer	188	86.6%	89.1%
Esophageal Cancer	2253	85.8%	93.0%
Duodenal Cancer	32	84.4%	87.5%
Lung Cancer	2277	82.4%	83.0%
Oral Cancer	60	78.3%	90.8%
Leukemia	196	77.6%	88.0%
Breast Cancer	493	74.6%	92.2%
Bladder Cancer	29	72.4%	88.3%

Source: Company presentation

When compared to other blood-based liquid biopsy techniques, the CDA is at least as sensitive and specific (see Figure 6).

Figure 6 – AnPac Bio-Medical – Head-to-head comparison to peers

Technology	Cancer	Stage	Sensitivity	Specificity	Remark
Anpac CDA	Lung Cancer	Stage I	85.2%	93%	Junjie Wu, *et al.*, A novel biophysical based marker with multilevel, multiparameter expression for early stage cancer detection. J Clin Oncol 37, 2019 (suppl; abstr e20673)
	Esophageal Cancer	Stage I	75.0%	99%	
Multi-analyze blood test "CancerSEEK" (ctDNA+Protein)	Lung Cancer	Stage I	Lower than 43%	99%	J. D. Cohen, *et al.*, Detection and localization of surgically resectable cancers with a multi-analyte blood test. Science 10.1126/science.aar3247(2018)
	Esophageal Cancer	Stage I	Lower than 20%	99%	
Gene Test (Grail)	Lung Cancer	I/II/III	59%	99%	GRAIL Announces Positive New Data with Multi-Cancer Early Detection Blood Test from CCGA Study May 31, 2019 https://grail.com/press-releases/grail-announces-positive-new-data-with-multi-cancer-early-detection-blood-test-from-ccga-study/
	Esophageal Cancer	I/II/III	76%	99%	

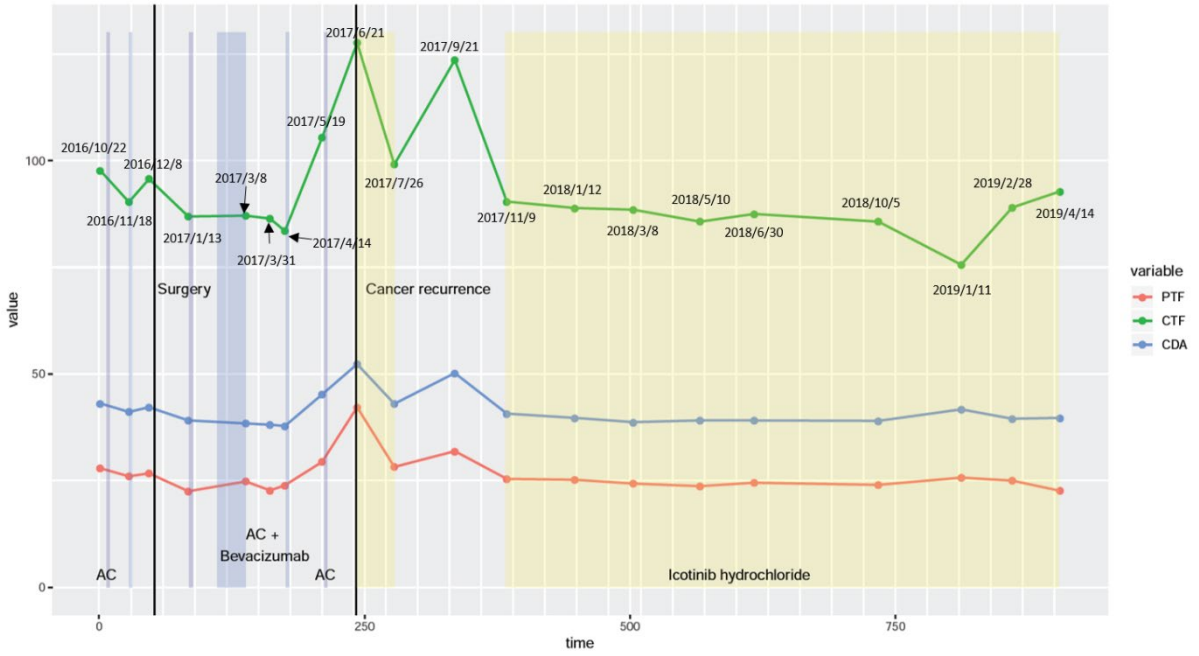
Source: Company presentation

In addition to testing for cancer, the company has demonstrated that its CDA test can:

- dynamically monitor a patient's treatment progression, indicating when the cancer is under control (namely, when the overall CDA value drops below the cut-off value) and when the patient enters the remission phase (namely, after the overall CDA value stays below the cut-off value for a period of time) and:
- correctly predict cancer recurrence ahead of time (namely, when the overall CDA value resurges and exceeds the cut-off value)

As shown in Figure 7, the CDA value correlated well with the protein tumor factor (PTF) and cell tumor factor (CTF). These are also known as tumor markers. The key takeaway from this is that unlike PTF and CTF, the CDA is designed to identify the presence of cancer. Tumor markers can be caused by other underlying conditions.

Figure 7 – AnPac Bio-medical – Dynamic Monitoring Results compared with tumor markers



Source: Company presentation

CDA Technology and Development

The CDA device, which was designed in-house and is covered by numerous patents, uses an integrated, multi-level and multi-parameter sensor system to detect multiple biophysical properties in a single blood test. We believe that ANPC is one of the first biotechnology companies to use such a sensor system to detect cancers biophysical properties. The critical difference between its CDA technology and other liquid-based cancer screening and detection technologies is that this technology focuses on biophysical properties rather than conventional biochemical or genomic properties. Recent studies have shown that there is a correlation between certain biophysical properties and cancer occurrence. These studies have revealed that certain biophysical properties could be important non-genetic aspects of the micro-environment regulating the balance between normal cell growth and carcinogenesis (cancerous growth), which may lead to cancer. The CDA technology developed by ANPC is based on the correlations between biophysical properties and cancer occurrence. Biophysical properties exist in all human beings, including healthy individuals, and the signals they express can be detected before a tumor has formed. Biophysical properties increase or decrease progressively in a statistically significant way from a healthy state to non-cancerous disease, pre-cancer disease, early- and late-stage cancer states. The change in biophysical properties is a potential cause for the loss of immunity and increased occurrence of cancer. On the other hand, the strength of biophysical signals expressed by these biophysical properties—which its CDA technology is designed to detect—increase progressively from healthy through late-stage cancer states.

The measurement tool consists of a blood sample input unit, a sample transport unit, a sample mixing chamber, a testing unit and a data storage unit. It begins with a microfluidic device, which is connected to a fluid delivery line inside the testing unit. This microfluidic device contains three primary components:

- micro-channels

- micro-sensors and;
- measurement instruments with automated data recording capabilities.

After a blood sample goes into the micro-channels of the microfluidic device, the sensors probe the blood and measure relevant data. The resulting raw data contains both dynamic and static information, which is read by a proprietary algorithm for analysis. Based on the resulting CDA values, ANPC can assess an individual's likelihood of having or developing cancers and issue the corresponding cancer risk assessment report. Figure 8 shows CDA equipment in operation.

Figure 8 – AnPac Bio-Medical – CDA Tool

Source: Company photo

Using standard semiconductor manufacturing technology for the detector, it is less costly to manufacture than the equipment used by competitors, especially gene sequencing machines used in circulating tumor DNA (ctDNA) based tests and micro-electrical mechanical devices used in Circulating Tumor Cells (CTC) based tests. This allows ANPC to offer customers accurate cancer screening and detection tests at a lower price. According to a Frost & Sullivan survey the company commissioned, it ranked first in China and second worldwide among companies offering next-generation early cancer screening and detection technologies in terms of the number of clinical samples for cancer screening and detection as of June 30, 2019.

Construction and licensing

The design and specification of all of the key components of the CDA device is done by ANPC and key components are produced by qualified contract manufacturers. Assembly is done in-house. The company received a Class II medical device manufacture license in June 2013 (renewed in 2018) and a Class II medical device registration certificate April 2015 from the National Medical Products Administration (NMPA), Zhejiang Branch. These licenses, along with its clinical laboratory license, allow it to manufacture the device in Lishui, Zhejiang and use the device commercially in its licensed clinical laboratories in China.

Currently, ANPC offers seven standardized tests (with or without cancer positioning services). Cost for the tests depend on the type of tests ordered. Generally, the more cancer types a standardized test with cancer positioning services can identify, the higher it is priced.

Analytical Validation

In order to validate the technology, the company has conducted numerous research studies. Since 2015, it has completed 25 research studies with its CDA technology with hospitals and medical institutes in China. Among them, the results of 15 research studies on which it collaborated with five Chinese hospitals and medical institutes have been published at the American Society of Clinical Oncology (ASCO) annual meetings and other medical conferences and in medical journal supplements. It has also completed an additional ten unpublished research studies with nine hospitals and medical institutes in China. Since 2015, it has tested more than 140,000 blood samples collected from various age, sex and disease groups, including approximately 100,000 samples from its commercial CDA-based tests and approximately 40,000 samples from its research studies.

As part of this research, it has collected data on biophysical properties measured in multiple serial samples collected from the same person over time and corresponding pathological data on 26 types of cancer. Its proprietary algorithm is based on this database, and it uses the testing data collected by its CDA device to determine the PTF value, CTF value and overall CDA value of a blood sample. The overall CDA value determined through its test factors in the PTF and CTF value, as well as other biophysical property characteristics of the blood sample. The overall CDA value, as the principal parameter for its CDA technology, is proportional to the cancer risk.

Based on the progressive changes of biophysical properties and their signals from healthy through late-stage cancer states, we believe that its CDA technology may be ideally suited for early cancer screening and detection, as well as assistance in cancer diagnosis, prognosis and reoccurrence.

Intellectual Property

Intellectual property rights are fundamental to its business, and it devotes significant time and resources to their development and protection. It relies on a combination of patent, trade secret and trademark laws, as well as confidentiality agreements, to establish and protect its proprietary rights. It does not rely on third-party licenses of intellectual property when developing its CDA technology and CDA device.

It has developed an early and strong patent position related to its CDA technology, and continuously seeks patent coverage over its new applications. As of September 30, 2019, it had filed 210 patent applications globally; among them, 121 patents had been granted, including 16 patents granted in the United States, 55 in greater China (including seven in Taiwan), and 50 in nearly 20 other countries and regions. Its granted patents are expected to expire between 2031 and 2037. As of the same date, it also had 89 pending patent applications, consisting of 19 in the United States, 28 in greater China (including one in Taiwan), 38 in nearly 20 other countries and regions, and four patent cooperation treaty, or PCT, applications.

The patents and patent applications broadly cover apparatus and methods for detecting diseases at early stages, and they strategically encompass the important specific embodiments of these apparatus and methods. They generally fall into the following categories:

- those relating to its CDA technology, including claims directed to methods for identifying and measuring various biophysical properties in blood samples and methods for detecting major cancer types and/or non-cancerous diseases, such as methods for detecting multiple cancers in a single blood test;
- those relating to its CDA device, including claims directed to its key components, such as the microfluidic device; and
- those relating to the multi-level, multi-parameter concept underlying its CDA technology, as well as its non-CDA early cancer screening and detection technologies, apparatus and methods.

It has also established a test database that as of September 30, 2019, consisted of over 140,000 blood samples of various age, sex and disease groups. This database included approximately 100,000 samples from its commercial CDA-based tests and approximately 40,000 samples from its research studies. Our test database helps us to continuously refine its algorithm and provide high accuracy tests. Substantially all of the blood samples in its database were collected and tested in China. It has cooperated with a number of Chinese hospitals and medical institutions to conduct retrospective validation studies on its CDA technology for single or multiple cancers. Leveraging its relationships with these research partners, it anticipates having a relatively stable supply of blood samples to support

future research and further expand its test database in China. In addition, it has entered into research agreements with U.S. universities and academic medical centers, and ANPC is in discussions with other U.S. hospitals, medical institutions, CROs, managed care companies and other health organizations, to conduct research studies on its CDA technology at this laboratory.

CDA Competitive Strengths

We believe that its CDA technology has the following advantages compared to other cancer screening and detection technologies:

Ability to detect the risk of cancer with high accuracy. The accuracy of cancer screening and detection technologies can be measured by two key performance metrics—sensitivity and specificity. Sensitivity indicates the ability of a test to correctly identify those who have cancer among the population with cancer, whereas specificity indicates the ability of the test to correctly identify those who do not have cancer among the population without cancer. These two metrics are critical for effective treatment selection based on the results of liquid-based testing. Numerous retrospective validation studies have shown that its CDA technology can successfully detect the risk of cancers with high sensitivity and specificity rates. For example, as of September 30, 2019, in completed research studies its CDA technology had successfully detected the risk of (i) lung cancer in 2,277 cases, with the meta-analysis sensitivity of 82.4% and specificity of 83.0%; and (ii) esophageal cancer in 2,253 cases, with the meta-analysis sensitivity of 85.8% and specificity of 93.0%. According to Frost & Sullivan, these high sensitivity and specificity rates are generally considered difficult for liquid-based cancer screening and detection technologies to achieve for lung and esophageal cancers, and they represent a leading position in terms of testing accuracy in the early cancer screening and detection industry.

Ability to detect the risk of multiple cancers using one blood test. Retrospective validation studies have shown that its CDA technology, combined with its CDA measurement tool, can detect the risk of 26 types of cancers in a single blood test. While its CDA test alone does not indicate precisely which specific type(s) of cancer an individual may have, if it indicates a medium or high risk of cancer, the tested individual can use concurrent combinations of tests, or follow-up screening tests, performed by ANPC or at hospitals or physical checkup centers, to determine the specific cancer type(s) that may exist or the location(s)of the cancer(s). For example, it offers a cancer-positioning service using a combination of its CDA technology and, on an auxiliary basis, biomarkers to indicate the risk of specific cancer type(s) in one blood test. This advantage of its CDA technology, as well as its CDA test's ability to work in combination with other auxiliary tests using its proprietary algorithm, enable it to maintain a comprehensive and flexible test menu to meet different customers' needs.

Simple operation. Compared to ctDNA and CTC tests, which involve multiple steps requiring human intervention along the way, the CDA technology does it all in one machine without any intervention. Whole blood samples remain stable for seven days and serum can be stored.

Low cost. ANPC owns all the intellectual property and its CDA device is less costly to manufacture and operate than the equipment used in ctDNA and CTC as well as others.

Minimally invasive, side effect-free and automated. Compared to conventional approaches to cancer screening and detection such as imaging technology and tissue biopsy, its CDA technology is liquid-based and requires only a standard blood sample from a tested individual. This minimizes the invasiveness of the tests and means they may not result in harmful side effects.

Improved Economics of Cancer Care. We believe that improving the quality of treatment decisions can result in significant economic benefits. By detecting cancer earlier, physicians may have multiple treatment options, some of which may be less costly.

Potential for assistance in diagnosis, prognosis and recurrence. Its CDA technology can be used to track variations in cancer-related biophysical properties as a disease progresses, regresses or recurs.

Its CDA technology can assist physicians in their cancer diagnosis by providing input complementary to pathologic information drawn from a tissue biopsy, which helps oncologists ensure that their cancer diagnoses are comprehensive and unbiased. Given these qualities, in addition to early cancer screening and detection, its CDA technology has demonstrated potential for assisting in diagnosis, prognosis and recurrence.

Current Standard Options for Early Cancer Screening and Detection

Because of its advantages, early cancer screening and detection represents a huge market potential in both China and the United States. However, early cancer screening and detection remains one of the most challenging tasks in the medical field, due to the difficulties in finding cancers early, accurately and cost-effectively. Major options for early cancer screening and detection currently include the following:

Tumor Markers

The two principal methods for tumor marker detection are immunoassays and molecular testing.

Immunoassays

Immunoassays are tests that detect the presence of a specific antibody or antigen in the body. Tumor markers used in immunoassays are proteins or other biomarkers produced by malignant cells and/or other cells of an organism in response to the onset of cancer. Because tumor markers can be observed in cancer-free subjects, immunoassays that are designed to detect tumor markers need to be used in combination with other tests to confirm cancer diagnoses. Immunoassays for tumor marker detection can be used for various purposes, including screening for cancer, assistance in cancer diagnosis, staging of disease, monitoring the effectiveness of therapy (or prognosis), providing evidence of cancer recurrence. Only a few tumor markers are useful for screening, while most can be used for prognosis or to provide evidence of cancer recurrence. Common tumor markers used in immunoassays include prostate-specific antigen, or PSA, for prostate cancer, cancer antigen 125, or CA-125, for ovarian cancer, and alpha-fetoprotein, or AFP, for hepatocellular carcinoma. Currently, there is no clinically validated tumor marker for esophageal cancer or brain cancer.

Molecular testing

Molecular testing analyzes biological markers associated with cancers in the genome. Two novel techniques of molecular testing are ctDNA test, which detects circulating tumor DNA in the bloodstream, and CTC test, which detects cells in the bloodstream that have been shed from primary tumors. Neither of these techniques has been used in routine clinical practice. CTC tests can be used in the management of cancer by isolating tumor cells, which allows for morphologic identification and molecular characterization, while ctDNA tests are currently limited to mutation detection.

Imaging

Screening for cancer using radiographic imaging, such as mammograms, X-rays and CT scans, has been available for decades, and numerous clinical studies have demonstrated its efficacy in specific instances. Breast cancer and lung cancer are the two cancers that benefit the most from early cancer screening and detection using imaging.

Biophysical-property based technologies

Biophysical-property based technologies, such as CDA technology, focus on biophysical properties that exist in human blood and that regulate cell-surface differentiations and intercellular communications. These biophysical properties can signal risks of pre-cancer states and cancers, and they change over time as cancer occurs, progresses or regresses.

Endoscopic exams

Endoscopy has a major role in the detection and characterization of neoplastic lesions along the digestive tract in all screening strategies. Typical endoscopic exams include cystoscopy, colonoscopy, endoscopic retrograde cholangiopancreatography, or ERCP, esophagogastroduodenoscopy, or EGD, and sigmoidoscopy, among others.

Current Product Revenue

Revenues are from two sources: (i) revenue from sales of cancer screening and detection tests (predominantly commercial CDA-based tests) and (ii) net revenue from sales of physical checkup packages. ANPC derives substantially all of its revenues from the sale of its CDA-based tests in China. Its business prospects depend significantly on its ability to increase market adoption of its CDA-based tests in China, as well as its ability to commercialize its CDA-based tests in the U.S. The table below (Figure 9) presents current revenues by type in absolute amount and as a percentage of total revenues for the periods indicated.

Figure 9 – AnPac Bio-Medical – Revenue Composition

			For the nine months ended	
	Year ended December 31,		September 30,	
($000)	2018		2019	
Cancer screening and detection tests	1,337	93.2%	1,074	94.6%
Physical checkup packages	97	6.8%	61	5.4%
Total revenues	1,434	100.0%	1,135	100.0%

Source: Company filings

Growth Strategy

AnPac's objective is to become the leading provider of highly accurate and cost-effective cancer screening and detection tests and to expand the application of its tests to other oncological areas, such as assistance in diagnosis, prognosis and recurrence. To achieve this, it intends to:

Enlarge the Total Addressable Market in China by Obtaining Additional Regulatory Approvals for Its CDA Device

The CDA test is currently licensed for use in its labs. It plans to seek license to place its CDA platform in hospital laboratories. In December 2018, it applied to the NMPA for a Class III medical device registration certificate for its CDA device to assist in multi-cancer diagnosis. After it obtains this license, it will apply to update its medical device manufacture license to include the manufacture of Class III medical devices. With these Class III medical device licenses, it will be able to place its equipment within Chinese hospitals' laboratories to conduct commercial tests there or sell its devices to the hospitals for the purposes of assisting in physicians' diagnoses of multiple cancers.

Grow Customer Base in China

The existing customer base in China consists primarily of life insurance companies and other large corporations. It plans to acquire customers for its CDA-based tests through the annual physical checkup packages it offers; it largely outsources these physical checkups (other than CDA-based tests) to third-party physical checkup centers. In addition, it plans to further develop non-CDA cancer screening and detection tests using other technologies, including expanding the genomics tests it currently conducts at its Haikou laboratory. After obtaining a Class III medical device registration certificate and updating its medical device manufacture license, we expect it to provide tests to more individual customers through Chinese hospitals.

Expand in the U.S.

Offices already in San Jose. Pursuing regulatory approval to market products in the U.S. The company is building its second bio-medical lab in Philadelphia and has entered into research agreements with U.S. universities and academic medical centers.

Sales and Marketing

ANPC currently sells its cancer screening and detection tests only in China. It sells tests primarily to customers directly, as well as through its sales agents such as health management companies and medical device dealers. It sets the prices of tests primarily based on the numbers of cancers tested. It does not set

Marketing is focused on expanding the market awareness of its cancer screening and detection test and continuously growing the customer base. As of September 30, 2019, it had 19 sales and marketing personnel. In addition to conducting direct sales to existing customers, sales and marketing personnel prepare and deliver its brochures and product presentations to potential customers and attend academic conferences and industrial exhibitions to advertise its CDA technology and tests. Sales and marketing personnel are generally well trained and educated about the complexities of the tests, and they typically have extensive experience in the cancer early screening and detection field or other medical areas.

Market Size

While early detection of cancers greatly improves clinical outcomes by providing clinical care and medical intervention at early stages, China's early cancer screening and detection industry is still at the starting stage. According to Frost & Sullivan, the market potential in China for early cancer screening and detection technologies increased at a CAGR of 20.7% from US$27.7 billion in 2014 to US$58.8 billion in 2018, and is expected to reach US$115.1 billion in 2023, representing a CAGR of 14.4% over this period. In addition, the percentage of people that conducted physical checkups in China in 2018 was estimated to be 31.2%, far below that of 77.0% in the U.S. for the same year. We believe that its CDA technology can address much of the reluctance of current early cancer screening and detection methods

The number of commercial CDA-based tests (inclusive of CDA tests and combination tests) it sold increased significantly from 19,336 in 2017 to 41,607 in 2018 and from 29,036 in the nine months ended September 30, 2018 to 41,544 in the same period of 2019. In the United States, it plans to commence marketing its CDA test as an LDT sometime in 2020 at its CLIA-registered laboratory in San Jose.

Expansion Plans

United States

In the United States, it has established a clinical laboratory in San Jose, California and obtained a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Registration for this laboratory in March 2019. This certificate is a requirement in the U.S. that performs even one test on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any diseases or impairment of or the assessment of the health of human beings.

Because it has received a CLIA Certificate of Registration for its San Jose laboratory, it may begin marketing its test as soon as it completes validation studies and obtains any state laboratory licenses or other accreditations that ANPC is required to hold in order to offer its CDA test in the corresponding states. Under CLIA, College of American Pathologists (CAP) and state licensing requirements, ANPC is required to validate its CDA test with applicable analytical and clinical studies prior to marketing the test as a Laboratory Developed Test (LDT). These studies are designed to demonstrate the performance of the test. It has entered into research agreements with U.S. universities and academic medical centers, and ANPC is in discussions with other health organizations, to conduct these studies.

It has voluntarily elected to seek accreditation for its San Jose laboratory from CAP. To receive CAP accreditation, it must demonstrate that the San Jose laboratory is in compliance with all applicable CAP program requirements and CLIA regulatory requirements. Among other things, the CAP inspection will evaluate laboratory's processes and procedures, personnel qualifications and competency assessment, proficiency testing and quality assurance, and test method validation. As an LDT, pursuant to the FDA's current LDT enforcement discretion policy, we do not expect that its CDA test will require premarket clearance, market authorization, or approval from the FDA prior to marketing.

Research and Development Team

We believe that the research and development team possess industry-leading expertise in the early cancer screening and detection field. As of September 30, 2019, this team had 23 members, including four with M.D. degrees and three with a Ph.D. degree. The research and development team have a multi-disciplinary background, and most members of this team specialize in areas related to the development of its CDA technology and device, including mechatronics,

physics, biomedical science or computer science. The founder and chairman, Dr. Chris Chang Yu, the vice president in charge of R&D, Mr. Xuedong Du, and chief medical officer, Dr. He Yu, have led the research and development team since inception. These key members have spearheaded the research and development team in achieving a number of technological breakthroughs, including the design and fabrication of the microfluidic device—the key functioning component of its CDA device—and the testing of multiple cancers in a single blood test. Since 2015, the research and development team has published 15 articles on ASCO and other medical conferences and medical journal supplements to demonstrate its CDA technology's clinical utility.

Competition

As early detection of cancer may lead to decreased morbidity with improved survival, more and more biotechnology companies have focused on the immense market opportunities it represents and are attempting to enter the space.

Biotechnology companies worldwide currently use various technologies for early cancer screening and detection. We believe that none of these technologies has yet acquired a dominant market position. As a novel cancer screening and detection technology that focuses on biophysical properties in blood, its CDA technology faces competition primarily from conventional biomarker-based technologies and other next-generation cancer screening and detection technologies, including those based on CTCs and ctDNAs. Recent major advances in CTC- and ctDNA-based technologies have introduced the possibility of using either or both as tests to screen for cancer, and they have made the possibility for simultaneous screening for multiple primary cancers particularly attractive.

Major competitors include biotechnology companies that conduct cancer screening and detection using next-generating technologies, such as Beijing Genomics Institute (BGI), GRAIL, Guardant Health, and Exact Sciences. All of these competitors' cancer screening and detection technologies target CTCs and/or genomics such as ctDNA, cfDNA and cfRNA, as opposed to the biophysical properties that its CDA technology focuses on. GRAIL, Guardant Health, and Exact Sciences have developed, or may develop, multi-cancer tests that compete with its CDA-based test, and BGI is developing services to evaluate the risk of various cancer types through ctDNA tests.

Facilities

AnPac's China headquarters are located in the Bihu Industrial Park in Lishui, Zhejiang Province. The facilities for manufacturing its CDA, principle licensed clinical laboratory to conduct commercial CDA-based tests, as well as warehouse are all in Lishui. Headquarters have an aggregate floor area of approximately 5,126 square meters. It also owns an additional 203 square meters in Lishui and 157 square meters of office space in Yangzhou, Jiangsu Province.

It currently leases several properties with an aggregate floor area of approximately 875 square meters in Shanghai, where it operates its primary research and development facilities. It leases approximately 142 square meters of properties in Haikou, Hainan Province, primarily to operate its government-approved clinical laboratory. It leases approximately 517 square meters of properties in Yangzhou, where it also operates a research and development facility. The leases for these properties vary in duration from one to three years.

In the United States, it currently leases approximately 1,050 square feet of office space in San Jose where it houses both its CLIA-registered laboratory and U.S. headquarters. These leases vary in duration from approximately three years to five years. It plans to open a new laboratory in Philadelphia in 2020 and will seek to obtain a CLIA certification and CAP accreditation for this laboratory.

Management

Dr. Chris Chang Yu is a co-founder of and has served as chairman of the board of directors and chief executive officer since inception in January 2010. As the first or principal inventor of more than 300 patent applications spanning semiconductor, materials and life science, Dr. Yu has innovated leading technologies and products during his long and successful career since 1990s. Dr. Yu and team have developed the CDA technology for cancer screening and detection. He is a member of the ASCO. Prior to founding the company, he co-founded Anji Microelectronics (Shanghai) Co., Ltd. (688019.SH) in 2004, and that company recently completed its IPO in China's science and technology innovation board market in July 2019. Dr. Yu served as a technical director at Semiconductor Manufacturing International Corporation (NYSE: SMI and SEHK: 981) from 2002 to 2004. Dr. Yu served as a vice president of the research and development team of Cabot Microelectronics Corporation, or Cabot, from 1996 to 2002. While working at Cabot, Dr. Yu took a multi-disciplinary approach to developing a new mechanism for a key integrated circuit material. Dr. Yu also worked at three U.S. Fortune 500 companies, including serving as a group leader in the research and development division at Rockwell Co., Ltd. from 1994 to 1995, engineer at Motorola Co., Ltd. from 1992 to 1994, and

senior engineer at Micron Technology Co., Ltd. from 1989 to 1992. He has also authored more than 80 papers, some of which are relevant to cancer detection. Dr. Yu received his bachelor and master's degrees in physics from the University of Missouri Kansas-City Campus in 1983 and 1984, respectively. He received his doctoral degree in physics from the Pennsylvania State University in 1990. His master's and doctoral dissertations both addressed innovative detection techniques.

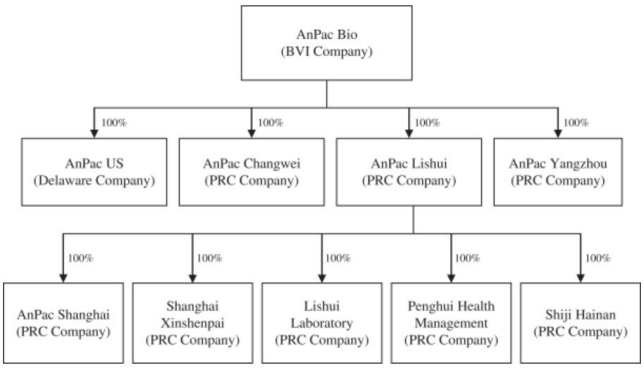
Ms. Rain Yu Zhang has served as CFO since March 2019. Prior to joining ANPC, Ms. Zhang served as a general manager-operation at Buckman Laboratories (Asia) Pte. Ltd. (Singapore) (a subsidiary of Bulab Holdings, Inc., a U.S. company) from 2017 to 2018 and a finance director at Buckman Laboratories Shanghai Chemicals Co., Ltd. from 2005 to 2016. She became a Chartered Global Management Accountant (CGMA) in 2016 and a Certified Public Accountant in 2002. Ms. Zhang received her bachelor's degree in accounting from Shanghai University of Finance and Economics in 1999 and master's degree in business administration from AnTai College of Economics & Management, Shanghai Jiao Tong University in 2015.

Dr. He Yu, co-founder and chief medical officer, is a renowned expert in molecular epidemiology, with training in medicine, epidemiology and clinical biochemistry. Dr. He Yu has served as a professor and program director of cancer epidemiology at the University of Hawaii Cancer Center and an adjunct professor at Yale School of Public Health since 2012. Relying on his over 20 years' experience in leading-edge cancer research, Dr. He Yu has contributed to the development of its CDA technology.

Corporate Structure

ANPC began operations by incorporating AnPac Bio-Medical Science Co., Ltd., or AnPac Bio, in January 2010 as a British Virgin Islands, or BVI, business company limited by shares under the BVI Business Companies Act. AnPac Bio was established primarily as a holding company and has established operating subsidiaries in China and the United States.

The chart below summarizes the corporate structure:



Below is a list of its operating subsidiaries:

Changhe Bio-Medical Technology (Yangzhou) Co., Ltd., or AnPac Yangzhou: a wholly foreign owned subsidiary established in the PRC in March 2010 to market and sell cancer screening and detection tests and conduct biology related research and development activities.

Changwei System Technology (Shanghai) Co., Ltd., or AnPac Changwei: a wholly foreign owned subsidiary established in the PRC in March 2011 as its global research and development center.

AnPac Bio-Medical Technology (Lishui) Co., Ltd. or AnPac Lishui: a wholly foreign owned subsidiary established in the PRC in October 2012 as its headquarters and to manufacture its CDA devices.

Shanghai Xinshenpai Technology Co., Ltd., or Shanghai Xinshenpai: a wholly owned subsidiary established in the PRC in October 2013 to market and sell cancer screening and detection tests.

AnPac Shanghai: a wholly owned subsidiary established in the PRC in April 2014 to market and sell cancer screening and detection tests.

AnPac US: a wholly owned subsidiary established in the United States in September 2015 to conduct research studies and clinical studies for research on cancer screening and detection tests.

Lishui AnPac Medical Laboratory Co., Ltd., or Lishui Laboratory: a wholly owned subsidiary established in the PRC in July 2016 to conduct cancer screening and detection tests.

Shiji (Hainan) Medical Technology Limited, or Shiji Hainan: a wholly owned subsidiary established in the PRC, which it acquired from third parties in November 2017 to conduct cancer screening and detection tests.

Penghui Health Management (Shanghai) Co., Ltd., or Penghui Health Management: a wholly owned subsidiary established in the PRC in May 2018 to market and sell cancer screening and detection tests.

Figure 10 – AnPac Bio-Medical Co. Ltd. – Comp Table

Company Name	Ticker	3/20 Close	Market Cap ($MM)	Enterprise Value ($MM)	EV / 2020 Revenue	EV / 2021 Revenue	Market Cap / 2020 Sales	Market Cap / 2021 Sales
Exact Sciences	EXAS.O	$50.21	7,429	7,934	4.90	3.84	4.58	3.59
Guardant Health	GH.O	$68.93	6,506	6,033	21.30	15.63	22.97	16.85
Bio-Techne Corp	TECH.O	$166.42	6,382	6,521	8.34	7.50	8.16	7.34
Mirati Therapeutics	MRTX.O	$72.32	3,145	2,729	NMF	NMF	NMF	NMF
Natera Inc.	NTRA.O	$24.17	1,891	1,574	4.61	3.90	5.54	4.69
Invitae Corp	NVTA.K	$9.79	969	849	2.57	1.78	2.93	2.03
Veracyte Inc.	VCYT.O	$19.02	946	787	5.66	4.70	6.80	5.64
Twist Bioscience Corp	TWST.O	$22.67	859	763	9.18	6.62	10.34	7.45
Puma Biotechnology Inc.	PBYI.O	$7.77	305	289	1.16	1.05	1.22	1.11
Interpace Biosciences Inc.	IDXG.O	$5.57	21	36	0.70	0.52	0.41	0.31
aTyr Pharma Inc.	LIFE.O	$2.48	20	(7)	NMF	NMF	7.08	NMF
Capricor Therapeutics Inc.	CAPR.O	$1.18	6	3	6.04	6.04	13.71	13.71
				Average	**6.45**	**5.16**	**7.61**	**6.27**
Where metrics would have skewed averages higher, we inserted NMF								

Source: Litchfield Hills Research LLC and Refinitiv Eikon

Source: Company filings and Litchfield Hills Research LLC

Figure 11 – AnPac Bio-Medical Co. Ltd. – Income Statement

December year-end ($000)	2018 Year	2019E Year	2020E Year	2021E Year
Total revenue	$1,434	$1,513	$2,000	$10,000
Growth	-98%	6%	32%	400%
Cost of Goods	794	832	1,100	5,000
Gross Profit	**640**	**681**	**900**	**5,000**
Gross Margin	**44.6%**	**45.0%**	**45.0%**	**50.0%**
Selling and marketing	$1,375	$2,000	$3,000	$3,500
% of total revenue	96%	132%	150%	35%
R&D	$1,414	$1,330	$1,200	$1,300
% of total revenue	99%	88%	60%	13%
General and administrative	$4,036	$9,350	$10,000	$11,000
% of total revenue	281%	618%	500%	110%
Other operating income	($84)	$25	$100	$100
Total Operating Expenses	6,741	12,705	14,300	15,900
Operating Income	**(6,101)**	**(12,024)**	**(13,400)**	**(10,900)**
Operating Margin	**-425.5%**	**-794.7%**	**-670.0%**	**-109.0%**
Total Other Items	156	(700)	(400)	(400)
Pre-Tax Income	**(5,945)**	**(12,724)**	**(13,800)**	**(11,300)**
Pre-Tax Margin	**-414.6%**	**-841.0%**	**-690.0%**	**-113.0%**
Taxes (benefit)	(28)	(50)	(50)	(100)
Tax Rate	0.5%	0.4%	0.4%	0.9%
Net Income (loss)	**(5,917)**	**(12,674)**	**(13,750)**	**(11,200)**
Net Margin	**-412.6%**	**-837.7%**	**-687.5%**	**-112.0%**
EPS, as reported	**(0.69)**	**(1.39)**	**(1.38)**	**(1.02)**
Diluted Shares Outstanding	8,524	9,100	11,530	12,100

Source: Company reports and Litchfield Hills Research LLC

Figure 12 – AnPac Bio-Medical Co. Ltd. – Balance Sheet

($ in thousands)				
December year-end	FY2021E	FY2020E	FY2019E	FY2018
Balance sheet				
Current Assets				
Cash and S.T.I.	$1,733	$3,433	$1,233	$1,803
Accounts receivable	1,200	1,000	500	385
Inventories	200	100	50	9
Other assets	2,000	2,000	2,000	720
Total Current Assets	**5,133**	**6,533**	**3,783**	**2,917**
Net PP&E	3,500	3,300	3,000	2,538
Other non-current assets	2,000	2,000	2,000	1,927
Total Assets	**$10,633**	**$11,833**	**$8,783**	**$7,382**
Current Liabilities				
Short-term debt	$4,000	$4,000	$4,200	$3,632
Accounts payable	$4,000	$2,000	$1,100	$227
Advance from customers	$600	$600	$600	$604
Amounts due to related parties	$4,150	$4,150	$4,150	$4,013
Accrued and other	$7,000	$6,000	$5,000	$1,519
Total current liabilities	**19,750**	**16,750**	**15,050**	**9,995**
Deferred tax liabilities	500	200	100	171
Other long-term liabilities	500	300	300	349
Total Liabilities	**20,750**	**17,250**	**15,450**	**10,515**
Stockholders' Equity				
Preferred stock	0	0	0	0
Common stock	100	100	100	80
Additional paid-in-capital	52,000	45,500	30,500	21,317
Retained earnings	(62,017)	(50,817)	(37,067)	(24,393)
Accumulated other comp. loss	(200)	(200)	(200)	(137)
Total stockholders' equity	(10,117)	(5,417)	(6,667)	(3,133)
Total Liabilities and equity	**$10,633**	**$11,833**	**$8,783**	**$7,382**

Source: Company reports and Litchfield Hills Research LLC

Figure 13 – AnPac Bio-Medical Co. Ltd. – Cash Flow

($ in thousands)			
	FY21E	FY20E	FY19E
Net Income	($11,200)	($13,750)	($12,674)
Accounts receivable	(200)	(500)	(115)
Inventories	(100)	(50)	(41)
Other assets	0	0	(1,280)
PP&E	(200)	(300)	(462)
Other non-current	0	0	(73)
Short-term debt	0	(200)	568
Accounts payable	2,000	900	873
Advance from customers	0	0	(4)
Amounts due to related parties	0	0	137
Accrued and other	1,000	1,000	3,481
Deferred tax liabilities	300	100	(71)
Other long-term liabilities	200	0	(49)
Preferred stock	0	0	0
Common stock	0	0	20
Additional paid-in-capital	6,500	15,000	9,183
Cum. trans. adj. and treasury stock	0	0	(63)
Dividends	0	0	0
Total Cash Flow	($1,700)	$2,200	($570)

Source: Litchfield Hills Research LLC

Disclosures:

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